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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0807; Project Identifier AD–2022–00214–R; Amendment 39–22188; AD 2022–20–04]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding airworthiness directive (AD) 2021–26–08, which applied to certain Bell Textron Canada Limited Model 206, 206A, 206A–1, 206B, 206B–1, 206L, 206L–1, 206L–3, and 206L–4 helicopters. AD 2021–26–08 required removing certain nuts from service; installing newly designed nuts; applying a specific torque, and a torque stripe to each newly installed nut; after the installation of each newly designed nut, inspecting the torque; and depending on the inspection results, either applying a torque stripe, or performing further inspections and removing certain parts from service. AD 2021–26–08 also prohibited installing any affected nut on any tail rotor drive shaft (TRDS) disc pack (Thomas) coupling. Since the FAA issued AD 2021–26–08, the FAA determined certain torque values and part numbers (P/Ns) need to be revised. This AD was prompted by reports of cracked or missing nuts installed on the TRDS Thomas couplings and the need to revise certain torque values and P/Ns in AD 2021–26–08. This AD requires removing certain nuts from service; installing newly designed nuts; applying torque and a torque stripe; and additional corrective actions if necessary. This AD also prohibits installing any affected nut on any TRDS Thomas coupling, as specified in a Transport Canada AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 23, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 23, 2022.

ADDRESSES: For Transport Canada material incorporated by reference (IBR) in this final rule, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, CANADA; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* internet *tc.canada.ca/en/aviation.* You may find the Transport Canada material on the Transport Canada website at *tc.canada.ca/en/aviation.* For Air Comm Corporation service information identified in this final rule, contact Air Comm Corporation, 1575 West 124th Ave. #210, Westminster, CO 80234; telephone (303) 440–4075; email *service@aircommcorp.com;* or at *aircommcorp.com.* For Bell service information identified in this final rule, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *bellflight.com/support/contact-support.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is IBRed is also available in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0807.

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0807; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the Transport Canada AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–26–08, Amendment 39–21867 (86 FR 72833, December 23, 2021) (AD 2021–26–08). AD 2021–26–08 applied to Bell Textron Canada Limited Model 206, 206A, 206A–1, 206B, 206B–1, 206L, 206L–1, 206L–3, and 206L–4 helicopters, with nut P/N MS21042L4 or P/N MS21042L5 installed on the TRDS Thomas couplings. AD 2021–26–08 required removing certain nuts from service, installing newly designed nuts, and applying a specific torque and a torque stripe to each newly installed nut. AD 2021–26–08 also required, after the installation of each newly designed nut, inspecting the torque and, depending on the inspection results, either applying a torque stripe or performing further inspections and removing certain parts from service. Finally, AD 2021–26–08 prohibited installing any affected nut on any TRDS Thomas coupling. The FAA issued AD 2021–26–08 to prevent failure or loss of a nut on any TRDS Thomas coupling.

AD 2021–26–08 was prompted by Transport Canada AD CF–2020–15, dated May 13, 2020 (Transport Canada AD CF–2020–15). Transport Canada, which is the aviation authority for Canada, issued Transport Canada AD CF–2020–15 to correct an unsafe condition for Bell Textron Canada Limited Model 206, 206A, 206A–1, 206B, 206B–1, 206L, 206L–1, 206L–3, and 206L–4 helicopters, all serial numbers. Transport Canada AD CF–2020–15 specifies for certain model helicopters, newly designed nuts cannot be installed because Supplemental Type Certificate (STC) SH2750NM and Transport Canada STC SH99–202 install a pulley at the Thomas coupling location causing insufficient clearance. Transport Canada advises, for certain

model helicopters with STC SH2750NM or Transport Canada STC SH99–202 installed, different part-numbered nuts may be installed and are now required to be replaced with a new part-numbered nut that is not vulnerable to the unsafe condition.

The NPRM published in the **Federal Register** on June 30, 2022 (87 FR 39015). The NPRM was prompted by reports of cracked or missing nuts installed on the TRDS Thomas couplings. The NPRM was also prompted by the determination that certain P/Ns and certain torque values in paragraph (g) of AD 2021–26–08 need to be revised. Furthermore, the FAA advises that the 50–70 in lb torque values are only applicable to certain bolts and nuts, and a 150–180 in lb torque value is required for other bolts and nuts that are required to be installed by this AD. The FAA also advises that certain part-numbered nuts that are required to be installed according to AD 2021–26–08 need to be removed from service and replaced due to a certain pulley configuration. The NPRM proposed to require removing certain nuts from service; installing newly designed nuts; applying torque and a torque stripe; and additional corrective actions if necessary. The NPRM also proposed to prohibit installing any affected nut on any TRDS Thomas coupling, as specified in Transport Canada AD CF–2020–15.

The FAA is issuing this AD to prevent failure or loss of a nut on the TRDS Thomas couplings, which if not addressed could result in loss of the tail rotor and subsequent loss of control of the helicopter. See Transport Canada AD CF–2020–15 for additional background information.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. This AD is adopted as proposed in the NPRM, except the FAA has removed the note to the applicability paragraph and updated the identification of Model 206A–1 helicopters in the applicability paragraph to Model 206A–1 (OH–58A) helicopters to match the FAA type certificate data sheet. None of these changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2020–15 requires the replacement of certain part-numbered nuts with newly designed nuts at each TRDS Thomas coupling and prohibits installing any affected nut on any TRDS Thomas coupling. The replacement includes applying torque, and a torque stripe.

The FAA reviewed Air Comm Corporation Service Bulletin SB 206EC–092619, Revision NC, dated September 26, 2019, which also specifies procedures for replacing the affected nuts with the newly designed corrosion-resistant nuts, but explains that affected helicopters equipped with Air Comm Corporation air conditioning systems installed under STC SH2750NM use the affected nut to attach a pulley onto the TRDS, which causes clearance issues for the nuts to be installed at the coupling. Therefore, this service bulletin specifies replacing the nut with a lower profile nut.

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

Other Related Service Information

The FAA also reviewed Bell Alert Service Bulletin (ASB) 206–19–136, dated August 27, 2019, for FAA-certificated Model 206, 206A-series, and 206B-series helicopters, and non FAA-certificated Model TH–67 helicopters; and Bell ASB 206L–19–181, dated August 27, 2019, and Revision A, dated August 29, 2019, for Model 206L, 206L–1, 206L–3, and 206L–4 helicopters. This service information specifies procedures for replacing the affected nuts with the newly designed corrosion-resistant nuts. Revision A of Bell ASB 206L–19–181 corrects a typographical error.

Additionally, the FAA reviewed Bell Service Instruction BHT–206–SI–2052, Revision 1, dated October 14, 2010. This service information specifies procedures to upgrade Model 206L–1 and 206L–3 helicopters to allow operations at an increased internal gross weight.

Differences Between This AD and Transport Canada AD CF–2020–15

Transport Canada AD CF–2020–15 requires compliance with certain actions within 600 hours air time or within the next 24 months, whichever occurs first, whereas this AD requires compliance within 600 hours time-in-service only. Service information referenced in Transport Canada AD CF–2020–15 specifies if any P/N MS21042L4 nuts are found loose or damaged, reporting the location and providing the information to Bell, whereas this AD requires if any P/N MS21042L4 nuts are found loose or damaged, inspecting each TRDS Thomas coupling, including each bolt, nut, and washer, for any elongated holes, fretting on the fasteners, and damaged fasteners, and depending on the results of the inspection, removing from service each affected part and replacing it with an airworthy part.

Costs of Compliance

The FAA estimates that this AD affects 1,359 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Replacing each affected nut with the newly designed nut and applying torque and a torque stripe takes about 4 work-hours, and parts cost about $75 for an estimated cost of $415 per nut replacement and $563,985 per nut replacement for the U.S. fleet.

In addition, the costs of the actions that are part of the required replacement are as follows:

If required, due to loose or damaged nuts found, inspecting each TRDS Thomas coupling, and each bolt, nut, and washer for elongated holes and fretting on the fasteners takes about 0.5 work-hour for an estimated cost of $43 per inspection.

If required, replacing each TRDS Thomas coupling takes about 4 work-hours, and parts cost about $4,000 for an estimated cost of $4,340 per TRDS Thomas coupling replacement.

If required, replacing a bolt or washer takes a minimal amount of time and parts cost a nominal amount.

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2021–26–08, Amendment 39–21867 (86 FR 72833, December 23, 2021); and

■ b. Adding the following new AD:

2022–20–04 Bell Textron Canada Limited: Amendment 39–22188; Docket No. FAA–2022–0807; Project Identifier AD–2022–00214–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 23, 2022.

(b) Affected ADs

This AD replaces AD 2021–26–08, Amendment 39–21867 (86 FR 72833, December 23, 2021) (AD 2021–26–08).

(c) Applicability

This AD applies to Bell Textron Canada Limited Model 206, 206A, 206A–1 (OH–58A), 206B, 206B–1, 206L, 206L–1, 206L–3, and 206L–4 helicopters, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6510, Tail Rotor Drive Shaft.

(e) Unsafe Condition

This AD was prompted by reports of cracked or missing nuts installed on the tail rotor drive shaft (TRDS) disc pack (Thomas) couplings. The FAA is issuing this AD to prevent failure or loss of a nut on the TRDS Thomas couplings. The unsafe condition, if not addressed, could result in loss of the tail rotor and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2020–15, dated May 13, 2020 (Transport Canada AD CF–2020–15).

(h) Exceptions to Transport Canada AD CF–2020–15

(1) Where Transport Canada AD CF–2020–15 requires compliance in terms of air time, this AD requires using hours time-in-service (TIS).

(2) Where Transport Canada AD CF–2020–15 refers to the effective dates specified in paragraphs (h)(2)(i) and (ii) of this AD, this AD requires using the effective date of this AD.

(i) October 9, 2019 (the effective date of Transport Canada AD CF–2019–34, dated September 25, 2019).

(ii) The effective date of Transport Canada AD CF–2020–15.

(3) Where Transport Canada AD CF–2020–15 defines Group 1 helicopters as those models ''that have not been modified by installing STC SH2750NM or STC SH99–202,'' replace ''that have not been modified by installing STC SH2750NM or STC SH99–202'' with ''that have not been modified by installing STC SH2750NM.''

(4) Where Transport Canada AD CF–2020–15 defines Group 4 helicopters as those models ''that have been modified by installing STC SH2750NM or STC SH99–202,'' replace ''that have been modified by installing STC SH2750NM or STC SH99–202'' with ''that have been modified by installing STC SH2750NM.''

(5) Where Transport Canada AD CF–2020–15 requires compliance within 600 hours air time or 24 months, whichever occurs first, this AD requires compliance within 600 hours TIS only and does not allow a compliance time of 24 months.

(6) Where any paragraph of Transport Canada AD CF–2020–15 specifies to replace part number (P/N) MS21042 nuts with P/N NAS9926 nuts, this AD requires removing P/N MS21042 nuts from service and replacing with P/N NAS9926 nuts.

(7) Where any paragraph of any service information referenced in Transport Canada AD CF–2020–15 specifies to replace P/N MS21042L4 nuts with P/N 90–132L4 nuts, this AD requires removing P/N MS21042L4 nuts from service and replacing with P/N 90–132L4 nuts, in accordance with Air Comm Corporation Service Bulletin SB 206EC–092619, Revision NC, dated September 26, 2019 (SB 206EC–092619 Rev NC).

(8) Where any paragraph of any service information referenced in Transport Canada AD CF–2020–15 specifies to replace P/N MS21042L5 nuts with P/N 90–132L5 nuts, this AD requires removing P/N MS21042L5 nuts from service and replacing with P/N 90–132L5 nuts, in accordance with SB 206EC–092619 Rev NC.

(9) Where any paragraph of any service information referenced in Transport Canada AD CF–2020–15 specifies if any P/N MS21042L4 nuts are found loose or damaged, report at which location and provide the information to Product Support Engineering at *productsupport@bellflight.com,* this AD requires if any P/N MS21042L4 nuts are found loose or damaged, before further flight, inspecting each TRDS Thomas coupling, including each bolt, nut, and washer, for any elongated holes, fretting on the fasteners, and damaged fasteners. If there is any elongated hole, fretting on the fasteners, or damaged fasteners, this AD requires before further flight, removing from service each affected part and replacing it with an airworthy part.

(i) No Reporting Requirement

Although the service information referenced in Transport Canada AD CF–2020–15 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(k) Related Information

For more information about this AD, contact Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational

Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Air Comm Corporation Service Bulletin SB 206EC–092619, Revision NC, dated September 26, 2019.

(ii) Transport Canada AD CF–2020–15, dated May 13, 2020.

(3) For Air Comm Corporation service information identified in this AD, contact Air Comm Corporation, 1575 West 124th Ave. #210, Westminster, CO 80234; telephone (303) 440–4075; email *service@aircommcorp.com;* or at *aircommcorp.com.* For Transport Canada AD CF–2020–15, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, CANADA; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* internet *tc.canada.ca/en/aviation.* You may find the Transport Canada material on the Transport Canada website at *tc.canada.ca/en/aviation.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0807.

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

Issued on September 19, 2022.

Christina Underwood,

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

[FR Doc. 2022–25028 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0599; Project Identifier MCAI–2021–00456–A; Amendment 39–22222; AD 2022–22–07]

RIN 2120–AA64

Airworthiness Directives; Piaggio Aviation S.p.A. (Type Certificate Previously Held by Piaggio Aero Industries S.p.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Piaggio Aviation S.p.A. (type certificate previously held by Piaggio Aero Industries S.p.A.) (Piaggio) Model P–180 airplanes. This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as corrosion in the bottom fuselage area of the cabin compartment due to inner and outer sides of fuselage skin panels of certain airplanes treated with the less effective primer. This AD requires repetitively inspecting the fuselage skin panels, visually inspecting the entire fuselage inner side skin if necessary, and taking any necessary corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 23, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 23, 2022.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–0599; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Piaggio Aviation S.p.A., P180 Customer Support, via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: +39 331 679 74 93; email: *technicalsupport@piaggioaerospace.it.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–0599.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Piaggio Model P–180 airplanes. The NPRM published in the **Federal Register** on June 17, 2022 (87 FR 36415). The NPRM was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2021–0104, dated April 15, 2021 (referred to after this as ''the MCAI''), to address the unsafe condition on certain serial-numbered Piaggio Model P.180 airplanes. The MCAI states:

> Occurrences were reported where, during routine inspections, diffused corrosion was detected on the fuselage inner side skin in the area of the passenger cabin. Evidence indicates that the presence of undetected (infiltrated or condensed) water, trapped in between the inner surface of fuselage skin panels and the thermo-acoustic insulation panels, could have started a galvanic corrosion phenomenon, mainly in the bottom fuselage area of the cabin compartment. Fuselage skin panels of certain aeroplanes, delivered from 2009 to 2013, were treated with the first type of ''chromate-free'' primer, chemically not as effective against corrosion when compared to those containing chrome. The phenomenon has been observed on aeroplanes subjected to prolonged inactivity and not stored in a hangar, or those operating in an environment with high humidity and/or frequent heavy precipitation, combined with a possible deterioration of window sealing due to normal aging, wear and tear.
>
> This condition, if not corrected, could affect the structural integrity of the fuselage.
>
> To address this potential unsafe condition, Piaggio published the [Piaggio Service Bulletin (SB) 80–0405, Revision 0, dated March 15, 2021] SB to provide inspection instructions.
>
> For the reason described above, this [EASA] AD requires repetitive inspections of

each affected area and, if necessary, an additional visual inspection of the entire fuselage inner side skin and, depending on findings, accomplishment of applicable repair. This [EASA] AD also requires reporting the inspection results to Piaggio.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2022–0599.

In the NPRM, the FAA proposed to require repetitively inspecting the fuselage skin panels, visually inspecting the entire fuselage inner side skin if necessary, and taking any necessary corrective actions. The FAA is issuing this AD to prevent degradation of the structural integrity of the fuselage. The unsafe condition, if not addressed, could lead to loss of control of the airplane.

Discussion of Final Airworthiness Directive

Comments

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

Request Not To Require Repetitive 26-Month Inspection

An individual commenter requested the FAA not require a 26-month repetitive inspection as proposed in the NPRM. The commenter stated that all U.S. operators follow the Piaggio P.180 Avanti II Maintenance Manual (MM) inspection program in which these areas are already being inspected every 5 years and 3,600 flight hours. The commenter also asserted that there could be patch repairs for previously inspected and repaired areas, and that, if patch repairs are found with no corrosion in previously inspected areas, no further action should be required. Therefore, the commenter believes implementing the 26-month repetitive inspection is excessive.

The FAA partially agrees. The FAA does not agree that all U.S.-registered airplanes are required to comply with Chapter 5 of the MM, which is where the inspections referenced by the commenter are located. Owners and operators must only comply with the Airworthiness Limitations section of the MM (located in Chapter 4 of this MM), as well as 14 CFR part 43, unless the airplane is operated under 14 CFR part 135 and its operating specifications require it. In addition, if the fuselage panels affected by this AD are replaced as part of the corrective actions required by paragraph (g)(1) of this AD, the repetitive inspections in paragraph (g)(2)(ii) of this AD are not required. Corrosion found outside of the affected fuselage areas of this AD should be repaired; however, these repairs are not mandated by this AD. Only the fuselage areas defined in the referenced service bulletin are affected by this AD. If corrosion is found as a result of the inspections required by this AD, this would show that the primer coating is inadequate to protect the material from corrosion; therefore, the repetitive inspections in this AD are necessary. The EASA, as the state of design, determined that a repetitive inspection interval of not to exceed 660 hours time-in-service (TIS) or 26 months, whichever occurs first, is appropriate. The FAA has no data to dispute this specified criteria concerning the time-in-service or calendar-month inspection interval determination. The FAA does agree that if repairs were previously accomplished on the areas required to be inspected by this AD and no corrosion was found during the inspections required by paragraph (g)(1) of this AD, the repetitive inspections in paragraph (g)(2)(ii) of this AD are not required. The FAA has not changed this final rule as a result of this comment.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for updating this AD to reflect that the type certificate holder changed from Piaggio Aero Industries S.p.A. to Piaggio Aviation S.p.A and changing the term ''fuselage wing skin panel'' used in paragraph (g)(1) of the NPRM to ''fuselage skin panel,'' this AD is adopted as proposed in the NPRM. None of the changes increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Piaggio SB 80–0405, Revision 0, dated March 15, 2021. This service information specifies procedures for inspecting the fuselage skin panels and inspecting the full inner fuselage skin. It also specifies repairing or replacing any parts where corrosion is found.

The FAA also reviewed Piaggio SB 80–0405, Revision 0, Errata Corrige No. 1, dated March 24, 2021, which addresses discrepancies identified in Piaggio SB 80–0405, Revision 0, dated March 15, 2021.

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

Differences Between This AD and the MCAI, Service Information, or NPRM

The MCAI allows credit for the fuselage inner skin inspection if previously done using Piaggio Aviation S.p.A. Temporary Revision No. 332 to Chapter 53–00–00 of Piaggio P.180 Avanti II MM, and this AD does not. The FAA will consider requests for an alternative method of compliance for this under paragraph (h) of this AD.

The MCAI specifies compliance times of 8 months and 12 months depending on when the P.180 Avanti II MM 3,600-flight-hour or 5-year inspection was accomplished. This AD has a 12-month compliance time for all airplanes because the 3,600-flight-hour and 5-year MM inspections are not required for all U.S. operators by FAA regulation.

The service information specifies contacting Piaggio for certain repair instructions, while this AD requires repair using a method approved by the FAA or EASA.

Costs of Compliance

The FAA estimates that this AD affects 14 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Inspections	Up to 150 work-hours × $85 per hour = $12,750.	$2,360	Up to $15,110	Up to $211,540.

The FAA estimates the following costs to do any necessary actions that may be required based on the results of the required inspections. The FAA has no way of estimating the number of airplanes that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per airplane
Repair	Up to 80 work-hours × $85 per hour = $6,800.	$1,220	Up to $8,020.
Replace skin panel	Up to 250 work-hours × $85 per hour = $21,250.	Up to $12,200	Up to $33,450.
Reporting inspection results	1 work-hour × $85 per hour = $85	Not Applicable	$1,190.

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–22–07 Piaggio Aviation S.p.A. (type certificate previously held by Piaggio Aero Industries S.p.A.): Amendment 39–22222; Docket No. FAA–2022–0599; Project Identifier MCAI–2021–00456–A.

(a) Effective Date

This airworthiness directive (AD) is effective December 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piaggio Aviation S.p.A. (type certificate previously held by Piaggio Aero Industries S.p.A.) (Piaggio) Model P–180 airplanes, serial number (S/N) 1174 through 1214 inclusive and S/N 1218 through 1230 inclusive, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5330, Fuselage Main, Plate/Skin.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as corrosion in the bottom fuselage area of the cabin compartment due to inner and outer sides of fuselage skin panels treated with less effective primer. The FAA is issuing this AD to prevent degradation of the structural integrity of the fuselage. This condition, if not addressed, could lead to loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 12 months after the effective date of this AD, do the applicable inspections and corrective actions on each fuselage skin panel in accordance with the Accomplishment Instructions, Part A, paragraphs (1) through (15) and (17) through (20), or Part A (Alternate Procedure), paragraphs (31) through (37), (41) through (43), (50) through (55), and (57) through (60), in Piaggio Service Bulletin 80–0405, Revision 0, dated March 15, 2021, as corrected by Piaggio Service Bulletin 80–0405, Revision 0, Errata Corrige No. 1, dated March 24, 2021 (Piaggio SB 80–0405), except for the following:

(i) You are not required to contact the manufacturer. Instead, for any repairs, use a method approved by the FAA or the European Union Aviation Safety Agency (EASA).

(ii) Where the steps in Part A or Part A (Alternate Procedure) reference Part B, you must follow the Accomplishment

Instructions, Part B, paragraphs (82) through (86), (88), and (104) of Piaggio SB 80–0405.

(2) If, as part of the corrective actions required by paragraph (g)(1) of this AD, you repaired areas of the fuselage skin but did not replace the panels, do the following:

(i) Within 60 days after completing the actions required by paragraph (g)(1) of this AD, report the inspection results, including the information specified in the Confirmation Slip attached to Piaggio SB 80–0405, to Piaggio at *technicalsupport@piaggioaerospace.it;* and

(ii) Repeat the requirements of paragraph (g)(1) of this AD at intervals not to exceed 660 hours time-in-service (TIS) or 26 months, whichever occurs first.

(3) If, as part of the corrective actions required by paragraph (g)(1) of this AD, you replaced the panels, within 60 days after completing the actions required by paragraph (g)(1) of this AD, report the inspection results, including the information specified in the Confirmation Slip attached to Piaggio SB 80–0405, to Piaggio at *technicalsupport@piaggioaerospace.it.*

(4) If, during all of the inspections required by paragraph (g)(1) of this AD, there is no corrosion and no primer inconsistencies, no further action is required by this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (i)(1) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email.

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

(i) Related Information

(1) For more information about this AD, contact Mike Kiesov, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov.*

(2) Refer to EASA AD 2021–0104, dated April 15, 2021, for more information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–0599.

(j) Material Incorporated by Reference

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

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

(i) Piaggio Service Bulletin 80–0405, Revision 0, dated March 15, 2021.

(ii) Piaggio Service Bulletin 80–0405, Revision 0, Errata Corrige No. 1, dated March 24, 2021.

(3) For service information identified in this AD, contact Piaggio Aviation S.p.A., P180 Customer Support, via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: +39 331 679 74 93; email: *technicalsupport@piaggioaerospace.it.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 20, 2022.

Christina Underwood,

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

[FR Doc. 2022–25029 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0286; Project Identifier AD–2021–01081–R; Amendment 39–22223; AD 2022–22–08]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) Model 206L, 206L–1, 206L–3, and 206L–4 helicopters with a certain part-numbered main rotor (M/R) blade installed under Supplemental Type Certificate (STC) SR02684LA. This AD was prompted by delamination of M/R blades. This AD requires a repetitive inspection for delamination, and depending on the results, removing the M/R blade from service and reporting certain information. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 23, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 23, 2022.

ADDRESSES: For service information identified in this final rule, contact Dean Rosenlof, Van Horn Aviation, LLC, 1510 West Drake Drive, Tempe, AZ, 85283, United States; phone: (480) 483–4202; email: *dean@vanhornaviation.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2022–0286.

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0286; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Payman Soltani, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Bell Textron Canada Limited Model 206L, 206L–1, 206L–3, and 206L–4 helicopters with a certain part-numbered M/R blade installed under STC SR02684LA. The NPRM published in the **Federal Register** on March 24, 2022 (87 FR 16652). The NPRM was prompted by testing by Van Horn Aviation, LLC (Van Horn), which revealed the potential for delamination in M/R blade part number (P/N) 20633000–101. Delaminations were then confirmed by inspection of in-service M/R blades. Testing by Van Horn confirmed that the 90° plies fail in spanwise tension (normal to the fiber

direction) at the inboard end of the weight receptacle near M/R blade station 186.0. Delamination then propagates outboard from M/R blade station 186.0 at the interface between the 0° and 90° plies. According to Van Horn, fatigue testing has shown that the delamination initiates almost immediately and progresses slowly in a stable, predictable manner. The delamination has been found to develop first on the lower surface and grow outboard from the inboard end of the weight receptacle and forward of the balance weight pocket. After approximately 4 to 6 inches growth of the delamination on the lower surface, a similar delamination becomes detectable on the M/R blade upper surface. Should the delaminations continue to grow to the point of static overload, the receptacle could depart the M/R blade. In the NPRM, the FAA proposed to require, at specified intervals, removing the affected M/R blade, drawing rectangular inspection areas ''Zone 1'' and ''Zone 2'' with a permanent marker, tap inspecting the inspection areas for delamination, marking and measuring the length of any delamination, and depending on the results, removing the M/R blade from service. The NPRM also proposed to require reporting certain information to Van Horn. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, Van Horn. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Changes to the Measurements of Inspection Areas

Van Horn stated that the M/R blade stations indicated for inspections are incorrect in the proposed AD and requested the FAA revise the required actions to change the M/R blade stations for ''Zone 1'' and ''Zone 2.'' However, the measurements Van Horn included in the comment in the AD docket to correct the M/R blade stations for ''Zone 1'' and ''Zone 2'' were also incorrect. Van Horn then contacted the FAA to correct these measurements; a record of this ex parte contact is included in the AD docket. For information on locating the docket, see ''Examining the AD Docket.'' According to Van Horn's revised comments, ''Zone 1'' described in the NPRM as M/R blade stations 186.0 and 191.0, beginning 1.1 inches from the leading edge of the M/R blade to 4.9 inches from the leading edge of the M/R blade should be revised to M/R blade stations 185.75 and 192.75, or measured from the tip end of the M/R blade between 36.25 inches and 29.25 inches beginning 1.2 inches from the leading edge of the M/R blade to 5.0 inches from the leading edge of the M/R blade. ''Zone 2'' described in the NPRM as M/R blade stations 186.0 and 191.0 should be revised to M/R blade stations 185.9 and 192.9, or measured from the tip end of the M/R blade between 36.1 inches and 29.1 inches.

The FAA agrees and has revised this AD accordingly.

Request for a Change to the Service Bulletin Cited in Note 1

Van Horn proposed that Note 1 to paragraph (g)(2)(i) cite Van Horn Service Bulletin Notice No. 33000–4R4, dated March 31, 2022 (SB33000–4R4) rather than Van Horn Service Bulletin Notice No. 33000–4R3, dated November 8, 2021 (SB 33000–4R3).

The FAA partially agrees. The FAA appreciates that the latest revision of that service bulletin is SB33000–4R4; however, the portions of that service bulletin that are specified in the proposed AD are identical in SB33000–4R3 and SB33000–4R4. Accordingly, the FAA has made updates throughout the Required Actions paragraph to allow both SB33000–4R3 and SB33000–4R4 in this final rule.

Request for a Reference to Additional Service Information in Note 1

Van Horn proposed edits in Note 1 to paragraph (g)(2)(i) to refer to the Van Horn Instructions for Continued Airworthiness, ICA Manual No. VMM–MR–206L–501, Revision N/C, dated May 24, 2018, for a blade configuration drawing.

The FAA disagrees because it does not provide information that could be helpful for operators to comply with this AD.

Request for Additional Tap Hammer Tool

Van Horn also requested the FAA revise the list of tap hammers in paragraph (g)(2)(iii) of the proposed AD to add Van Horn Aviation Tap Hammer P/N VHACS0003 to the list of tap hammers.

The FAA agrees and has revised this AD as requested.

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed SB 33000–4R3 and SB 33000–4R4. This service information specifies procedures to identify ''Zone 1'' and ''Zone 2'' inspection areas, accomplish repetitive visual and tap inspections of the zones to detect and monitor the growth of any delamination, and depending on the results, remove the M/R blade from service and contact Van Horn. SB 33000–4R3 applies to M/R blade P/N 20633000–101 serial numbers A012 through A104. SB 33000–4R4 expanded the applicability to include M/R blade P/N 20633000–101 with serial numbers A007, A008, and A009; these serial-numbered parts were included in the NPRM's applicability.

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

Differences Between This AD and the Service Information

This AD requires using certain part-numbered composite tap hammers, whereas SB 33000–4R3 and SB 33000–4R4 do not. SB 33000–4R3 and SB 33000–4R4 specify procedures to visually inspect the M/R blade, whereas this AD does not. If there is any delamination in the upper surface inspection zone (''Zone 1''), this AD requires removing the M/R blade from service, whereas SB 33000–4R3 and SB 33000–4R4 do not specify procedures for this condition.

Interim Action

The FAA considers this AD to be an interim action. The inspection reports that are required by this AD will enable the FAA to obtain better insight into the unsafe condition. If final action is later identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD will affect 23 helicopters of U.S. registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Removing, tap inspecting, and re-installing an M/R blade will take about

4.5 work-hours for an estimated cost of $383 per M/R blade, per inspection cycle and up to $8,809 for the U.S. fleet per M/R blade, per inspection cycle. Replacing an M/R blade will take about 4 work-hours and parts will cost about $71,500 per M/R blade for a total of $71,840 per M/R blade. Reporting information to Van Horn will take about 1 work-hour for an estimated cost of $85 per report.

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–22–08 Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited): Amendment 39–22223; Docket No. FAA–2022–0286; Project Identifier AD–2021–01081–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) Model 206L, 206L–1, 206L–3, and 206L–4 helicopters, certificated in any category, with main rotor (M/R) blade part number (P/N) 20633000–101 with serial number A007, A008, A009, or A012 through A104 inclusive, installed under Supplemental Type Certificate SR02684LA.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6210, Main Rotor Blades.

(e) Unsafe Condition

This AD was prompted by reports of delamination of M/R blades. The FAA is issuing this AD to address delamination of an M/R blade initiating in the 90° plies at the lower inboard end of the weight pocket receptacle. The unsafe condition, if not addressed, could result in reduced structural integrity of the M/R blade, excessive vibration, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Accomplish the actions required by paragraph (g)(2) of this AD at the following compliance time, whichever occurs later:

(i) Before the M/R blade accumulates 400 total hours time-in-service (TIS) or 2,400 engine starts since initial installation on any helicopter, whichever occurs first; or

(ii) Within 100 hours TIS after the effective date of this AD.

(2) Remove each M/R blade from the helicopter, place it on a flat, stable surface, and accomplish the following:

(i) Use a permanent marker to draw rectangular inspection ''Zone 1'' on the upper surface of the M/R blade at M/R blade stations 185.75 and 192.75, or measured from the tip end of the M/R blade between 36.25 inches and 29.25 inches, beginning 1.2 inches from the leading edge of the M/R blade to 5.0 inches from the leading edge of the M/R blade. Draw lines from the inboard end to the outboard end to connect each end at 1.2 inches and 5.0 inches. Draw parallel lines from the inboard end of the inspection zone to the outboard end of the inspection zone, with the lines spaced 0.50 inch apart.

Note 1 to paragraph (g)(2)(i): This note applies to paragraphs (g)(2)(i) and (ii) of this AD. Figure 4 of Van Horn Aviation, LLC, Service Bulletin Notice No. 33000–4R3, dated November 8, 2021 (SB 33000–4R3), and Van Horn Aviation, LLC, Service Bulletin Notice No. 33000–4R4, dated March 31, 2022 (SB 33000–4R4) depict ''Zone 1'' and ''Zone 2.''

(ii) Use a permanent marker to draw rectangular inspection ''Zone 2'' on the lower surface of the M/R blade at M/R blade stations 185.9 and 192.9, or measured from the tip end of the M/R blade between 36.1inches and 29.1 inches, beginning from the forward edge of the weight receptacle pocket and extending 1 inch in the direction towards the leading edge of the M/R blade. Draw lines from the inboard end to the outboard end to connect each end at the weight receptacle pocket and 1 inch forward of the weight receptacle pocket. Draw parallel lines from the inboard end of the inspection zone to the outboard end of the inspection zone, with the lines spaced 0.50 inch apart.

(iii) Using composite tap hammer Abaris Training Tap Hammer P/N ABATH, HeatCon

Tap Hammer P/N HCS1104–01, Brown Tool Composite Tap Hammer P/N BAT–CTH8, MATCO Tools Composite Tap Hammer P/N T4BAT–CTH8, or Van Horn Aviation Tap Hammer P/N VHACS0003, tap inspect the areas within ''Zone 1'' and ''Zone 2'' for any delamination by following Tap Inspect Balance Receptacle, paragraph A.(4) of SB 33000–4R3 or SB 33000–4R4. Where SB 33000–4R3 and SB 33000–4R4 specify to mark the location where the delamination starts, use a permanent marker.

(iv) If there are any marks where the delamination starts, connect the marks indicating the delamination location and measure the length at the farthest point from the inboard end of the inspection area.

(v) If there is any delamination in the lower surface inspection zone (''Zone 2'') that is 6.0 or more inches in length or if there is any delamination in the upper surface inspection zone (''Zone 1''), before further flight, remove the M/R blade from service.

(3) Thereafter repeat the actions required by paragraph (g)(2) of this AD at intervals not to exceed 400 hours TIS or 2,400 engine starts, whichever occurs first.

(4) If there is any delamination, within 30 days after accomplishing the actions required by paragraphs (g)(1) or (3) of this AD, report each delamination size and location, and the total hours TIS and total engine starts since initial installation of the M/R blade, to Mr. Dean Rosenlof, Van Horn Aviation, LLC, 1510 West Drake Drive, Tempe, AZ 85283, or by email to *info@vanhornaviation.com.*

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-REQUESTS@faa.gov.*

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

(i) Related Information

For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov.*

(j) Material Incorporated by Reference

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

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

(i) Van Horn Aviation, LLC, Service Bulletin Notice No. 33000–4R3, dated November 8, 2021.

(ii) Van Horn Aviation, LLC, Service Bulletin Notice No. 33000–4R4, dated March 31, 2022.

(3) For Van Horn Aviation, LLC, service information identified in this AD, contact Dean Rosenlof, Van Horn Aviation, LLC, 1510 West Drake Drive, Tempe, AZ, 85283, United States; phone: (480) 483–4202; email: *dean@vanhornaviation.com.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 21, 2022.

Christina Underwood,

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

[FR Doc. 2022–25030 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0711; Airspace Docket No. 21–ANM–64]

RIN 2120–AA66

Amendment of Class E Airspace; Colorado Plains Regional Airport, CO.

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

ACTION: Final rule.

SUMMARY: This action modifies the Class E airspace designated as a surface area, modifies the Class E airspace extending upward from 700 feet above the surface, and removes the Class E airspace extending upward from 1,200 feet above the surface at Colorado Plains Regional Airport, CO. Additionally, this action makes several administrative modifications to update the airport's existing Class E airspace legal descriptions. These actions will support the safety and management of instrument flight rule (IFR) operations at the airport.

DATES: Effective 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference under Title 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11, Airspace Designations and Reporting Points, and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Nathan A Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would modify the Class E airspace at Colorado Plains Regional Airport, CO, to support IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** for FAA–2022–0711 (87 FR 45723; July 29, 2022) to modify the Class E airspace designated as a surface area, modify the Class E airspace extending upward from 700 feet above the surface, remove the Class E airspace extending upward from 1,200 feet above the surface, and make administrative changes to the Class E legal descriptions. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Subsequent to publication of the NPRM in the **Federal Register**, the FAA identified a discrepancy with the proposed Class E2 legal description. The airport name is removed from the description, as it is in the second line of the header and duplication is not necessary.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the ''**ADDRESSES**'' section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by modifying the Class E airspace designated as a surface area, modifying the Class E airspace extending upward from 700 feet above the surface, and removing the Class E airspace extending upward from 1,200 feet above the surface at Colorado Plains Regional Airport, CO.

The Class E airspace designated as a surface area is expanded to a 4.6-mile radius around the airport to more appropriately contain circling maneuvers.

Additionally, the Class E airspace extending upward from 700 feet above the surface is expanded to the southeast to contain aircraft conducting procedure turns for the VOR RWY 29 approach, as terrain exists within 1,500 feet of the minimum procedure turn altitude.

This action also removes the Class E airspace extending upward from 1,200 feet above the surface at the airport. This area is already contained within the Denver en route domestic airspace area and duplication is not necessary.

Finally, this action makes several administrative modifications to the airport's legal descriptions. The airport name in the text header was incorrect in the existing Class E2 and E5 legal descriptions. They now read ''Colorado Plains Regional Airport, CO.'' The geographic coordinates for the airport are updated to match the FAA's database. Lastly, the navigational aid (NAVAID) used in the existing Class E2 legal description is removed. The NAVAID has been reclassified and is not needed to describe the airspace. Its removal simplifies the airspace description.

Class E2 and E5 airspace designations are published in paragraphs 6002 and 6005, respectively, of FAA Order JO 7400.11G, dated August 19, 2022, and became effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11 is published annually and becomes effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory policies and procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, incorporation by reference, navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the FAA amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR part 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

ANM CO E2 Akron, CO [Amended]

Colorado Plains Regional Airport, CO
(Lat. 40°10′32″ N, long. 103°13′19″ W)

That airspace extending upward from the surface within a 4.6-mile radius of the airport.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM CO E5 Akron, CO [Amended]

Colorado Plains Regional Airport, CO
(Lat. 40°10′32″ N, long. 103°13′19″ W)

That airspace extending upward from 700 feet above the surface within 6.6 miles of the airport, and that airspace between 4 miles southwest and 8 miles northeast of the 123° bearing from the airport, extending from the 6.6-mile radius to 18.3 miles southeast of the airport.

Issued in Des Moines, Washington, on November 14, 2022.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–25106 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1404

RIN 3076–AA23

Rescission of the Arbitration Policy; Schedule of Fees

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule; rescission of regulation.

SUMMARY: On April 18, 2019, the Federal Mediation and Conciliation Service (FMCS) published a final rule amending the ''Arbitration Policy; Schedule of Fees'' to implement an increase in user fees. After careful review, FMCS finds that this rule is no longer suitable for publication. Therefore, this final rule rescinds the appendix regarding the Arbitration Policy; Schedule of Fees.

DATES: This final rule is effective November 18, 2022.

FOR FURTHER INFORMATION CONTACT: Anna Davis, Deputy General Counsel, Office of General Counsel, Federal Mediation and Conciliation Service, 250 E St. SW, Washington, DC 20427; Office/Fax/Mobile 202–606–3737; *adavis@fmcs.gov*.

SUPPLEMENTARY INFORMATION:

I. Discussion

On April 18, 2019, at 84 FR 16205, the Federal Mediation and Conciliation Service (FMCS) published a final rule amending the ''Appendix to Part 1404—Arbitration Policy; Schedule of Fees,'' which implemented a modest increase in user fees that had remained unchanged for more than eight years. FMCS increased fees to more accurately reflect FMCS' costs of maintaining the Arbitration Roster and the technology to support it, as well as responding to requests for arbitrator panels and biographical data.

After consideration and review, FMCS has concluded that the rule addressing fees is duplicative and currently incorporated in subparts of the rule. Therefore, FMCS is issuing this final rule, which rescinds the rule on the Appendix to Part 1404—Arbitration Policy; Schedule of Fees.

II. Final Rule

FMCS has determined that this rule is suitable for final rulemaking. The revisions to FMCS' policies and requirements surrounding arbitrators are purely internal matters of agency management, as well as the agency's procedure, and practice. Accordingly, FMCS is not required to engage in a notice and comment process to issue this rule under the Administrative Procedures Act, See U.S.C. 553(a)(2), 553(b)(A). Furthermore, because this rule is procedural rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable. FMCS also finds good cause to provide an immediate effective date for this rule because it imposes no obligations on parties outside the federal government and therefore no advance notice is required to enable employers or other private parties to come into compliance.

List of Subjects in 29 CFR Part 1404

Administrative practice and procedure, Labor management relations.

For the reasons discussed in the preamble, and under the authority of 29 U.S.C. 172 and the Taft-Hartley Act of 1947, FMCS amends 29 CFR part 1404 as follows:

PART 1404—ARBITRATION SERVICES

■ 1. The authority citation for part 1404 continues to read as follows:

Authority: 29 U.S.C. 172 and 29 U.S.C. 173 *et seq.*

Appendix to Part 1404 [Removed]

■ 2. Remove the appendix to part 1404.

Dated: November 15, 2022.

Anna Davis,

Deputy General Counsel.

[FR Doc. 2022–25141 Filed 11–17–22; 8:45 am]

BILLING CODE 6732–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0930]

RIN 1625–AA00

Safety Zone; Brakes Bayou, Beaumont, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within 200-feet of an unnamed railroad bridge that crosses Brakes Bayou in approximate position 30°05′22.3″ N 094°05′53.5″ W. The safety zone is needed to protect personnel, vessels and the marine environment from potential hazards created by demolition of the bridge. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Port Arthur.

DATES: This rule is effective without actual notice from November 18, 2022 through December 9, 2022. For the purposes of enforcement, actual notice will be used from November 9, 2022 until November 18, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0930 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Scott Whalen, Marine Safety Unit Port Arthur, TX, U.S. Coast Guard; telephone 409–719–5086, email *scott.k.whalen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port, Marine Safety Unit Port Arthur
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with because it is impracticable to publish a Notice of Proposed Rulemaking because the Coast Guard must establish this safety zone by November 9, 2022, and lacks sufficient time to provide a reasonable comment period and to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to protect personnel, vessels, and the marine environment from the potential safety hazards created by the demolition of the railroad bridge.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Port Arthur (COTP) has determined that potential hazards associated with demolition of the railroad bridge that crosses Brakes Bayou will be a safety concern for anyone within 200-feet of bridge located in approximate position 30°05′22.3″ N 094°05′53.5″ W (NAD83). For this reason, this rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the bridge is being demolished.

IV. Discussion of the Rule

This rule establishes a safety zone from November 9, 2022 through December 9, 2022. The safety zone will cover all navigable waters within 200-feet of vessels and machinery being used by personnel to demolish the railroad bridge that crossed Brakes Bayou in Beaumont, TX. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the bridge is being demolished.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the limited size and location of the safety zone. This safety zone will impact a small bayou tributary to the Neches River in Beaumont, TX. The bayou above the railroad bridge is approximately 2.2 NM, possess no residences, boat houses or public boat ramps and no commercial docks.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves safety zone lasting 30 days that will prohibit entry within 200-feet the abandoned railroad bridge that crossed Brakes Bayou in approximate position 30°05′22.3″ N 094°05′53.5″ W (NAD83) during demolition operations. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0930 to read as follows:

§ 165.T08–0930 Safety Zone; Brakes Bayou, Beaumont, TX.

(a) *Location.* The following area is a safety zone: all navigable waters of Brakes Bayou, shoreline-to-shoreline, extending 200-feet on either side of the

abandoned railroad bridge that crosses Brakes Bayou in approximate position 30°05′22.3″ N 094°05′53.5″ W. The duration of the safety zone is intended to protect personnel, vessels and the marine environment from potential hazards created by bridge demolition operations.

(b) *Effective period.* This section is effective from November 9, 2022 through December 9, 2022.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry of vessels or persons into the safety zone described in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur (COTP) or a designated representative. They may be contacted on VHF–FM channel 13 or 16, or by phone at by telephone at 409–719–5070.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs).

Dated: November 8, 2022

Molly A. Wike,

Captain, U.S. Coast Guard, Captain of the Port, Marine Safety Zone Port Arthur.

[FR Doc. 2022–25092 Filed 11–17–22; 8:45 am]

BILLING CODE 9110–04–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR 1151

[Docket No. ATBCB–2022–0005]

RIN 3014–AA49

Bylaws

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Direct final rule.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (hereafter, ''Access Board,'' or ''Board'') has amended its bylaws. These amendments update agency procedures and enhance efficiency of operations.

DATES: This final rule is effective November 18, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Kuczynski, General Counsel, U.S. Access Board, (202) 272–0042, *kuczynski@access-board.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

At its November 9, 2022 meeting, the Access Board approved a number of changes to its bylaws, published at 36 CFR 1151. Specifically:

- A new section (to be codified at 36 CFR 1151.3) sets out requirements for Board membership, consistent with section 502 of the Rehabilitation Act (29 U.S.C. 792), and prescribes rules for the designation in writing of federal members and federal liaisons to the Board. Federal members are heads of agencies listed in paragraph (b) of § 1151.3, or their designees, who must be at Level IV of the Executive Schedule or higher. Federal members may include individuals serving in positions on a temporary or acting basis, in accordance with federal law and with agency rules, policies, and practices (paragraph (c)(2)). Federal members and federal liaisons to the Board must be designated in writing (paragraphs (c)(1) and (3)), (which may include designation by electronic mail from a verifiable account), by someone who has authority to make the designation (paragraph (c)(4)). Written designations for members may identify the particular position within the agency, an individual, or both. Previously, the Board bylaws had no requirements concerning designation in writing of federal members or liaisons.
- The language in what was, prior to amendment of the bylaws, § 1151.3(a) (concerning officers), which says that the Board is the governing body of the agency, is now the first sentence in § 1151.2. Additionally, former paragraph (b) (Chair and Vice Chair) and former paragraph (c) (Elections), have been combined and redesignated as paragraphs (a)(1) and (2), former paragraph (d) (Executive Director) is now paragraph (b), and former paragraph (e) (General Counsel) is now paragraph (c).
- Section 1151.5 (previously § 1151.4), entitled ''Delegations,'' has been revised slightly. The title of paragraph (a) is now ''Delegations to the Executive Committee,'' since that is more consistent with the overall title of the section and better describes the contents of the paragraph, which describe delegations to, not by, the Executive Committee. A cross-reference to § 1151.7(a), which establishes the Executive Committee is also provided here, since this is the first reference to the Executive Committee in the bylaws.
- Section 1151.6 (previously § 1151.5) makes several changes with respect to Board meetings.

○ Paragraph (a) reduces the number of meetings from six annually to four. One of the meetings may be a public event outside of the Washington, DC area. Such a public event is not, as it previously had been, required each year, but may instead be a regular meeting of the Board.

○ Paragraph (b) says that meetings ordinarily will occur in January, April, July, and October, but does not specify a particular day or week during each month that the meeting must occur. Previously, the bylaws said that regular meetings of the Board would occur on the Wednesday following the second Tuesday of the month. The Chair may reschedule a meeting to the month before or after the month specified in the bylaws.

○ Paragraph (c) which is new, specifies that two meetings will be in-person, with an option for participation remotely, and two meetings may be entirely remote. This paragraph also states that the Board will comply with all applicable laws in the manner in which it conducts meetings, including the obligation to provide reasonable accommodations for Board members, employees, members of the public, and other participants (who might include, for example, individuals making presentations to the Board or a committee). Because of the addition of this paragraph, the lettering of subsequent paragraphs has been adjusted.

○ Paragraph (d) alters the requirement, in former paragraph (c), that the Chair establish the agenda for Board meetings to say that the Chair may consult with the Executive Director as necessary and appropriate. This merely clarifies existing practice.

○ Paragraph (e) provides for notice to the Board and to the public of the dates for each year's Board meetings at least 30 days prior to the January meeting. Notice may be provided on the Access Board's website and/or through any other means by which the public is likely to access it. Notice to members of the public will include language indicating that reasonable accommodation will be provided to enable participation in the meeting by individuals with disabilities, absent undue burden. Although the Board has historically provided reasonable accommodations for Board members, staff, and members of the public, inclusion of this language in the notice promotes the broadest level of participation possible by informing individuals with disabilities who may not be aware of the right to reasonable accommodation, and is consistent with the Board's mission of promoting accessibility and inclusion for people with disabilities.

○ Paragraph (f) says that the Chair will give notice of a meeting's cancelation at least 10 days prior to the meeting where practical, and if the meeting is a public meeting, will give notice to the public of the cancelation at the same time.

○ Paragraph (g) requires reasonable advance notice of a special meeting, as well as the time place and purpose of the meeting. This is consistent with the current bylaws. However, anticipating the possibility that a special meeting could be a public meeting, the amendment provides for notice to the public of the meeting, including language indicating that the Board will provide reasonable accommodation to enable participation, absent undue burden.

○ Paragraph (k)(5) provides five business days for a notational vote. The Chair has discretion to extend the period of time if, at the end of the voting period, there are an insufficient number of votes for the Board to take action. An amendment specifying that notational voting may occur through electronic mail reflects current practice. The bylaws previously provided for notational voting for actions taken between meetings of the Board, but did not describe the manner or form in which it would occur.

○ Paragraph (l), which says that Board members shall be considered present at any meeting in which they participate by teleconference or other equipment that allows all participants to communicate with each other is unchanged from former paragraph (k). Its labeling simply changed when a new paragraph (c) was inserted.

Section 1151.7 (previously 1151.6) makes some changes to requirements related to committees.

○ Paragraph (a)(1) has been revised to make certain duties of the Executive Committee discretionary rather than mandatory. For example, the Executive Committee now may, but is not required to, review and recommend changes to the bylaws prior to submission of proposed amendments to the Board.

○ Paragraph (b)(2) has been revised to require the Board to vote only for the Chair of a subject matter committee. Previously, paragraph (b)(2) said that the Board elects both the Chair and Vice Chair of a subject matter committee; however, this contradicted the language in paragraph (b)(3) immediately following, which said that the Chair of the Board appoints members of standing committees other than the Chair, who is elected by the Board. The revised bylaws resolve the contradiction in favor of the Board voting on the Chair only, since this would simplify the voting process and have no impact on the operation of committees.

○ Paragraph (b)(3) reduces the number of members on a subject matter committee from seven to nine to five to seven). Currently, the Board has four subject matter committees and three special committees, as well as an Executive Committee. The amendment to the bylaws reducing the number of committee members will actually facilitate committee work while limiting the number of committees to which specific Board members need to be assigned.

II. Regulatory Process Matters

Administrative Procedure Act

This final rule implements amendments to the Access Board's bylaws and solely addresses internal matters related to agency management and practices. As such, this rule is exempt from the notice-and-comment process pursuant to the Administrative Procedures Act. See 5 U.S.C. 553(a)(2), 553(b)(3)(A).

Executive Order 12866

This final rule establishes internal rules of agency procedure only. OMB has determined that the rule is not a significant regulatory action within the meaning of Executive Order 12866.

Congressional Review Act

This final rule is not a major rule within the meaning of the Congressional Review Act. *See* 5 U.S.C. 801 *et seq.*

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires Federal agencies to analyze regulatory options that may assist in minimizing any significant impact of a rule on small businesses and small governmental jurisdictions. See 5 U.S.C. 604, 605(b). Because this final rule relates solely to agency internal procedures and, moreover, is not subject to notice-and-comment rulemaking, the RFA is inapplicable.

Federalism (Executive Order 13132)

The Access Board has analyzed this final rule in accordance with the principles and criteria set forth in Executive Order 13132. The Board has determined that this action will not have a substantial direct effect on the States, the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

Paperwork Reduction Act

This final rule does not specify any new collections of information or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act. See 44 U.S.C. 3501 *et seq.*

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (codified at 2 U.S.C. 1531 *et seq.*) (''UMRA'') generally requires that Federal agencies assess the effects of their discretionary regulatory actions that may result in the expenditure of $100 million (adjusted for inflation) or more in any one year by the private sector, or by State, local, and tribal governments in the aggregate. Because this final rule is not subject to notice-and-comment rulemaking, UMRA's analytical requirements do not apply. See 2 U.S.C. 1532(a).

For the reasons set forth in the preamble, the Access Board amends 36 CFR part 1151 as follows:

PART 1151—BYLAWS

■ 1. The authority citation for part 1151 continues to read as follows:

Authority: 29 U.S.C. 792

■ 2. Amend § 1151.2 by adding a new first sentence:

§ 1151.2 Authority

The Board is the governing body of the agency. * * *

§§ 1151.3 through 1151.7 [Redesignated]

■ 3. Redesignate §§ 1151.3 through 1151.7 as §§ 1151.4 through 1151.8.

■ 4. Add a new § 1151.3 to read as follows:

§ 1151.3 Membership

(a) *Public Members.* (1) The Board shall have thirteen members appointed by the President from among members of the general public, at least a majority of whom shall have disabilities.

(2) Members shall be appointed for a term of four years, may be reappointed to one successive term, and thereafter may not be reappointed unless they have not served on the Access board for at least two years prior to their reappointment. Each year, the terms of at least three members of the Board shall expire. A public member may continue to serve following expiration of the member's term if a successor has not been appointed.

(b) *Federal Members.* The remaining members of the Board shall be the heads of the following agencies or their designees whose positions are Executive Level IV or higher:

(1) The Department of health and Human Services;
(2) The Department of Transportation;
(3) The Department of Housing and Urban Development;
(4) The Department of Labor;
(5) The Department of the Interior;
(6) The Department of Defense;
(7) The Department of Justice;
(8) The General Services Administration;
(9) The Department of Veterans Affairs;
(10) The United States Postal Service;
(11) The Department of Education; and
(12) The Department of Commerce.

(c) *Designation of Federal Board Members and Liaisons.* (1) Designation of a Federal Board member other than an agency head shall be made in writing by the agency head or by anyone authorized to provide such designation on behalf of the agency head. The designation may either be of a particular position, an individual, or both. If only a specific person is designated and not the position, a new designation will be required where appointment of another person to fill the position is subsequently made. The designation shall remain in effect for as long as provided for under applicable agency rules, regulations, or policies.

(2) An individual serving in an acting capacity, or who is otherwise temporarily serving, in a position at Executive Level IV or higher may be designated to serve on the Board, subject to any time limitations under applicable law, or under agency rules, regulations, or policies.

(3) Any newly-appointed Federal Board member shall designate in writing a liaison to the Board. A newly appointed Federal Board member may allow an individual previously serving as a liaison to the Board to continue to do so, but must provide a new designation in writing.

(4) Written designation of a Federal Board member or liaison may be in any form (including from a verifiable email address) indicating the identity of the person making the designation and that the person is authorized to do so.

■ 5. Revise newly redesignated § 1151.4 to read as follows:

§ 1151.4 Officers

(a) *Chair; Vice Chair.* (1) The head of the agency is the Chair of the Board and, in his or her absence or disqualification, the Vice-Chair of the Board. As head of the agency, the Chair represents the Board whenever an applicable Federal statute or regulation imposes a duty or grants a right or authority to the head of the agency and has the authority to act in all matters relating to the operation of the Board. The Chair may delegate any such duties and responsibilities by written delegation of authority. The Chair supervises the Executive Director and evaluates his or her performance and approves performance evaluations of employees who report directly to the Executive Director. The authority to supervise, evaluate, and approve performance evaluations of the Executive Director and those employees who report directly to the Executive Director may only be delegated to the Vice-Chair of the Board.

(2) The Chair and the Vice-Chair of the Board shall be elected by a majority of the membership of the Board (as fixed by statute) and serve for terms of one year. Elections shall be held as soon as possible upon completion of the one year term of the Chair and Vice-Chair, ordinarily at the April meeting of the Board. If no new Chair or Vice-Chair has been elected at the end of the one-year term, the incumbents shall continue to serve in that capacity until a successor Chair or Vice-Chair has been elected. When the Chair is a public member, the Vice-Chair shall be a Federal member; and when the Chair is a Federal member, the Vice-Chair shall be a public member. Upon the expiration of the term as Chair of a Federal member, the subsequent Chair shall be a public member; and vice versa.

(b) *Executive Director.* The Executive Director is nominated by the Chair and confirmed by the Board. The Executive Director provides administrative leadership and supervision and management of staff activities in carrying out the policies and decisions of the Board under the direction and supervision of the Chair. The Executive Director has the authority to execute contracts, agreements, and other documents necessary for the operation of the Board; hire, fire and promote staff (including temporary or intermittent experts and consultants); procure space, equipment, and supplies; and obtain interagency and commercial support services. The Executive Director directs compliance and enforcement activities in accordance with the procedures set forth in 36 CFR part 1150, including issuing citations and determinations not to proceed, conducting negotiations for compliance, entering into agreements for voluntary compliance, and performing all other actions authorized by law pertaining to compliance and enforcement not otherwise reserved to the Board.

(c) *General Counsel.* The General Counsel is nominated by the Chair and confirmed by the Board. The General Counsel is responsible to the Board under the supervision of the Executive Director.

■ 6. In newly redesignated § 1151.5, revise the section heading and the first sentence of paragraph (a) as follows:

§ 1151.5 Delegations

(a) *Delegations to the Executive Committee.* The Board may delegate to the Executive Committee (provided for in § 1151.7(a)) authority to implement its decisions by a majority vote of the members present at a meeting and any proxies. * * *

* * * * *

■ 7. Revise newly redesignated § 1151.6 to read as follows:

§ 1151.6 Board meetings.

(a) *Number.* The Chair shall schedule four meetings of the Board each year starting January 2023, one of which may be a Board sponsored public event outside the Washington, DC area.

(b) *Timing.* Regular meetings of the Board shall ordinarily be held in January, April, July, and October of each calendar year. The Chair may reschedule a regular meeting of the Board to another date during the month preceding or following the month in which the regularly scheduled meeting was to occur.

(c) *Manner of conducting meetings.* Two regular Board meetings will be in person, but allow for participation by the Board, liaisons, and members of the public remotely, and two meetings may be entirely remote. The Board shall comply with all legal requirements concerning the manner of conducting meetings, including the requirement to provide reasonable accommodations for Board members, employees, members of the public, and other participants.

(d) *Agenda.* The Chair establishes the agenda for the meetings, in consultation with the Executive Director as necessary and appropriate. Members or committees may forward submissions for agenda items to the Chair and/or to the Executive Director. Except for items concerning the adoption, amendment, or rescission of the bylaws in this part, an item may be placed before the Board for consideration without the approval of the Chair upon a two-thirds vote of the members present at a Board meeting and any proxies to suspend the rules of order. Items concerning the adoption, amendment, or rescission of the bylaws in this part may be placed on a future Board agenda without the approval of the Chair upon a vote of two-thirds of the membership of the Board (as fixed by statute).

(e) *Notice.* (1) The Chair shall provide a schedule in writing of Board meetings

for the upcoming year at least thirty (30) days prior to the January Board meeting and shall provide to each Board member the agenda and supporting materials for each meeting at least ten (10) work days prior to each meeting. The ten (10) days notice requirement may be waived upon a two-thirds vote by the members present at the Board meeting and any proxies to suspend the rules of order.

(2) The public shall receive notice of the dates of meetings for the upcoming year at least thirty (30) days prior to the January Board meeting. Notice may be by publication of the schedule of meetings on the agency's website and/or through any other means by which interested members of the public are likely to access it. The notice shall include a statement that the Board will provide reasonable accommodations, absent an undue burden, that will enable members of the public to participate in meetings.

(f) *Cancellation.* The Chair may cancel a regular meeting of the Board by giving written notice of the cancellation at least ten (10) work days prior to the meeting where practical. If the canceled meeting is a public meeting, members of the public will be given notice of its cancelation at the same time as Board members.

(g) *Special meetings.* The Chair may call special meetings of the Board to deal with important matters arising between regular meetings which require action by the Board prior to the next regular meeting. Voting and discussion shall be limited to the subject matter which necessitated the call of the special meeting. All Board members shall receive reasonable advance notice of the time, place, and purpose of the special meeting. If the special meeting is also a public meeting, members of the public shall be given notice of its occurrence at the same time as Board members, and such notice shall indicate that the Board will provide reasonable accommodations for members of the public to participate in the meeting, absent undue burden.

(h) *Record.* The Executive Director shall maintain a permanent record of the minutes of all meetings and attendance. The Board shall approve the final minutes after all corrections and additions have been incorporated.

(i) *Rules for Board meetings.* Meetings of the Board shall be held in accordance with Robert's Rules of Order, except as otherwise prescribed in the bylaws in this part.

(j) *Quorum.* (1) A quorum shall be the majority of the membership of the Board (as fixed by statute). A majority of the members required for a quorum shall be public members.

(2) Proxies shall not be counted for purposes of establishing a quorum.

(3) If a quorum is not present, a meeting shall be held only for the purpose of discussion and no vote may be taken.

(k) *Voting.* (1) Only Board members may vote.

(2) Except as otherwise prescribed in the bylaws in this part, a majority vote of the members present and any proxies is necessary for action by the Board.

(3) The presiding officer shall have the same right to vote as any other member.

(4) Any member may give his or her directed or undirected proxy to any other Board member present at the meeting. Proxies shall be given in writing and submitted to the Chair prior to or at the meeting. A directed proxy shall be voided as to a specific issue if the question on which the vote is eventually taken differs from the question to which the proxy is directed.

(5) The Board may act on items of business between meetings by notational voting. At the request of the Chair, the Executive Director shall send a written ballot (which may be in the form of electronic mail) to each Board member describing each item submitted for notational voting. If any Board member requests discussion on an item, the ballots shall not be counted and the Chair shall place the item on the next Board meeting agenda for discussion and voting. Notational votes shall ordinarily occur over a period of five (5) business days, but may be extended, at the Chair's discretion, if, at the conclusion of the voting period, an insufficient number of votes have been cast to approve or disapprove an action.

(l) *Telecommunications.* A member of the Board shall be considered present at a meeting when he or she participates in person or by conference telephone or similar communication equipment that enables all persons participating in the meeting to communicate with each other.

■ 8. In newly redesignated § 1151.7, revise paragraphs (a)(1) and (b)(2) and (3) to read as follows:

§ 1151.7 Committees.

(a) * * * (1) *Establishment.* The Board shall have an Executive Committee to serve as a leadership and coordinating committee. The Executive Committee acts on behalf of the Board in between regularly scheduled Board meetings as necessary and as authorized by delegation of the Board. In addition, the Executive Committee may perform one or more of the following duties:

(i) Review and consider recommendations and proposals from the various subject matter committees;

(ii) Review and make recommendations to the Board to amend or approve the Board's bylaws; and

(iii) Request and review all committee charters.

* * * * *

(b) * * *

(2) *Chair.* The Chair of a subject matter committee shall be elected by the Board after the election of the Chair and Vice-Chair of the Board. The Chair of a subject matter committee shall serve as a member of the Board's Executive Committee.

(3) *Membership.* Each subject matter committee shall be comprised of a minimum of five (5), and a maximum of seven (7), members. Except for the Chair of the committee who is elected by the Board, the members of the committee shall be appointed by the Chair of the Board. Members shall serve a term of one year corresponding to that of the Chair of the Board, and continue their duties until their successors have been appointed.

* * * * *

Christopher Kuczynski,

General Counsel.

[FR Doc. 2022–25147 Filed 11–17–22; 8:45 am]

BILLING CODE 8150–01–P

POSTAL SERVICE

39 CFR Part 111

Domestic Competitive Products Pricing and Mailing Standards

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), to reflect changes to prices and mailing standards for competitive products.

DATES: Effective January 22, 2023.

FOR FURTHER INFORMATION CONTACT: Karen F. Key at (202) 268–7492, Margaret Pepe (202) 268–3078, or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: This final rule describes new prices and product features for competitive products, by class of mail, established by the Governors of the United States Postal Service®. New prices are available under Docket Number CP2023–42 on the Postal Regulatory Commission PRC website at *http://www.prc.gov,* and on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service will revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), to reflect changes to prices and mailing standards for the following competitive products:

- Priority Mail Express®.
- Priority Mail®.
- First-Class Package Service®.
- Parcel Select®.
- USPS Retail Ground®.
- Extra Services.
- Return Services.
- Mailer Services.
- Recipient Services.
- Other.

Competitive product prices and changes are identified by product as follows:

Priority Mail Express

Prices

Overall, Priority Mail Express prices will increase 6.6 percent. Priority Mail Express will continue to offer zoned and Flat Rate, Retail and Commercial pricing.

Retail prices will increase an average of 6.7 percent. The Flat Rate Envelope price will increase to $28.75, the Legal Flat Rate Envelope will increase to $28.95, and the Padded Flat Rate Envelope will increase to $29.45.

Commercial prices will increase an average of 6.0 percent.

Priority Mail Express Commercial Base and Plus Pricing Consolidated

The Postal Service is consolidating Priority Mail Express ''Commercial Base'' and ''Commercial Plus'' into one ''Commercial'' price category. Consolidating the ''Commercial Base'' and ''Commercial Plus'' price categories will simplify the Priority Mail Express pricing structure. The eligibility standards for Priority Mail Express Commercial will mirror the current ''Commercial Base'' price category.

Priority Mail

Prices

Overall, Priority Mail prices will increase 5.5 percent. Priority Mail will continue to offer zoned and Flat Rate, Retail and Commercial pricing.

Retail prices will increase an average of 6.8 percent. The Flat Rate Envelope price will increase to $9.65, the Legal Flat Rate Envelope will increase to $9.95, and the Padded Flat Rate Envelope will increase to $10.40. The Small Flat Rate Box price will increase to $10.20, and the Medium Flat Rate Boxes will increase to $17.10. The Large Flat Rate Box will increase to $22.80 and the APO/FPO/DPO Large Flat Rate Box will increase to $21.20.

Commercial prices will increase an average of 3.6 percent.

Priority Mail Commercial Base and Plus Pricing Consolidated

The Postal Service is consolidating the Priority Mail ''Commercial Base'' and ''Commercial Plus'' price categories into one ''Commercial price category. Consolidating the ''Commercial Base'' and ''Commercial Plus'' price categories will simplify the Priority Mail pricing structure. The eligibility standards for Priority Mail Commercial will mirror the current ''Commercial Base'' price category.

Priority Mail Regional Rate Boxes Discontinued

The Postal Service is discontinuing the Priority Mail Regional Rate product offering. The decision to discontinue Regional Rate Boxes will simplify the Priority Mail offering.

First-Class Package Service

Prices

Overall, First-Class Package Service prices will increase 7.8 percent.

First-Class Package Service—Retail prices will increase 6.9 percent.

First-Class Package Service—Commercial prices will increase 8.0 percent.

Parcel Select

Prices

The prices for Parcel Select Destination Entry will increase an average of 5.1 percent. Parcel Select Ground will have a 0.0 percent price change, but prices will be updated in zones 1 and 2. The prices for Parcel Select Lightweight® will increase an average of 6.1 percent. The prices for USPS Connect® Local will remain the same.

USPS Retail Ground

Overall, USPS Retail Ground prices will increase an average of 6.4 percent.

Extra Services

Adult Signature Service

Adult Signature Required and Adult Signature Restricted Delivery service prices are increasing 6.5 and 6.8 percent respectively. The price for Adult Signature Required will increase to $9.05 and Adult Signature Restricted Delivery will increase to $9.35.

Return Services

Parcel Return Service

The Postal Service is revising the standards for Parcel Return Service (PRS) to be a competitive product only available through a Negotiated Service Agreement (NSA). As a nonpublished offering, the standards will be removed from the DMM and the prices will be removed from the Price List, Notice 123.

USPS Returns

The Postal Service is discontinuing the Certificate of Mailing and Signature Confirmation extra service options for USPS Returns products.

In an effort to provide product simplification, the Postal Service believes it is in the best interest to no longer offer Certificate of Mailing or Signature Confirmation services for USPS Returns products.

Mailer Services

Pickup on Demand Service

The Pickup on Demand® service fee will increase 6.0 percent to $26.50.

USPS Tracking Plus Service

The USPS Premium Tracking Service™ prices will remain the same.

USPS Label Delivery Service

The Postal Service is implementing USPS Label Delivery Service™ to provide customers with an option to have their domestic outbound and return mailing labels printed and delivered for a fee per label at a Post Office where available. USPS Label Delivery Service is not available for APO/FPO/DPO addresses. Customers requesting USPS Label Delivery Service will be provided the tracking information for tracking purposes. A customer may request USPS Label Delivery Service at *www.usps.com.*

USPS Label Delivery Service is available for Retail and Commercial Priority Mail Express and Priority Mail, First-Class Package Service—Retail, First Class Package Service—Commercial, USPS Retail Ground, Parcel Select Ground, Priority Mail Return service, and First-Class Package Return service.

There are no extra services available with labels requested through USPS Label Delivery Service.

For USPS Label Delivery Service, the Postal Service will refund the postage and USPS Label Delivery Service fee if the label is not delivered. The Postal Service will refund the postage only if the label is delivered and not used.

Recipient Services

Post Office Box Service

The competitive Post Office Box™ service prices will increase an average of 6.5 percent within the updated price ranges.

Premium Forwarding Service

Premium Forwarding Service® (PFS®) prices will increase between 6.5 and 6.6 percent depending on the specific price element. The enrollment fee paid at the retail counter for PFS-Residential will increase to $25.45 and the PFS-Residential, PFS-Commercial, and PFS-Local enrollment fee paid online will increase to $23.40 per application. The price of the weekly shipment charge for PFS-Residential and per container charge for PFS-Local will increase to $25.45.

USPS Package Intercept

The USPS Package Intercept® fee will increase 6.6 percent to $17.00.

Other

Address Enhancement Service

Address Enhancement Service competitive product prices will remain the same.

Small Parcel Forwarding Fee

The small parcel forwarding fee will remain the same at $5.25.

Zone Modification

The Postal Service is modifying zone price categories for all applicable Competitive products. This zone modification will redefine the local zone and remove it as a zone price category. The Postal Service will also split zones 1 and 2 into separate price categories. This will result in nine individual zone price categories.

Additionally, the Postal Service is clarifying that the zone 1 price applies to pieces mailed within the same 3 Digit O/D Pairs and pieces mailed with different 3 Digit O/D Pairs whose centroids are up to 50 miles in distance.

Resources

The Postal Service provides additional resources to assist customers with this price change for competitive products. These tools include price lists, downloadable price files, and **Federal Register** Notices, which may be found on the Postal Explorer® website at *http://pe.usps.com.*

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401–404, 414, 416, 3001–3018, 3201–3220, 3401–3406, 3621, 3622, 3626, 3629, 3631–3633, 3641, 3681–3685, and 5001.

■ 2. Revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

100 Retail Mail Letters, Flats, and Parcels

* * * * *

120 Retail Mail Priority Mail

123 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Delete 1.5, Regional Rate Boxes, and renumber 1.6 and 1.7 as 1.5 and 1.6.]

* * * * *

1.6 Nonstandard Fees

[Revise the introductory text of renumbered 1.6 to read as follows:]

Except for Flat Rate packaging, a Priority Mail piece is subject to a nonstandard fee (see Notice 123—Price List) as follows:

* * * * *

125 Mail Preparation

1.0 Preparation

* * * * *

[Revise the heading of 1.2 to read as follows:]

1.2 Sealing Flat Rate Packaging

[Revise the first sentence of 1.2 to read as follows:]

When sealing a Flat Rate Envelope or Flat Rate Box, the container flaps must be able to close within the normal folds.

* * *

* * * * *

200 Commercial Mail, Letters, Flats, and Parcels

201 Physical Standards

* * * * *

7.0 Physical Standards for Parcels

* * * * *

7.3 Maximum Weight and Size

[Revise the second sentence of 7.3 to read as follows:]

* * * Lower weight limits apply to parcels mailed at Priority Mail Cubic, First-Class Package Service—Commercial, USPS Marketing Mail, and Bound Printed Matter prices. * * *

* * * * *

8.0 Additional Physical Standards by Class of Mail

* * * * *

8.2 Priority Mail

[Revise the first sentence of 8.2 to read as follows:]

The maximum weight is 70 pounds, except for cubic (20 pounds) parcels.

* * *

* * * * *

202 Elements on the Face of a Mailpiece

* * * * *

3.0 Placement and Content of Mail Markings

* * * * *

3.3 Priority Mail Express and Priority Mail Markings

* * * * *

3.3.3 Additional Markings for Priority Mail Express and Priority Mail

[Revise the text of 3.3.3 to read as follows:]

In addition to the basic price marking in 3.3.1 and 3.3.2, except for pieces paid using a USPS Returns service or permit imprint, Priority Mail Express and Priority Mail pieces claimed at Commercial prices also must bear the ''Commercial'' price marking, printed on the piece or produced as part of the meter imprint or PC Postage indicia. Place the ''Commercial'' price marking directly above, directly below, or to the left of the postage.

* * * * *

3.4 Priority Mail Cubic Markings

* * * * *

3.4.2 Price Marking—Permit Imprint

[Revise the first sentence of 3.4.2 to read as follows:]

Priority Mail permit imprint pieces claiming the cubic price must be marked ''Priority Mail'' and bear the ''cubic'' marking (see 3.4.3 for soft pack and padded envelopes), printed on the piece or produced as part of the permit imprint indicia. * * *

* * * * *

204 Barcode Standards

* * * * *

2.0 Standards for Package and Extra Service Barcodes

2.1 Intelligent Mail Package Barcode

2.1.1 Definition

[Revise the last sentence of 2.1.1 to read as follows:]

* * * A ZIP + 4 is required to be encoded into the barcode for all returns products.

* * * * *

2.2 Other Package Barcodes

* * * * *

2.2.11 Service Banner Text

[Revise the text of 2.2.11 to read as follows:]

Except with Certified Mail, Registered Mail, Adult Signature, and Priority Mail Express or Priority Mail Open and Distribute services, mailers preparing extra service barcodes under 2.2 must use a ''USPS TRACKING #'' human-readable service banner text above the barcode on packages not requiring a signature at delivery, or a ''USPS SIGNATURE TRACKING #'' service banner text above the barcode on packages where a signature is required at delivery.

* * * * *

210 Commercial Mail Priority Mail Express

213 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Revise the heading and introductory text of 1.3 to read as follows:]

1.3 Commercial Prices

Priority Mail Express commercial prices are less than Priority Mail Express retail prices (see Notice 123—Price List). These prices are available to:

* * * * *

[Delete 1.4, Commercial Plus Prices, in its entirety and renumber 1.5 through 1.10 as 1.4 through 1.9.]

* * * * *

214 Postage Payment and Documentation

1.0 Basic Standards for Postage Payment Options

[Renumber 1.1 and 1.2 as 1.2 and 1.3. Revise 1.0 by renumbering the current text as 1.1 to read as follows:]

1.1 General

Federal agency and USPS official Priority Mail Express may use the appropriate indicia, subject to 703.7.0. The mailer is responsible for proper payment of postage.

* * * * *

[Revise the heading and introductory text of renumbered 1.2 to read as follows:]

1.2 Commercial Pricing

Commercial Priority Mail Express postage may be paid with:

* * * * *

[Delete renumbered 1.3, Commercial Plus Pricing, in its entirety.]

* * * * *

220 Commercial Mail Priority Mail

223 Prices and Eligibility

1.0 Prices and Fees

1.1 Price Application

The following price applications apply:

[Revise the first sentence of item a to read as follows:]

a. Except for cubic items (see 1.1c), customers mailing Priority Mail mailpieces are charged per pound of the mailpiece; any fraction of a pound is rounded up to the next whole pound.

* * *

* * * * *

[Delete item c in its entirety and renumber items d through g as items c through f.]

[Delete renumbered item d in its entirety and renumber items e and f as items d and e.]

[Revise renumbered item d to read as follows:]

d. Priority Mail Open and Distribute tray boxes mailed at commercial prices are not based on weight but are charged based on the tray box and zone to which it is sent.

* * * * *

[Revise the heading and introductory text of 1.2 to read as follows:]

1.2 Commercial Prices

For prices, see Notice 123—Price List. Commercial prices are available for:

[Delete item a and renumber items b through f as items a through e.]

* * * * *

[Delete the last sentence of renumbered item c referencing Regional Rate Boxes.]

* * * * *

[Delete 1.3 in its entirety and renumber 1.4 through 1.13 as 1.3 through 1.12.]

* * * * *

[Delete renumbered 1.6, Regional Rate Box Prices, in its entirety and renumber 1.7 through 1.12 as 1.6 through 1.11.]

* * * * *

1.10 Nonstandard Fees

[Revise the introductory text of renumbered 1.10 to read as follows:]

Except for Flat Rate packaging and Priority Mail Return service packages, a Priority Mail piece is subject to a nonstandard fee (see Notice 123—Price List) as follows:

* * * * *

3.0 Basic Eligibility Standards for Priority Mail

3.1 Description of Service

[Revise the last sentence of 3.1 to read as follows:]

* * * Lower weight limits apply to cubic pieces (see 1.4); APO/FPO mail subject to 703.2.0 and 703.4.0 and Department of State mail subject to 703.3.0.

* * * * *

224 Postage Payment and Documentation

1.0 Basic Standards for Postage Payment

1.1 Postage Payment Options

[Revise the heading and introductory text of 1.1.1 to read as follows:]

1.1.1 Commercial Pricing

Priority Mail commercial postage may be paid with:

[Delete item a in its entirety and renumber items b through e as items a through d.]

* * * * *

[Delete 1.1.2, Commercial Plus Pricing, in its entirety and renumber 1.1.3 as 1.1.2.]

* * * * *

225 Mail Preparation

1.0 General Information for Mail Preparation

* * * * *

[Revise the heading of 1.2 to read as follows:]

1.2 Sealing Flat Rate Packaging

[Revise the first sentence of 1.2 to read as follows:]

When sealing a Flat Rate Envelope or Flat Rate Box, the container flaps must be able to close within the normal folds.

***

* * * * *

500 Additional Mailing Services

503 Extra Services

1.0 Basic Standards for All Extra Services

* * * * *

1.4 Eligibility for Extra Services

* * * * *

1.4.3 Eligibility—Domestic Returns

* * * * *

Exhibit 1.4.3 Eligibility—Domestic Returns

[Delete the ''Signature Confirmation'' option from both the ''Paid by EPS Account or by Permit Holder'' and the ''Paid by Sender'' sections of the table. Delete the ''Certificate of Mailing'' option from the ''Paid by Sender'' section of the table.]

[Delete the ''Parcel Return Service'' line item from Exhibit 1.4.3.]

* * * * *

503 Extra Services

* * * * *

4.0 Insured Mail

* * * * *

4.2 Insurance Coverage—Priority Mail

Priority Mail pieces, including Priority Mail Return service, are insured against loss, damage, or missing contents, up to a maximum of $100.00, subject to the following:

* * * * *

[Revise the text of item b to read as follows:]

b. Insurance coverage is provided against loss, damage, or missing contents and limited to a maximum liability of $50.00 when the Priority Mail pieces bear an IMpb or USPS retail tracking barcode, and the mailer pays retail or commercial prices.

* * * * *

4.3 Basic Standards

4.3.1 Description

* * * The following additional standards apply to insured mail:

[Revise the third sentence of item a to read as follows:]

a. * * * For customer-generated integrated barcodes used for USPS Returns service, the returns account holder must provide USPS with electronic data in a shipping services file, version 1.6 or higher, that identifies the USPS Tracking number of the insured return package, total postage paid, insurance fee paid, declared value, mailing date, origin ZIP Code, and delivery ZIP Code, along with the recipient's name and address information. * * *

* * * * *

505 Return Services

* * * * *

3.0 USPS Returns Service

3.1 Basic Standards

* * * * *

3.1.3 Postage and Prices

Postage and prices are subject to the following:

* * * * *

b. Prices for Priority Mail Return Service, First-Class Package Return Service, and Ground Return Service (Parcel Select Ground) packages are charged as follows:

[Revise the text of item b1 to read as follows:]

1. Priority Mail commercial prices are available for account holders using Priority Mail Return Service, when all applicable requirements are met.

[Delete item b2 and renumber items b3 and b4 as items b2 and b3.]

* * * * *

c. The account holder or mailer may obtain extra and additional services as follows:

* * * * *

[Delete items c2 and c3 in their entirety and renumber item c4 as item c2.]

* * * * *

3.1.4 Labels

Distribution and preparation of labels are subject to the following:

a. *Distribution of Labels.* USPS Returns service labels may be distributed to customers via the following:

[Add new item a6 to read as follows:]

6. Through USPS Label Delivery Service under 507.12.0.

* * * * *

3.2 Additional Standards

Additional mailing standards applicable to each service option are as follows:

[Revise the last sentence of item a to read as follows:]

a. * * * Commercial prices are the same as for outbound Priority Mail in Notice 123—Price List.

* * * * *

4.0 Parcel Return Service

[Delete the text under 4.0 in its entirety (4.1 through 4.3) and add new text under 4.0 to read as follows:]

Parcel Return Service (PRS) applies to parcels that are picked up in bulk by authorized permit holders or their agents. Parcel Return Service is only available through a Negotiated Service Agreement (NSA) (709.1.0). Please contact a USPS Sales Representative for additional details.

* * * * *

507 Mailer Services

* * * * *

5.0 Package Intercept

* * * * *

5.2 Postage and Fees

[Revise the third sentence in the introductory text of 5.2 to read as follows:]

* * * The new Priority Mail piece is charged Priority Mail commercial prices from the location where intercepted to the new destination based on the dimensions, weight, and zone of the piece or the flat rate price, if applicable, along with any applicable extra services fees. * * *

* * * * *

7.0 Pickup on Demand Service

7.1 Postage and Fees

7.1.1 Postage

[Revise the text of 7.1.1 to read as follows:]

The correct amount of postage must be affixed to each piece except for a Priority Mail Express label paid with a corporate account, packages with a USPS Returns label affixed (under 505.3.0), and manifest mailings paid by permit imprint indicia approved by Business Mailer Support (BMS).

* * * * *

7.2 Basic Standards

7.2.1 Availability

* * * Incidental amounts of other postage-affixed, full-price mail also may be collected when Pickup on Demand service is provided for:

* * * * *

[Delete item i, Parcel Return Service, and renumber items j through n as items i through m.]

* * * * *

[Add new 12.0 to read as follows:]

12.0 USPS Label Delivery Service

12.1 Description

USPS Label Delivery Service provides customers with an option to have the Postal Service print and deliver their domestic outbound and return mailing labels for a fee per label at a Post Office where available. USPS Label Delivery Service is not available for APO/FPO/DPO addresses. Customers requesting USPS Label Delivery Service will be provided the tracking information for tracking purposes.

12.2 Eligibility

USPS Label Delivery Service is available as follows:

a. Retail and Commercial Priority Mail Express and Priority Mail.

b. First-Class Package Service—Retail.

c. First Class Package Service—Commercial.

d. USPS Retail Ground.

e. Parcel Select Ground.

f. USPS Returns Service.

12.3 Extra Services

There are no extra services available with labels requested through USPS Label Delivery Service.

12.4 Requesting USPS Label Delivery Service

A customer may request USPS Label Delivery Service at *www.usps.com.*

12.5 Fee

The USPS Label Delivery Service fee is listed in Notice 123—Price List.

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

1.0 Elements of Addressing

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1.5.3 Required Use of Return Addresses

The sender's domestic return address must appear legibly on:

* * * * *

[Revise the text of item q to read as follows:]

q. USPS Returns service.

* * * * *

604 Postage Payment Methods and Refunds

* * * * *

9.0 Exchanges and Refunds

* * * * *

9.2 Postage and Fee Refunds

* * * * *

9.2.3 Full Refund

A full refund (100 percent) may be made when:

* * * * *

[Add new item ''o'' to read as follows:]

o. For USPS Label Delivery Service the Postal Service will refund the postage and USPS Label Delivery Service fee when the label was not delivered. The Postal Service will refund the postage only if the label is delivered and not used.

* * * * *

608 Postal Information and Resources

* * * * *

608 Postal Information and Resources

* * * * *

7.0 Trademarks and Copyrights of the USPS

7.1 USPS Trademarks

* * * Information on USPS trademarks can be found on *USPS.com* or by contacting General Counsel, USPS Headquarters (see 8.1 for address).

* * * * *

[Delete ''Commercial Base'' and Commercial Plus'' from the list of trademarks under 7.1.]

* * * * *

9.0 Postal Zones

* * * * *

9.2 Application

Zones are used to compute postage on zoned mail sent between 3-digit ZIP Code areas, including Military Post Offices (MPOs), as follows:

* * * * *

[Revise the text of item c to read as follows:]

c. The postage price for zoned mail mailed at or addressed to an MPO and transported directly to or from MPOs at Department of Defense expense, without transiting any of the 48 contiguous states (including the District of Columbia), is the applicable zone 1 price. If such mail transits any area served by the USPS at USPS expense and the distance from the place of mailing to the embarkation point or from the debarkation point to the place of delivery is more than zone 1 for such mail, postage is assessed by the distance from the place of mailing to the embarkation point or from the debarkation point to the place of delivery of such mail, as the case may be.

* * * * *

[Revise the headings of 9.4 and 9.4.1 to read as follows:]

9.4 Definition

9.4.1 Local

Local applies to USPS Connect Local and USPS Connect Local Mail pieces deposited at any Post Office for delivery to addresses within the delivery area of that Post Office. For various types of Post Offices, local applies to all mail that both originates and destinates within:

* * * * *

[Revise the heading and introductory text of 9.4.2 to read as follows:]

9.4.2 Zones

Zones are defined as follows:

[Revise the text of item a to read as follows:]

a. The zone 1 price applies to pieces mailed within the same 3 Digit O/D Pairs. The zone 1 price also includes pieces mailed with different 3 Digit O/D Pairs, whose centroids are up to 50 miles in distance.

* * * * *

10.0 Forms of Identification

* * * * *

10.2 Products and Services Requiring Acceptable Identification

* * * * *

Exhibit 10.2 Products and Services Requiring Acceptable Identification

* * * * *

[Revise Exhibit 10.2 by deleting the ''Parcel Return Service'' line item.]

* * * * *

10.3 Acceptable Primary Forms of Photo Identification

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Exhibit 10.3 Acceptable Primary Forms of Photo Identification per Product and Service

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[Revise Exhibit 10.3 by deleting the ''Parcel Return Service'' line item.]

* * * * *

700 Special Standards

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705 Advanced Preparation and Special Postage Payment Systems

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18.0 Priority Mail Express Open and Distribute and Priority Mail Open and Distribute

18.1 Prices and Fees

18.1.1 Basis of Price

The basis of price for Priority Mail Express and Priority Mail Open and Distribute is as follows:

* * * * *

[Revise the text of item b to read as follows:]

b. Priority Mail commercial tray box postage is based on the tray box and zone. The maximum weight for each container is 70 pounds.

* * * * *

Index

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L

[Add Label Delivery Service, 507.12.0. alphabetically under ''L''.]

* * * * *

P

* * * * *

[Delete ''Parcel Return Service (PRS)'' in its entirety.]

* * * * *

Parcel Select

[Delete the ''Parcel Return Service, 505.4.0'' line item under ''Parcel Select''.]

* * * * *

Priority Mail

[Delete the ''Regional Rate'' line item under ''Priority Mail''.]

* * * * *

R

* * * * *

return services

[Delete the ''Parcel Return Service, 505.4.0'' line item under ''return services''.]

* * * * *

Notice 123 (Price List)

[Revise competitive prices as applicable.]

* * * * *

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–25180 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2016–0166; FRL–10414–01–R1]

Air Plan Approval; Connecticut; Plan Submittals for the 2008 Ozone National Ambient Air Quality Standard; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that was published in the **Federal Register** on October 1, 2018, which became effective on October 31, 2018. The final rule approved State Implementation Plan (SIP) revisions submitted by the State of Connecticut to address SIP revisions submitted to meet moderate area nonattainment requirements for the 2008 ozone standard. The SIP revisions are for the Greater Connecticut and the Connecticut portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT moderate ozone nonattainment areas, and include these areas 2011 base year emissions inventories, an emissions statement certification, reasonable further progress (RFP) demonstrations, reasonably available control measures (RACM) analyses, motor vehicle emissions budgets, and contingency measures. This correction does not change any final action taken by EPA on October 1, 2018; today's action merely corrects the Clean Air Act (CAA) citation for moderate area contingency measures. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because we are merely correcting an incorrect citation in a previous action. Thus, notice and public procedure are unnecessary.

DATES: This rule became effective on October 31, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2016–0166. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Bob McConnell, Environmental Engineer, Air Quality Planning Unit, Air Programs Branch (Mail Code OEP05–02), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912; (617) 918–1046; *mcconnell.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

In FR doc. 2018–21150 appearing on page 49297 at 83 FR 49297 in the **Federal Register** of October 1, 2018, the following correction to the regulatory text is made:

§ 52.377 [Corrected]

On page 49298, in the second column, in § 52.377, in amendment 2, correct paragraph (t) *Approval,* to read as follows:

(t) *Approval.* Revisions to the State Implementation Plan submitted by the Connecticut Department of Energy and Environmental Protection on January 17, 2017, September 5, 2017, and August 8, 2017, to meet, in part, requirements of the 2008 ozone NAAQS. These revisions satisfy the rate of progress requirement of section 182(b) through 2017, the contingency measure requirements of section 172(c)(9), the emission statement requirements of section 182(a)(3)(B), and the reasonably available control measure requirement of section 172(c)(1) for the Connecticut portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT area, and the Greater Connecticut moderate ozone nonattainment areas. The January 17, 2017 revision establishes motor vehicle emissions budgets for 2017 of 15.9 tons per day of VOC and 22.2 tons per day of NO_X to be used in transportation conformity in the Greater Connecticut moderate ozone nonattainment area. The August 8, 2017 revision establishes motor vehicle emissions budgets for 2017 of 17.6 tons per day of VOC and 24.6 tons per day of NO_X to be used in transportation conformity in the Connecticut portion of the New York-Northern New Jersey-Long Island, NYNJ–CT moderate ozone nonattainment area.

Dated: November 4, 2022.

David Cash,

Regional Administrator, EPA Region 1.

[FR Doc. 2022–24792 Filed 11–17–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0219; FRL–9911–02–R4]

Air Plan Approval; Mississippi; Revision of Excess Emissions Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the Mississippi Department of Environmental Quality (MDEQ) on November 17, 2016, on

behalf of the State of Mississippi. The revision was submitted in response to EPA's SIP Call published on June 12, 2015, concerning excess emissions during startup, shutdown, and malfunction (SSM) events. EPA is approving the SIP revision and finds that such SIP revision corrects the deficiencies identified in the June 12, 2015, SIP Call.

DATES: This rule is effective December 19, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2022–0219. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: D. Brad Akers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Akers can be reached via electronic mail at *akers.brad@epa.gov* or via telephone at (404) 562–9089.

SUPPLEMENTARY INFORMATION:

I. Background

On June 7, 2022, EPA proposed to approve MDEQ's November 17, 2016, SIP revision. *See* 87 FR 34609. In that notice of proposed rulemaking (NPRM), EPA also proposed to determine that the SIP revision corrects the deficiency with respect to Mississippi that the Agency identified in the June 12, 2015, action titled ''State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction'' (''2015 SSM SIP Action''). *See* 80 FR 33839 (June 12, 2015). The reasons for the proposed approval and determination are stated in the proposed action (87 FR 34609, June 7, 2022) and will not be restated here. The public comment period for EPA's proposed approval and determination ended on July 7, 2022. EPA received one set of comments in a joint letter submitted by the Sierra Club and the Environmental Integrity Project (hereinafter collectively referred to as the commenter) on this date. The comments are available in the docket for this action.

II. Response to Comments

EPA will not address the comments that express support for the proposed action. Instead, this section of the rulemaking will focus on the portions of the July 7, 2022, letter which did not support the proposed action or which called on EPA to provide advice to the State.

a. Rule 1.10.B(1) Is Not Approvable

Comment 1: The commenter asserts that Rule 1.10.B(1) is not fully approvable as included in the November 17, 2016, submittal. Specifically, the commenter states that as a standalone provision, paragraph B(1) could be read to impermissibly exempt sources from otherwise applicable SIP emission limits. Paragraph B(1) states, ''Startups and shutdowns are part of normal source operation. Emission limitations apply during startups and shutdowns unless source-specific emission limitations or work practice standards for startups and shutdowns are defined by an applicable rule, regulation, or permit.'' The commenter goes on to note EPA's past comments on the proposed changes to Rule 1.10.B in 2016 during prehearing review, which stated that EPA was ''concerned that this provision appears to provide that an 'applicable rule, regulation, or permit' that is not approved into the SIP might contain limitations that apply during startups and shutdowns *in lieu of an applicable SIP limit*'' (emphasis in original).

The commenter points to EPA's analysis in the June 7, 2022, NPRM which states that Rule 1.10.B(1) and B(2) ''taken together'' sufficiently address the finding of substantial inadequacy in the final 2015 SSM SIP Action, and argues that to ensure Rule 1.10.B(1) is administered correctly, EPA should conditionally approve the SIP revision pursuant to Clean Air Act (CAA) section 110(k)(4), requiring Mississippi to submit, within one year of the effective date of the final conditional approval, a corrective SIP revision. According to the commenter, the corrective revision should either remove Rule 1.10.B(1) or replace the phrase ''defined by an applicable rule, regulation, or permit'' with ''defined by an applicable SIP provision or permit as provided in section 1.10.B(2)(d) below.''

Response 1: EPA disagrees that Rule 1.10.B(1) is not approvable as transmitted in the November 17, 2016, SIP submittal. As MDEQ notes in its SIP revision responding to EPA's September 16, 2016, comment letter, the regulatory language must be read in conjunction with other air program regulations.[1] Specifically, the language at Rule 1.10.B(1) correctly acknowledges that ''source specific emission limitations or work practice standards for startups and shutdowns'' may be established in applicable rules, regulations, or permits. First, MDEQ has the ability to establish emission limitations via new or revised regulatory requirements at 11 MAC, Part 2, Chapter 1, *Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants,* or Chapter 11, *Regulations for Ambient Air Quality Nonattainment Areas,* where MDEQ could consider whether any specific alternative emission limitations (AELs) would be justifiable for startups and/or shutdowns.

Next, MDEQ has the ability to establish emission limits in permits pursuant to its program at 11 MAC, Part 2, Chapter 2, *Permit Regulations for the Construction and/or Operation of Air Emissions Equipment,* where MDEQ could consider establishing specific AELs for startups and/or shutdowns. Pursuant to Rule 1.10.B(2), alternatives to existing SIP emission limits in any such permits are not effective until MDEQ adopts the alternatives into Rule 1.10.B, MDEQ submits them to EPA for approval and inclusion in the SIP, and EPA approves them into the SIP.

Other possible sources of an ''applicable rule [or] regulation'' are the New Source Performance Standards (NSPS) at 40 CFR part 60 and the National Emissions Standards for Hazardous Air Pollutants (NESHAP) at 40 CFR part 63,[2] which MDEQ incorporates by reference at 11 MAC, Part 2, Chapter 1, Rule 1.6, *New Sources,* at 1.6.C and Rule 1.8, *Provisions for Hazardous Air Pollutants,*

[1] MDEQ's response to EPA's September 16, 2016, comment letter on the prehearing version of the regulatory changes is part of the November 17, 2016, SIP submittal available in the docket for this action.

[2] The NESHAP are found at 40 CFR parts 61 and 63, with NESHAP promulgated after 1990 found at part 63.

at 1.8.A, respectively. Several of the NSPS and NESHAP include AELs that ''impose different numerical levels during different modes of source operation or impose emission limitations that are composed of a combination of a numerical limitation during some modes of operation and a specific technological control requirement or work practice requirement during other modes of operation'' such as startup and shutdown. *See* 80 FR 33839, 33889 (June 12, 2015). Rule 1.10.B(1) accurately acknowledges that as to applicable emission limits in general, the limits will apply during startup and shutdown periods unless some applicable rule, regulation or permit specifies different requirements for those periods. EPA interprets this to mean that those other limits cannot replace or relax the SIP emission limit without EPA approval via a SIP revision that meets CAA requirements.

Our interpretation stems from MDEQ's assertion in its SIP revision that the ability to establish AELs during startups and shutdowns does not mean that alternatives to any SIP emission limits can be established via the rules, regulations, or permit requirements without a SIP revision. In response to EPA's comment letter, MDEQ revised its Rule 1.10.B(2) to provide greater clarity that any specific AELs established by rules, regulations, or permits not yet incorporated into the SIP and applicable to startups and/or shutdowns would not replace any existing SIP emission limit for those periods of operation unless and until the AELs were approved into the SIP. Specifically, Rule 1.10.B(2)(d) provides, ''Following permit issuance, the emission limitations or work practice standards are considered State-only requirements until they have been adopted into [Rule 1.10] and approved by the EPA into the SIP.'' In this way, Rule 1.10.B(2) operates in conjunction with B(1) to explain what must happen in the context of providing alternatives to existing SIP emission limits.

b. Rule 1.10.B(2) Should Not Only Consider a Source's Existing Control Strategy

Comment 2: Among factors MDEQ will consider in possibly establishing AELs for periods of startups and/or shutdowns, Rule 1.10.B(2)(a) provides, ''The source must demonstrate that it is technically infeasible, considering its specific control strategy, to comply with existing SIP emission limitations during startups and shutdowns.'' The commenter argues that the phrase ''considering its specific control strategy'' creates an ''illogical loophole that would allow sources with pollution controls that are outdated, undersized, not well maintained, not operated properly, or otherwise inadequate to claim technical infeasibility based on their controls, even though those sources, if properly designed, operated, and/or maintained, could comply with applicable SIP emission limits.''

The commenter points to EPA's statement in the 2015 SSM SIP Action that ''alternative requirements applicable to the source during startup and shutdown should . . . take into account considerations such as . . . the control technology that is feasible during startup and shutdown.'' *See* 80 FR 33839, 33980 (June 12, 2015). The commenter states that EPA should conditionally approve the SIP revision pursuant to CAA section 110(k)(4), requiring Mississippi to submit, within one year of the effective date of the final conditional approval, a corrective SIP submission to remove the phrase ''considering its specific control strategy.''

Response 2: EPA disagrees that Rule 1.10.B(2)(a) is not approvable as transmitted in the November 17, 2016, SIP submittal. Consideration of a specific control strategy is consistent with EPA guidance in the 2015 SSM SIP Action. Mississippi's SIP requires that any potential AELs ''be narrowly tailored and take into account considerations such as the technological limitations of the specific source category and the control technology that is feasible during startup and shutdown'' as recommended by EPA. *See* 80 FR 33839, 33980. EPA's restatement of the 1999 SSM Guidance in the 2015 SSM SIP Action includes the following two (of seven total) criteria recommended for developing a SIP revision with potential AELs: ''(1) The revision is limited to specific, narrowly defined source categories using specific control strategies (*e.g.,* cogeneration facilities burning natural gas and using selective catalytic reduction); (2) Use of the control strategy for this source category is technically infeasible during startup or shutdown periods.'' *Id.* Mississippi Rule 1.10.B(2) is consistent with these criteria, requiring at B(2)(c) that the AELs must be specific to the source and its particular control strategy, which EPA interprets as the control strategy that corresponds to the relevant narrowly defined source category (*e.g.,* cogeneration facilities burning natural gas and using selective catalytic reduction), and requiring at B(2)(a) a demonstration that the control strategy is technically infeasible during startup and shutdown periods.

Additionally, EPA does not agree that the language at Rule 1.10.B(2)(a), or EPA's language in the 2015 SSM Action or the 1999 SSM Guidance, would necessarily limit such a demonstration to considering existing controls only. Rule 1.10.B(2)(a) makes no reference to actual installed equipment. This rule requires the source to demonstrate that its strategy for emissions control is not capable of achieving compliance during startup and shutdown, and such demonstration should be made based on an assumption of properly designed and maintained equipment as well as the control strategy's suitability for the narrowly defined source category.

Moreover, EPA and the public will have an opportunity to evaluate any specific AELs, as they will be submitted as source-specific SIP revisions to act as alternatives to SIP emission limits. The record supporting any such AELs would show how the criteria at Rule 1.10.B(2) were satisfied.

c. Numerical Emission Limits vs. Work Practice Standards

Comment 3: The commenter states that EPA should clarify in its rulemaking record that ''even for those sources (if any) that truly cannot meet normal limits during startup and shutdown, Rule 1.10.B(2) should in most cases establish alternative numerical limits, rather than allow for work practices.'' The commenter references the 2015 SSM Action, 80 FR 33839, 33980, where EPA states: ''In cases in which measurement of emissions during startup and/or shutdown is not reasonably feasible, it may be appropriate for an emission limitation to include as a component a control for startup and/or shutdown periods other than a numerically expressed emission limitation.'' The commenter asserts that under EPA's guidance, work practice standards are only appropriate during those periods where emissions cannot be measured. The commenter also states that EPA's approval should include the guidance that numerical limits are preferable to work practice standards because they are the ''most legally and practicably enforceable SIP requirements,'' and cites to the 2015 SSM SIP Action, 80 FR 33839, 33974–75. The commenter goes on to state that for situations in which a work practice is appropriate, EPA should advise that pollution control equipment should be operated while fuel-burning equipment are burning primary fuels or when power plants are generating electricity, and that the SIP should require clean fuels to be burned until the point at which the pollution controls are engaged.

Response 3: EPA does not believe clarification is necessary regarding a preference for numerical emission limits versus work practice standards. In this action, EPA is evaluating the November 17, 2016, SIP revision in light of the 2015 SSM SIP Action. Rule 1.10.B(2) states that, where a source is unable to comply with an existing SIP emission limit, MDEQ will consider establishing ''source specific emission limitations or work practice standards for startups and shutdowns'' as alternatives to those SIP limits. As outlined in the June 7, 2022, NPRM, Rule 1.10.B(2) goes on to specify criteria that EPA believes to be appropriate in considering establishing either a numerical emission limit or a work practice standard to apply as an AEL. Provisions 1.10.B(2)(a)–(d) are consistent with the guidance criteria EPA has established for setting AELs, as discussed in the same section of the 2015 SSM SIP Action cited by the commenter.[3] [4]

As EPA notes in the 2015 SSM SIP Action, SIP emission limitations ''(i) do not need to be numerical in format; (ii) do not have to apply the same limitation (*e.g.,* numerical level) at all times; and (iii) may be composed of a combination of numerical limitations, specific technological control requirements and/or work practice requirements, with each component of the emission limitation applicable during a defined mode of source operation.'' *See* 80 FR 33839, 33889. Therefore, if MDEQ establishes AELs comprised of work practice standards in some part, pursuant to Rule 1.10.B(2), the emission limit overall ''must be continuous, must meet applicable CAA stringency requirements, and must be legally and practically enforceable.'' *Id.* Moreover, EPA and the public will have an opportunity to evaluate any specific AELs, as they will be submitted as source-specific SIP revisions to act as alternatives to SIP emission limits. At that time, EPA can evaluate the AELs in consideration of the criteria established in the SIP and the guidance referenced above.

Next, in the 2015 SSM SIP Action, EPA noted that ''there *may be* sources for which a numerically expressed emission limitation is the most legally and practically enforceable,'' (emphasis added) and that ''there are many sources for which a numerically expressed emission limitation will be the most appropriate and will result in the most legally and practically enforceable SIP requirements. However, . . . for some source categories, under some circumstances, it may be appropriate for the SIP emission limitation to include a specific technological control requirement or specific work practice requirement that applies during specified modes of source operation such as startup and shutdown.'' *See id.* at 33974–75. Therefore, EPA disagrees that the approval of the November 17, 2016, SIP revision must include any additional guidance regarding a preference for numerical emission limits versus work practice standards.

Additionally, EPA does not agree with the commenter's conclusion that the 2015 SSM SIP Action and EPA guidance would only find work practice standards appropriate when emissions measurements cannot be made during startup and/or shutdown. While the language referenced by the commenter suggests that work practice standards may be appropriate in cases in which measurement of emissions during startup or shutdown is not reasonably feasible, EPA does not assert that this is the only circumstance in which work practice standards may be utilized as part of a continuous emission limitation. Thus, EPA believes that a work practice standard could be a sufficient AEL in various other circumstances. The 2015 SSM SIP Action notes, for example, regarding sources of sulfur dioxide (SO_2), ''if the otherwise applicable numerical SO_2 emission limitation in the SIP is not achievable, and the otherwise required SO_2 control measure is not effective during startup and shutdown and/or measurement of emissions during startup and shutdown is not reasonably feasible, then it may be appropriate for that emission limitation to impose a different control measure, such as use of low sulfur coal, applicable during defined periods of startup and shutdown in lieu of a numerically expressed emission limitation.'' *See* 80 FR 33839, 33975.

The 2015 SSM SIP Action goes on to discuss instances of where the Agency has established work practice standards as components of emission limits that are consistent with the definition of ''emission limitation'' or ''emission standard'' at CAA section 302(k), such as 40 CFR part 63, subpart UUUUU, *National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units,* and 40 CFR part 60, subpart Da, *Standards of Performance for Electric Utility Steam Generating Units. See id.* at 33891. These examples are rules which require use of continuous emission monitoring systems, so measurement during periods of startup and/or shutdown would not necessarily be infeasible, and yet EPA chose to establish work practice standards as components of the emission limits applicable to these sources. For the reasons stated above, EPA believes that Mississippi's November 17, 2016, SIP revision adequately addresses situations for which AELs may need to be established and appropriately notes that the AELs can take the form of a numerical emission limit or some work practice standard.

Finally, regarding potential work practice standards for fuel-burning equipment, EPA does not find it appropriate to speculate on any specific work practice requirements in absence of specific information on the source or source category. However, EPA notes that the Agency indicated regulations and technical materials supporting the NSPS and NESHAP could be helpful in developing emission limits or AELs and that definitions of startup and shutdown and work practices for those periods could be appropriate for incorporation into a SIP. *See* 80 FR 33839, 33980. Several of the suggestions for fuel-burning equipment made by the commenter are included in the NSPS and NESHAP, indicating that these could be appropriate components of work practice standards.[5] So, although some of the suggestions made by the commenter could be reasonable depending on the specific circumstances, they are not relevant to this action; EPA will address the contents of any proposed work practice standards in the source-specific SIP revisions that Mississippi submits to EPA for approval and incorporation into the SIP.

d. Reporting of Compliance With Work Practice Standards

Comment 4: The commenter states that Rule 1.10.B(2)(c)(iv) requires sources ''only to document startup and shutdown events in contemporaneous logs and does not require sources to report to the MDEQ any information to assure that sources are complying with the requirements of the rule.'' The commenter asserts that, as written, any work practice standards would not be practically enforceable by MDEQ, EPA, or citizens, and therefore, would not comply with CAA section 110(a)(2)(A). The commenter goes on to recommend

[3] *See* Memorandum to EPA Regional Administrators, Regions I–X from Steven A. Herman and Robert Perciasepe, USEPA, ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown'' (September 20, 1999). This is referred to as the 1999 SSM Guidance.

[4] *See* 80 FR 33839, 33980 (June 12, 2015).

[5] *See, e.g.,* 40 CFR 60.42Da(e)(1)(ii), 40 CFR 63.7500, 40 CFR 63.9991(a)(1).

that EPA advise Mississippi that if work practices are selected for any sources, that MDEQ should ''require the work-practice compliance information from the proposed rule to be reported by sources through, at the least, their quarterly Title V compliance reports.'' [6]

Response 4: EPA disagrees that it is necessary to advise Mississippi regarding the reporting of work practice compliance information. CAA section 110(a)(2)(C) provides that the SIP shall include a program to provide for the enforcement of the measures described in section 110(a)(2)(A), including a permit program to regulate the construction and modification of stationary sources. Therefore, the permitting process can establish the means by which an emission limitation is enforceable, including recordkeeping and reporting requirements, particularly in the case of source-specific emission limits submitted for inclusion in the SIP. Generally, Rule 1.10.B(2)(d) provides that any source-specific emission limitations or work practice standards intended as an alternative to existing SIP emission limits must be established in a permit issued pursuant to 11 MAC Part 2, Chapter 2, and then submitted to EPA for incorporation into the SIP. MDEQ's Rule 2.2, *General Standards Applicable to All Permits,* and Rule 2.9, *Recordkeeping and Reporting,* provide that the permit board in Mississippi has the authority to establish requirements for determining compliance with applicable requirements, including recordkeeping and reporting of necessary monitoring. EPA will review these permit conditions as part of any source-specific SIP revision and evaluate the adequacy of the AELs (including the practicable enforceability of any applicable work practice standards) pursuant to the CAA and EPA guidance.

Additionally, for any major sources, facilities will also be subject to semiannual reporting, which would outline any deviations from permit requirements, and annual certification, pursuant to EPA's title V regulations at 40 CFR part 70 and Mississippi's federally approved title V program at 11 MAC Part 2, Chapter 6, *Air Emissions Operating Permit Regulations for Purposes of Title V of the Federal Clean Air Act.*[7] These reporting requirements would include the information needed for determining compliance with any applicable source-specific work practices standards, including those that may be approved into the SIP. For example, 11 MAC Part 2, Chapter 2, Rule 6.3(C)(5) provides requirements for a ''compliance certification with terms and conditions contained in the permit, including emission limitations, standards, or work practices,'' consistent with 40 CFR 70.6(c)(5).

Furthermore, as stated in the NPRM, EPA considers the requirements of Rule 1.10.B(2) to be consistent with the seven criteria EPA has recommended for the development of AELs and that this provision is sufficient to guide the development of specific AELs. In the 2015 SSM SIP Action, EPA recommended that ''to be approvable (*i.e.,* meet CAA requirements)'' an AEL should be developed with seven specific criteria, including that it ''requires that the owner or operator's actions during startup and shutdown periods are documented by properly signed, contemporaneous operating logs or other relevant evidence.'' [8] Mississippi's Rule 1.10.B(2)(c)(iv) fulfills that recommendation by providing that ''the source must document all startups and shutdowns using properly signed contemporaneous logs or other relevant evidence.''

e. Definitions of Startup and Shutdown

Comment 5: The commenter states that EPA should require Mississippi to more narrowly define ''startup'' and ''shutdown'' in Rule 1.2, *Definitions.* The commenter asserts that these definitions are vague and would allow for unlimited periods of startup or shutdown. As an example, the commenter claims that the term ''operation,'' as used in the definitions of these two terms, is ambiguous. The commenter states that the terms must be specific and narrowly tailored, citing to a section of EPA's 2015 SSM SIP Action that addresses the seven criteria EPA developed in the 1999 SSM Guidance and clarified in the 2015 SSM SIP Action, for approval of alternative emissions limits. The commenter then claims that it is preferable that ''startup'' be defined as beginning when primary fuel-burning sources start burning their primary fuel, and ''shutdown'' be defined as beginning when fuel-burning sources stop burning their primary fuel. The commenter closes by stating that CAA section 110(a)(2) would be violated if these definitions are not properly bounded.

Response 5: EPA disagrees that the Agency should require Mississippi to more narrowly define the terms ''startup'' and ''shutdown'' in its general definitions rule as part of this rulemaking. First, Rule 1.2, *Definitions,* is not part of the SIP call in EPA's 2015 SSM Action and is not part of the SIP revision before EPA for consideration in this rulemaking.

Second, Mississippi's definitions of startup and shutdown are consistent with the definitions used in the 2015 SSM SIP Action and are not inconsistent with 40 CFR part 51, which does not define these terms.[9] [10] Mississippi's definitions and those used in the 2015 SSM SIP Action are designed to generally convey what these modes of operation consist of and when they begin. As noted in the 2015 SSM Action, it may be appropriate in individual SIP provisions to include a specifically tailored definition to address a particular source category for a particular purpose. However, EPA does not believe that Mississippi's definitions need to be further tailored because emission limits now apply during startup and shutdown periods, and sources must comply with those limits during startup and shutdown periods unless an AEL is approved. Presently, there are no specific AELs approved for periods of startup or shutdown in the SIP, and therefore, there are no current concerns about unlimited periods of startups or shutdowns.

Third, any future AELs will need to adequately define the modes of operation during which the AELs apply. The requirements of Rule 1.10.B(2) are consistent with the seven criteria EPA has recommended for the development of AELs—including the third criteria regarding minimizing the frequency and duration of startup and shutdown

[6] The commenter refers to quarterly title V compliance reports. EPA believes the commenter is referring to the requirement at 40 CFR 70.6(a)(3)(iii)(A) requiring the submittal of reports of any required monitoring at least every 6 months, *i.e.,* semiannually.

[7] *See, e.g.,* 40 CFR 70.6(a)(3)(iii)(A) and (c)(5), 11 MAC Part 2, Chapter 6, Rule 6.3(A)(3)(c)(1), and 11 MAC Part 2, Chapter 6, Rule 6.3(C)(5).

[8] *See also* the 1999 SSM Guidance.

[9] Mississippi defines ''startup'' at Rule 1.2.HH as, ''[t]he bringing into operation from a non-operative condition. Relative to fuel-burning equipment, a startup shall be construed to occur only when a unit is taken from a non-fired to a fired state.'' The 2015 SSM SIP Action defines ''startup'' as ''generally, the setting in operation of a source for any reason. In this document, the EPA uses this term in the generic sense. In an individual SIP provision it may be appropriate to include a specifically tailored definition of this term to address a particular source category for a particular purpose.''

[10] Mississippi defines ''shutdown'' at Rule 1.2.CC as, ''[t]he termination of operation of equipment. Relative to fuel-burning equipment, a shutdown shall be construed to occur only when a unit is taken from a fired to a non-fired state.'' The 2015 SSM SIP Action defines ''shutdown'' as ''generally, the cessation of operation of a source for any reason. In this document, the EPA uses this term in the generic sense. In individual SIP provisions it may be appropriate to include a specifically tailored definition of this term to address a particular source category for a particular purpose.''

modes [11]—and this rule is sufficient to guide the development of specific AELs. Specifically, Rule 1.10.B(2)(c)(i) states: ''the source must limit the frequency and duration of startups and shutdowns to the greatest extent practicable.'' Thus, MDEQ will establish the necessary requirements specific to the source in the permit or rule, including the boundaries of the startup and shutdown periods during which the AELs will apply. Subsequently, those conditions will be reviewed by EPA and the public through EPA's proposed action to approve or disapprove the source-specific AELs replacing any applicable SIP emission limits for startups and/or shutdowns. EPA will review the contents of any source-specific SIP revision and evaluate the adequacy of the AELs (including the startup and shutdown parameters) pursuant to the CAA and EPA guidance.

Therefore, EPA disagrees that Mississippi must revise its current SIP-approved definitions of ''startup'' and ''shutdown'' included in Rule 1.2 and that these definitions are inconsistent with the CAA.

f. Clarification of State-Only Versus SIP-Approved Requirements

Comment 6: Regarding MDEQ's revised rules at Rule 1.10.B generally, the commenter states that ''EPA should advise Mississippi that it should help provide clarity for the public and regulated entities by including notes or parenthetical information in its published regulations about which requirements are state-only and which are SIP-approved.''

Response 6: EPA notes that this action clearly delineates which portions of Rule 1.10 are not approved into the SIP, including notation at 40 CFR 52.1270(c), and will ultimately also be reflected in the compilation of approved Mississippi rules available at EPA's website.[12] Regarding any further notation that MDEQ may elect to include in the portions of the rules which are state-only, EPA has no authority to prescribe such alterations of the text. Therefore, this comment is outside the scope of this action.

III. Final Action

EPA is approving Mississippi's November 17, 2016, SIP submission revising Rule 1.10.B, *Startups and Shutdowns,* and requesting removal of Rule 1.10.A, *Upsets,* Rule 1.10.B(3), and Rule 1.10.C, *Maintenance,* from the Mississippi SIP-approved version of Rule 1.10, *Provisions for Upsets, Startups, and Shutdowns.* EPA has also determined that this SIP revision corrects the deficiency identified in the 2015 SSM SIP Action. Mississippi is retaining Rules 1.10.A and Rule 1.10.B(3) for state law purposes only, with changes to clarify that the upset provisions of Rule 1.10.A apply to enforcement actions by the State (specifically, the Mississippi Commission on Environmental Quality) only and ''are not intended to prohibit EPA or third-party enforcement actions.'' [13] *See* 87 FR 34609.

IV. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, as discussed in Sections I and II of this preamble, EPA is finalizing the incorporation by reference of 11 Mississippi Administrative Code, Part 2, Chapter 1, Rule 1.10, *Provisions for Upsets, Startups, and Shutdowns,* state effective December 10, 2016, except for Rule 1.10.A and 1.10.B(3), which MDEQ is not requesting EPA to incorporate into the SIP. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[14]

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9,

[11] The third criteria states, ''[t]he alternative emission limitation requires that the frequency and duration of operation in startup or shutdown mode are minimized to the greatest extent practicable.'' *See* 80 FR 33839, 33980.

[12] This website is located at *https://www.epa.gov/sips-ms/epa-approved-statutes-and-regulations-mississippi-sip.* It is a sub-site of the website titled ''Approved Air Quality Implementation Plans in Mississippi,'' located at *https://www.epa.gov/sips-ms,* which is a sub-site of the website titled ''Approved Air Quality Implementation Plans in Region 4,'' located at *https://www.epa.gov/air-quality-implementation-plans/approved-air-quality-implementation-plans-region-4.*

[13] Additionally, the existing Rule 1.10.B(3) is being removed from the SIP as requested, and the revised Rule 1.10.B(3) is not being requested for SIP approval, as the revised provision simply provides that ''upset'' provisions at Rule 1.10.A apply if an upset occurs during periods of startup and shutdown.

[14] *See* 62 FR 27968 (May 22, 1997).

2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 17, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 10, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart Z—Mississippi

■ 2. In § 52.1270(c), amend the table by revising the entry for ''Rule 1.10,'' under the center heading ''11 MAC Part 2—Chapter 1 Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants,'' to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSISSIPPI REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
11 MAC Part 2—Chapter 1 Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants				
*	*	*	*	*
Rule 1.10	Provisions for Upsets, Startups, and Shutdowns.	12/10/2016	11/18/2022, [Insert citation of publication].	Except for Rule 1.10.A and 1.10.B(3).
*	*	*	*	*

* * * * *

[FR Doc. 2022–25080 Filed 11–17–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2015–0174; FRL–7253.1–02–OW]

RIN 2040–AG21

Restoring Protective Human Health Criteria in Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 1, 2022, the Environmental Protection Agency (EPA) determined that Washington's human health criteria (HHC) for certain pollutants were not protective of Washington's designated uses and were not based on sound scientific rationale and, accordingly, proposed to restore protective HHC for those pollutants in Washington's waters. EPA is finalizing protective and science-based Federal HHC in this final rule to protect Washington's waters, including waters where tribes hold treaty-reserved rights to fish.

DATES: This final rule is effective on December 19, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2015–0174. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Erica Fleisig, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1057; email address: *fleisig.erica@epa.gov.*

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

I. General Information
A. Does this action apply to me?
B. How did EPA develop this final rule?

II. Background
A. Statutory and Regulatory Background
B. EPA's General Approach for Deriving Human Health Criteria
C. Prior EPA Actions Related to Washington's Human Health Criteria
III. Derivation of Human Health Criteria for Washington
A. Scope of EPA's Final Rule
B. Washington-Specific Human Health Criteria Inputs
C. Final Human Health Criteria for Washington
D. Applicability
E. Alternative Regulatory Approaches and Implementation Mechanisms
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A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
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C. Regulatory Flexibility Act (RFA)
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act of 1995
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Entities that are subject to Clean Water Act (CWA) regulatory programs such as industrial facilities, stormwater management districts, or publicly owned treatment works (POTWs) that discharge pollutants to surface waters of the United States under the State of Washington's jurisdiction could be affected by this rulemaking because the Federal water quality standards (WQS) promulgated by EPA are applicable WQS for surface waters in Washington for CWA purposes. Categories and entities that could potentially be affected by this rulemaking include the following:

Category	Examples of potentially affected entities
Industry	Industrial point sources discharging pollutants to waters of the United States in Washington.
Municipalities	Publicly owned treatment works or similar facilities discharging pollutants to waters of the United States in Washington.
Stormwater Management Districts.	Entities responsible for managing stormwater in the State of Washington.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How did EPA develop this final rule?

In developing this final rule, EPA carefully considered the public comments and feedback received from interested parties. EPA provided a 60-day public comment period after publishing the proposed rulemaking in the **Federal Register** on April 1, 2022.[1] In addition, EPA held two online public hearings on May 24 and 25, 2022, to discuss the contents of the proposed rulemaking and accept verbal public comments.

Over 20 organizations and individuals submitted comments on a range of issues. EPA also received over 300 letters from individuals associated with a mass letter writing campaign. Some comments addressed issues beyond the scope of the rulemaking, and thus EPA did not consider them in finalizing this rule. In this preamble, EPA provides summaries of certain comments received on aspects of the proposal that generated the most commenter interest. For a complete summary of all comments received and EPA's responses, see EPA's Response to Comments document in the official public docket.

II. Background

A. Statutory and Regulatory Background

CWA section 101(a)(2) establishes as a national goal ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, wherever attainable.'' EPA interprets these CWA section 101(a)(2) goals to include, at a minimum, designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish.[2]

Consistent with the CWA, EPA's WQS program assigns to states and authorized tribes the primary authority for adopting WQS.[3] CWA section 303(c)(2)(A) and EPA's implementing regulations at 40 CFR part 131 require, among other things, that a state's WQS specify appropriate designated uses of the waters, and water quality criteria that protect those uses. EPA's regulations at 40 CFR 131.11(a)(1) provide that ''[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive designated use.''

Under CWA section 304(a), EPA periodically publishes criteria (including HHC) recommendations for states to consider when adopting water quality criteria for particular pollutants to protect CWA section 101(a) goal uses. Where EPA has published recommended criteria, states should establish numeric water quality criteria based on EPA's CWA section 304(a) criteria recommendations, CWA section 304(a) criteria recommendations modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)).

After a state adopts a new or revised WQS, the state must submit it to EPA for review and action in accordance with CWA section 303(c).[4] If EPA determines that a state's new or revised WQS is not consistent with the requirements of the Act, the state has 90 days to submit a modified standard. If the state fails to adopt a revised WQS that EPA approves, CWA section 303(c)(4)(A) requires EPA to propose and promulgate a revised or new standard for the waters involved. In addition, CWA section 303(c)(4)(B) grants the EPA Administrator discretion

[1] See *Restoring Protective Human Health Criteria in Washington: Proposed Rule,* 87 FR 19046, April 1, 2022.

[2] USEPA. 2000. Memorandum 1BWQSP–00–03. U.S. Environmental Protection Agency, Office of Water, Washington, DC, *https://www.epa.gov/sites/production/files/2015-01/documents/standards-shellfish.pdf.*

[3] 33 U.S.C. 1313(a), (c).

[4] 33 U.S.C. 1313(c)(2)(A), (c)(3).

to determine ''that a revised or new standard is necessary to meet the requirements of [the Act].'' [5] After making such a determination, known as an Administrator's Determination,[6] the agency must ''promptly'' propose an appropriate WQS and finalize it within ninety days unless the state adopts an acceptable standard in the interim.[7]

B. EPA's General Approach for Deriving Human Health Criteria

EPA's 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* [8] (2000 Methodology) describes the methods EPA uses when developing national CWA section 304(a) recommended HHC and when promulgating Federal HHC. The 2000 Methodology also serves as guidance to states and authorized tribes for developing their own HHC. EPA's guidance informs, but does not dictate, EPA's implementation of the applicable statutory and regulatory requirements noted above. EPA's 2000 Methodology recommends that HHC be designed to reduce the risk of adverse cancer and non-cancer effects occurring from lifetime exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish obtained from inland and nearshore waters. Consistent with the 2000 Methodology, EPA's practice is to establish a criterion for both drinking water ingestion and consumption of fish/shellfish from inland and nearshore waters combined and a separate criterion based on ingestion of fish/shellfish from inland and nearshore waters alone. This latter criterion applies in cases where the designated uses of a waterbody include supporting fish/shellfish for human consumption but not drinking water supply sources (*e.g.,* non-potable estuarine waters).

Consistent with EPA's 2000 Methodology, EPA establishes HHC based on two types of toxicological endpoints: (1) carcinogenicity; and (2) noncancer toxicity (*i.e.,* all adverse effects other than cancer). Where sufficient data are available, EPA derives criteria using both carcinogenic and non-carcinogenic toxicity endpoints and uses the lower (*i.e.,* more health-protective) value. EPA calculates HHC for carcinogenic effects using the following input parameters: cancer slope factor (CSF), cancer risk level (CRL), body weight, drinking water intake rate, fish consumption rate (FCR), and a bioaccumulation factor(s). EPA calculates HHC for both non-cancer and nonlinear carcinogenic effects using a reference dose (RfD) and relative source contribution (RSC) in place of a CSF and CRL (the remaining inputs are the same for both toxicology endpoints). The RSC is applied to apportion the RfD among the media and exposure routes of concern for a particular chemical to ensure that an individual's total exposure from all exposure sources does not exceed the RfD. Each of these inputs is discussed in more detail in sections II.B.a through II.B.d of this preamble and in EPA's 2000 Methodology.[9]

a. Cancer Risk Level

Consistent with the 2000 Methodology, EPA generally assumes, in the absence of data to indicate otherwise, that carcinogens exhibit linear ''non-threshold'' dose-responses which means that there are no ''safe'' or ''no-effect'' levels. Therefore, EPA calculates HHC for carcinogenic effects as pollutant concentrations corresponding to lifetime increases in the risk of developing cancer. EPA calculates HHC values at a 10^{-6} (one in one million) CRL and recommends that states and authorized tribes use CRLs of 10^{-6} or 10^{-5} (one in one hundred thousand) when deriving HHC for the general population.[10] EPA notes that states and authorized tribes can also choose a more health protective risk level, such as 10^{-7} (one in ten million), when deriving HHC.

b. Cancer Slope Factor and Reference Dose

A dose-response assessment is required to understand the quantitative relationships between exposure to a pollutant and adverse health effects. EPA evaluates dose-response relationships based on the available data from animal toxicity and human epidemiological studies to derive dose-response metrics. For carcinogenic effects, EPA uses an oral CSF to derive the HHC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a pollutant. For non-carcinogenic effects, EPA uses the reference dose (RfD) to calculate the HHC. A RfD is an estimate of a daily oral exposure of an individual to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. A RfD is often derived from a laboratory animal toxicity multi-dose study from which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose level can be identified. However, human epidemiology studies can also be used to derive a RfD. Uncertainty factors are applied to account for gaps or deficiencies in the available data (*e.g.,* differences in response among humans) for a chemical. For the majority of EPA's latest (2015) updated national CWA section 304(a) recommended HHC, EPA's Integrated Risk Information System (IRIS) [11] was the source of both cancer and noncancer toxicity values (*i.e.,* RfD and CSF).[12] For some pollutants, EPA selected risk assessments produced by other EPA program offices (*e.g.,* Office of Pesticide Programs, Office of Water, Office of Land and Emergency Management), other national and international programs, and state programs.

c. Exposure Assumptions

EPA's exposure assumptions provide an overall level of protection targeted at the high end of the general population, as stated in the 2000 Methodology. EPA selects a combination of high-end and central tendency inputs to the criteria derivation equation and avoids ''double counting'' of exposures and combining unlikely co-occurrences. Consistent with the 2015 national CWA section 304(a) recommended HHC, EPA uses a default drinking water intake rate of 2.4 liters per day (L/day) and default rate of 22 grams per day (g/day) for consumption of fish and shellfish from inland and nearshore waters, multiplied by pollutant-specific bioaccumulation factors (BAFs) to account for the amount of the pollutant in the edible portions of the ingested species.

EPA's national default drinking water intake rate of 2.4 L/day represents the per capita estimate of combined direct and indirect community water ingestion at the 90th percentile for adults ages 21

[5] *Id.* at (c)(4)(B).

[6] 40 CFR 131.22(b)

[7] 33 U.S.C. 1313(c)(4)(B).

[8] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[9] *Id.*

[10] EPA's 2000 Methodology also states: ''Criteria based on a 10^{-5} risk level are acceptable for the general population as long as states and authorized tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level.''

[11] USEPA. Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency, Office of Research and Development, Washington, DC *www.epa.gov/iris.*

[12] Final Updated Ambient Water Quality Criteria for the Protection of Human Health (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC, *https://www.epa.gov/wqc/human-health-water-quality-criteria.*

and older.[13] EPA's national FCR of 22 g/day represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on National Health and Nutrient Examination Survey (NHANES) data from 2003 to 2010.[14] [15] EPA calculates HHC using a default body weight of 80 kilograms (kg), the average weight of a U.S. adult age 21 and older, based on NHANES data from 1999 to 2006.

Prior to publication of the 2000 Methodology, in which EPA began recommending the use of BAFs to reflect the uptake of a contaminant from all sources by fish and shellfish,[16] EPA relied on bioconcentration factors (BCFs) to estimate chemical accumulation of waterborne chemicals by aquatic organisms. However, BCFs only account for chemical accumulation in aquatic organisms through exposure to chemicals in the water column. In 2000, EPA noted that ''there has been a growing body of scientific knowledge that clearly supports the observation that bioaccumulation and biomagnification occur and are important exposure issues to consider for many highly hydrophobic organic compounds and certain organometallics.'' For that reason, the 2000 Methodology observed that ''[f]or highly persistent and bioaccumulative chemicals that are not easily metabolized, BCFs do not reflect what the science indicates.'' [17] Therefore, consistent with the 2000 Methodology EPA uses, when data are available, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes, including, but not limited to, food, sediment, and water.[18] EPA uses separate BAFs for each trophic level to account for potential biomagnification of chemicals in aquatic food webs, as well as physiological differences among organisms that may affect bioaccumulation.[19]

EPA derives national default BAFs, in part, as a resource for states and authorized tribes with limited resources for deriving site-specific BAFs.[20] EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. In the 2015 national CWA section 304(a) recommended HHC update, EPA relied on field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases to develop national BAFs for three trophic levels of fish.[21] If this information was not available, EPA selected octanol-water partition coefficients (K_{ow} values) from publicly available, published peer-reviewed sources for use in calculating national BAFs. As an additional line of evidence, EPA reported model-estimated BAFs for every chemical based on the Estimation Program Interface (EPI) Suite to support the field-measured or predicted BAFs.[22]

Although EPA uses national default exposure-related input values to calculate national CWA section 304(a) recommended criteria, EPA's methodology notes a preference for the use of local data, when available, to calculate HHC (*e.g.,* locally derived FCRs, drinking water intake rates and body weights, and waterbody-specific bioaccumulation rates) over national default values. Using local data helps ensure that HHC represent local conditions.[23] EPA also recommends, where sufficient data are available, selecting an FCR that reflects consumption that is not suppressed by fish availability or concerns about the safety of available fish.[24] Deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA and ensures protection of human health as pollutant levels decrease, fish habitats are restored, and fish availability increases. Moreover, as explained further below, selecting an FCR that reflects unsuppressed fish consumption could be necessary where tribal treaty or other reserved fishing rights apply. In such circumstances, if sufficient data regarding unsuppressed fish consumption levels are unavailable or inconclusive, states should consult with tribes when deciding which fish consumption data should be used in selecting an FCR.

d. Relative Source Contribution

The inclusion of an RSC factor [25] is important for protecting public health. When deriving HHC for non-carcinogens and nonlinear carcinogens, EPA includes an RSC factor to account for sources of exposure other than drinking water and consumption of fish and shellfish from inland and nearshore

[13] USEPA. 2011. EPA Exposure Factors Handbook. 2011 edition (EPA 600/R–090/052F). *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.*

[14] USEPA. 2014. Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003–2010). United States Environmental Protection Agency, Washington, DC, EPA 820–R–14–002.

[15] EPA's national FCR is based on the total rate of consumption of fish and shellfish from inland and nearshore waters (including fish and shellfish from local, commercial, aquaculture, interstate, and international sources). This is consistent with a principle that each state does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions.

[16] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf* at 5–4. (Explaining that ''[t]he 1980 Methodology for deriving 304(a) criteria for the protection of human health emphasized the assessment of bioconcentration (uptake from water only) through the use of the BCF. . .The 2000 Human Health Methodology revisions contained in this chapter emphasize the measurement of bioaccumulation (uptake from water, sediment, and diet) through the use of the BAF.'').

[17] 65 FR 66444 (November 3, 2000).

[18] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[19] USEPA. 2003. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document Volume 2: Development of National Bioaccumulation Factors. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–03–030. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[20] 65 FR 66444 (November 3, 2000).

[21] Final Updated Ambient Water Quality Criteria for the Protection of Human Health (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC, *https://www.epa.gov/wqc/human-health-water-quality-criteria.*

[22] *Id.*

[23] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[24] As noted by the National Environmental Justice Advisory Council in the 2002 publication *Fish Consumption and Environmental Justice,* ''a suppression effect may arise when fish upon which humans rely are no longer available in historical quantities (and kinds), such that humans are unable to catch and consume as much fish as they had or would. Such depleted fisheries may result from a variety of affronts, including an aquatic environment that is contaminated, altered (due, among other things, to the presence of dams), overdrawn, and/or overfished. Were the fish not depleted, these people would consume fish at more robust baseline levels. . . . In the Pacific Northwest, for example, compromised aquatic ecosystems mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights.''). National Environmental Justice Advisory Council, *Fish Consumption and Environmental Justice,* p.44, 46 (2002) (NEJAC Fish Consumption Report), *available at https://www.epa.gov/sites/default/files/2015-02/documents/fish-consump-report_1102.pdf.*

[25] ''[RSC] defines the portion of the total exposure that comes from ingestion of water and fish from the ambient water body of interest. Other exposure information such as that from dietary, inhalation, and dermal routes should be considered and accounted for as part of the RSC human exposure analysis.'' *https://www.epa.gov/wqs-tech/supplemental-module-human-health-ambient-water-quality-criteria.*

waters. These other sources of exposure include but are not limited to ocean fish consumption (which is not included in EPA's default national FCR), non-fish food consumption (*e.g.,* fruits, vegetables, grains, meats, poultry), dermal exposure, and inhalation exposure. Using an RSC ensures that the level of a chemical allowed by a water quality criterion, when combined with other exposure sources, will not result in exposures that exceed the RfD, thus helping to prevent adverse health effects from aggregate exposure to a given chemical over a person's lifetime. EPA's guidance [26] includes an approach for determining an appropriate RSC for a given pollutant ranging in value from 0.2 to 0.8 to ensure that drinking water and fish consumption alone are not apportioned the entirety of the RfD. This approach, known as the Exposure Decision Tree, considers the adequacy of available exposure data, levels of exposure, relevant sources/media of exposure, and regulatory agendas. As explained below in section III.B.d of this preamble, EPA made science-based adjustments to the application of the RSC in this rulemaking to avoid ''double counting'' exposures.

C. Prior EPA Actions Related to Washington's Human Health Criteria

In 1992, EPA promulgated the National Toxics Rule (NTR) at 40 CFR 131.36, establishing chemical-specific numeric criteria for 85 priority toxic pollutants for 14 states and territories (states), including Washington, that were not in compliance with the requirements of CWA section 303(c)(2)(B). Subsequently, when states covered by the NTR adopted their own criteria for toxic pollutants that were consistent with the CWA and EPA's implementing regulations, EPA amended the NTR to remove those chemical-specific criteria for those states. In 2015, Washington was one of the states that remained covered by the NTR.

On September 14, 2015, the EPA Administrator determined that updated HHC for Washington were ''necessary'' pursuant to CWA section 303(c)(4)(B). EPA proposed HHC to protect the health of Washington residents, including tribes with treaty-reserved rights to fish.[27] In that proposal, EPA explained that the majority of waters under Washington's jurisdiction are subject to tribal treaty-reserved fishing rights.[28] To give effect to such rights in establishing revised WQS for Washington waters, EPA determined that tribal treaty fishing rights ''appropriately must be considered when determining which criteria are necessary to adequately protect Washington's fish and shellfish harvesting designated uses.'' [29] Specifically, EPA proposed to consider the tribal populations exercising their legal right to harvest and consume fish and shellfish as the general population for purposes of deriving protective HHC. To this end, EPA proposed HHC based on an FCR of 175 g/day and CRL of 10^{-6} to reflect consideration of tribal treaty-reserved rights, as informed by consultation with the tribes and fish consumption surveys of tribal members.[30] In addition to an FCR and CRL calculated to ensure protection of applicable tribal treaty-reserved rights, EPA also utilized other inputs to derive the proposed HHC based on the agency's latest scientific knowledge. Specifically, EPA calculated the proposed HHC using the national trophic level four BAFs and updated chemical-specific RSC values from its June 2015 CWA section 304(a) recommended criteria updates.[31]

Before EPA finalized the proposed Federal criteria, the State of Washington adopted HHC following an extensive public process and submitted the updated HHC to EPA for review on August 1, 2016. The updated HHC incorporated some of the new data and information from EPA's June 2015 CWA section 304(a) criteria updates. Washington's HHC were based on the same 175 g/day FCR and 10^{-6} CRL that EPA used to derive the proposed Federal HHC, with the exception of the CRL for polychlorinated biphenyls (PCBs).[32] Although Washington used the same FCR and CRL as EPA, Washington used BCFs instead of BAFs and used an RSC of 1. The scientific inputs of BCFs and an RSC of 1 do not reflect the latest scientific knowledge.

On November 15, 2016, EPA partially approved and partially disapproved Washington's HHC.[33] For the criteria that were disapproved, EPA concurrently signed a final rule promulgating the Federal criteria it had proposed in 2015.[34] Like EPA's 2015 proposal, the 2016 final rule articulated EPA's conclusion that it is necessary and appropriate to consider tribal treaty-reserved rights within the framework of the CWA and provided a discussion of the tribal treaties relevant to the State of Washington and applicable case law.[35] The 2016 final rule was informed by public comment that addressed both the proposed criteria and EPA's consideration of tribal treaties, as well as consultation with a number of federally recognized tribes.

EPA's disapproval of Washington's HHC in 2016 was largely predicated on Washington's use of input values that were not reflective of sound scientific rationale. In its letter to the State, EPA explained that the agency ''evaluated Washington's criteria values against criteria that EPA determined would be protective of the State's designated uses and scientifically defensible (*e.g.,* based on appropriate bioaccumulation factors (BAFs) and protective relative source contribution (RSC) values of less than 1).'' [36] EPA found that Washington had not demonstrated that the majority of its criteria were based on sound scientific rationale as required by the CWA and EPA's implementing regulations.[37] Specifically for PCBs, EPA found that Washington had not provided adequate support or analysis to justify its use of a chemical-specific CRL (2.3×10^{-5}) that was less stringent than the CRL used for all other pollutants, and did not explain how the use of this CRL was protective of the State's designated uses.[38]

With respect to the criteria that EPA approved, the agency also explained that ''while the EPA carefully considers the scientific defensibility and protectiveness of both the inputs used to derive criteria and the resulting criteria values, it is ultimately on the criteria values that the EPA takes approval or disapproval action under CWA section 303(c).'' [39] After evaluating Washington's criteria against criteria using appropriate scientific inputs, EPA determined that certain of Washington's criteria were as or more stringent than

[26] *Id.*

[27] 80 FR 55063 (September 14, 2015).

[28] *Id.* at 55067.

[29] *Id.*

[30] *Id.* at 55067–68.

[31] *Id.* at 55068–69.

[32] For PCBs, Washington's criteria were based on a chemical-specific CRL of 2.3×10^{-5}.

[33] Letter from Dan D. Opalski, Director, EPA Region 10 Office of Water and Watersheds to Maia Bellon, Director, Department of Ecology, Re: EPA's Partial Approval/Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools; Enclosure, Technical Support Document (November 15, 2016) (2016 Partial Approval/Partial Disapproval).

[34] 81 FR 85417 (November 28, 2016).

[35] 81 FR 85422–27 (November 28, 2016).

[36] 2016 Partial Approval/Disapproval at 3.

[37] *Id.* at 16–17.

[38] *Id.* at 26 (Determining that Washington ''did not provide adequate justification for using the Washington Department of Health cancer risk level for this specific chemical and then adjusting that cancer risk level so that the criteria would be equivalent to the NTR criteria'' and ''did not demonstrate how the criteria were derived using a cancer risk level that is based on scientifically sound rationale and protective of applicable designated uses, including the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved fishing rights.'').

[39] *Id.* at 8.

scientifically defensible criteria that the EPA determined would be protective of Washington's designated uses.[40] Accordingly, EPA approved those criteria.[41]

In a petition dated February 21, 2017, several regulated entities requested that EPA reconsider its November 15, 2016, partial disapproval and repeal its concurrent promulgated Federal criteria.[42] Following the 2017 petition, Washington and several federally recognized tribes with treaty-reserved fishing rights sent letters urging EPA to deny the petition and to leave the federally promulgated HHC in place.[43]

Despite objections from the State and several tribes, on May 10, 2019, EPA granted the 2017 industry petition by reversing the agency's prior partial disapproval to an approval of certain HHC ('2019 Reconsidered HHC') and subsequently issuing a final rule withdrawing the federally promulgated criteria.[44] EPA's May 10, 2019 approval concluded that the State's reliance on scientific inputs that were not reflective of the latest science was an appropriate risk-management decision.[45] The withdrawal of the Federal criteria went into effect on June 12, 2020, and as of that date, the HHC submitted by Washington on August 1, 2016 and approved by EPA on May 10, 2019 were in effect for CWA purposes.

On June 6, 2019, the State of Washington filed a complaint challenging the legality of EPA's May 2019 decision to reverse its November 2016 partial disapproval.[46] The Sauk-Suiattle Indian Tribe and Quinault Indian Nation subsequently joined Washington's lawsuit as plaintiff-intervenors. On June 6, 2020, following EPA's withdrawal of the promulgated Federal HHC, another lawsuit was filed by the Makah Indian Tribe, the Pacific Coast Federation of Fishermen's Associations, and environmental groups challenging both EPA's withdrawal of the federally promulgated HHC and its May 10, 2019 decision to reverse the November 2016 partial disapproval.[47] In September 2020, the Plaintiffs in the case filed by the State of Washington amended their complaints to also challenge EPA's rule withdrawing the Federal HHC.

Consistent with Executive Order 13990,[48] in February 2021, EPA sought and was granted an abeyance in both cases to conduct an initial review to determine whether it intended to reconsider the challenged actions. During this initial three-month abeyance, EPA decided to reconsider the challenged actions. Based on its initial review of the agency's prior actions, EPA sought a longer abeyance from the court, expressing substantial concern that Washington's HHC may not be adequately protective and may not be based on sound scientific rationale. On July 6, 2021, the Court granted EPA an abeyance to reconsider its prior actions and to propose protective HHC for Washington and take final action on the proposal within 18 months. EPA proposed protective HHC for Washington on April 1, 2022,[49] and is now finalizing protective HHC for Washington in this final rule.

III. Derivation of Human Health Criteria for Washington

A. Scope of EPA's Final Rule

After consideration of all comments received on EPA's proposed rulemaking, EPA is finalizing Federal criteria that supersede the 2019 Reconsidered HHC for CWA purposes.[50] EPA's final rule does not change or supersede the Federal HHC that EPA promulgated for arsenic,[51] methylmercury, or bis (2-chloro-1-methylethyl) ether in 2016 and that remain in place for CWA purposes, nor Washington's HHC that EPA approved in 2016 and have remained in effect since that time. EPA's final rule also does not change or supersede Washington's HHC for dioxin and thallium that EPA approved in 2019. EPA had previously taken no action on these two pollutants in 2016.

Some commenters asked EPA to quickly take separate prompt action to strengthen dioxin criteria and establish criteria for per- and polyfluoroalkyl substances (PFAS) unless Washington addresses those pollutants itself in a future State rulemaking. As noted in EPA's Response to Comment document in the docket for this rule, such comments are beyond the scope of this rulemaking.

Finally, certain commenters referred to EPA's prior actions related to HHC for arsenic and mercury in Washington. EPA's proposed rulemaking did not address those prior actions, which were based on the administrative record before the agency at that time, nor did EPA solicit comment on those actions. Therefore, such comments are also beyond the scope of this rule.

The HHC in this final rule apply to surface waters under the State of Washington's jurisdiction, and not to waters within Indian country,[52] unless otherwise specified in Federal law.

B. Washington-Specific Human Health Criteria Inputs

a. Fish Consumption Rate, Body Weight, Drinking Water Intake

EPA is finalizing HHC for Washington using the same FCR of 175 g/day, body weight of 80 kg and drinking water intake rate of 2.4 L/day that the agency proposed in its April 1, 2022, proposed rulemaking,[53] which are the same values Washington used in 2016 [54] and that EPA used in its 2016 Federal rule.[55] The comments addressing these input values are briefly summarized below.

With respect to the FCR, some commenters asserted that protective HHC should accurately account for the amount of fish people are eating, and that EPA was right to propose HHC using an FCR of 175 g/day. However, the same commenters state that 175 g/day is a compromise rate and is therefore, not conservative because many communities in Washington eat more than 175 g/day, even with suppressed fish stocks. Those

[40] *Id.*

[41] *Id.*

[42] Petition submitted by Northwest Pulp and Paper Association, America Forest and Paper Association, Association of Washington Business, Greater Spokane Incorporated, Treated Wood Council, Western Wood Preservers Institute, Utility Water Act Group and the Washington Farm Bureau.

[43] EPA received letters from the Washington State Department of Ecology, Washington State Attorney General, the Northwest Indian Fisheries Commission, the Lower Elwha Klallam Tribe, the Nooksack Indian Tribe, the Jamestown S'Klallam Tribe, and Earthjustice (on behalf of the Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, and several Washington Waterkeepers).

[44] May 10, 2019 letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Department of Ecology, Re: EPA's Reversal of the November 15, 2016 Clean Water Act section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria; Withdrawal of Certain Federal Water Quality Criteria Applicable to Washington, 85 FR 28494 (May 13, 2020).

[45] May 10, 2019 letter at pp. 8, 14–15.

[46] *State of Washington* v. *U.S. Envt'l Prot. Agency,* No. 2:19–cv–884–RAJ (W.D. Wash.).

[47] *Puget Soundkeeper Alliance et al.* v. *U.S. Envt'l Prot. Agency,* No. 2:20–cv–907–RAJ (W.D. Wash.).

[48] 86 FR 7037 (January 25, 2021).

[49] See *Restoring Protective Human Health Criteria in Washington: Proposed Rule,* 87 FR 19046, April 1, 2022.

[50] See 40 CFR 131.21(c).

[51] EPA promulgated arsenic HHC for Washington in the National Toxics Rule of 1992. EPA's Federal rule in 2016 moved the arsenic criteria from 40 CFR 131.36 to 40 CFR 131.45.

[52] *See* 18 U.S.C. 1151 for definition of Indian Country.

[53] See *Restoring Protective Human Health Criteria in Washington: Proposed Rule,* 87 FR 19046, April 1, 2022.

[54] Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16–10–025.

[55] *Revision of Certain Water Quality Standards Applicable to Washington,* 81 FR 85417 (November 28, 2016).

commenters assert that 175 g/day is only acceptable if that rate is paired with a CRL of one in one million (10^{-6}) and the most recent science for the other inputs.

Other commenters asserted that 175 g/day is an inappropriate FCR to use to derive HHC in Washington, and/or that it should not be paired with a 10^{-6} CRL. These commenters state that lower FCRs, or greater CRLs of one in one hundred thousand (10^{-5}) or one in ten thousand (10^{-4}), would be protective of all consumers in Washington, including tribes. Some commenters characterized 175 g/day as a high-biased estimate of fish consumption that is based on an outdated survey method. Additionally, commenters assert that 175 g/day is too high to use to derive HHC for Washington because it includes consumption of fish that predominantly accumulate pollutants in waters outside of Washington's jurisdiction (*i.e.,* the open ocean). Commenters state that EPA relies in part on an argument that fish consumption in Washington is suppressed but assert that EPA has not provided scientific evidence of such suppression or guidance on how to account for suppression. These commenters state that there is no evidence of lower fish stocks limiting consumption, and that fish availability should not be a factor in setting HHC since those criteria do not impact fish availability.

EPA reiterates its explanation in the proposed rulemaking that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule.[56] Thus, EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule. The agency has concluded that it is important to keep these values consistent between the HHC in this rule and the other HHC that this rule will not impact (*i.e.,* the HHC that Washington adopted and EPA approved in 2016, and the Federal HHC that remain in place for arsenic, methylmercury, or bis (2-chloro-1-methylethyl) ether), because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

b. Pollutant-Specific Reference Doses and Cancer Slope Factors

EPA is finalizing HHC for Washington using the same reference doses and cancer slope factors that the agency proposed in its April 1, 2022, proposed rulemaking,[57] which are the same values Washington used in 2016[58] and that EPA used in its 2016 Federal rule.[59] These are the same toxicity values that EPA uses in its national CWA section 304(a) recommended HHC. While there may be new toxicity information available for certain pollutants that is not yet reflected in EPA's CWA section 304(a) national recommended HHC, such information has not yet been reviewed through EPA's comprehensive CWA section 304(a) criteria development process and therefore is not incorporated into this final rule.[60] See Table 1, columns B1 and B3 of this preamble for a list of EPA's toxicity factors by pollutant.

EPA only received comments on reference doses and cancer slope factors in the context of specific pollutants, namely PCBs and mercury. As noted above, comments on mercury are beyond the scope of this rulemaking. For comments on PCBs, see below and EPA's Response to Comment document in the docket for this rule.

c. Cancer Risk Level

EPA is finalizing HHC for Washington using the same CRL of 10^{-6} that the agency proposed in its April 1, 2022, proposed rulemaking for all pollutants, including PCBs.[61] This is the same CRL Washington used in 2016 for all pollutants except for PCBs[62] and that EPA used in its 2016 Federal rule for all pollutants.[63]

EPA's selection of a 10^{-6} CRL is consistent with EPA's 2000 Methodology, which states that EPA intends to use the 10^{-6} level, which reflects an appropriate risk for the general population, when promulgating water quality criteria for states and tribes.[64] Additionally, many of Washington's rivers are in the Columbia River basin, upstream of Oregon's portion of the Columbia River. Oregon's criteria for PCBs and other pollutants are based on an FCR of 175 g/day and a CRL of 10^{-6}. EPA's final Federal HHC for Washington using a CRL of 10^{-6} along with an FCR of 175 g/day helps ensure that Washington's criteria will provide for the attainment and maintenance of Oregon's downstream WQS as required by 40 CFR 131.10(b).

As noted in EPA's 2016 final rule for Washington,[65] several tribes in Washington have treaty-reserved rights to fish on waters throughout the State. Consistent with those rights, tribal members catch and consume fish for their subsistence. EPA determined that a 10^{-6} CRL was appropriate independent of treaty rights, for the reasons explained in this section and EPA's Response to Comment document in the docket for this rule. Nonetheless, EPA's selection of a 10^{-6} CRL is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels.[66]

Some commenters asserted that EPA's use of a CRL of 10^{-6} is consistent with EPA's guidance and national precedent. These commenters agreed with EPA's proposal of HHC for PCBs based on a CRL of 10^{-6} paired with an FCR of 175 g/day and asserted that it violates the CWA and civil rights to expose high fish consumers to a higher cancer risk due to PCBs. Commenters stated that EPA did not show why Washington's criteria that it previously disapproved in 2016 were protective in 2019. Finally, commenters asserted that upstream pollution impacts the Spokane Tribe's ability to safely exercise their treaty reserved fishing rights and EPA's proposed PCB criteria are closer to the Tribe's criteria and therefore more likely to provide for downstream protection. Commenters also state that use of a CRL

[56] *Id.* at 85420; 85426–428.

[57] See *Restoring Protective Human Health Criteria in Washington: Proposed Rule,* 87 FR 19046, April 1, 2022.

[58] Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16–10–025.

[59] *Revision of Certain Water Quality Standards Applicable to Washington,* 81 FR 85417 (November 28, 2016).

[60] For example, there are 7 polycyclic aromatic hydrocarbons for which there is new toxicity information available since the promulgation of the 2016 Federal rule. Because the CWA section 304(a) criteria development process can take several years, EPA is not able to review this information and complete this rulemaking by the end of the 18-month abeyance. Once EPA has developed updated CWA section 304(a) criteria for these pollutants, the State may evaluate its HHC for these pollutants (*e.g.,* during a triennial review), adopt new HHC based on the CWA section 304(a) updates, and submit these HHC to EPA for review.

[61] See *Restoring Protective Human Health Criteria in Washington: Proposed Rule,* 87 FR 19046, April 1, 2022.

[62] Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16–10–025.

[63] *Revision of Certain Water Quality Standards Applicable to Washington,* 81 FR 85417 (November 28, 2016).

[64] EPA 2000 Methodology, p. 2–6. The Methodology recommends that states set human health criteria CRLs for the target general population at either 10^{-5} or 10^{-6} (p. 2–6) and also notes that states and authorized tribes can always choose a more stringent risk level, such as 10^{-7} (p. 1–12).

[65] 81 FR 85422–26 (November 28, 2016).

[66] In 2016, tribes in Washington State generally viewed 175 g/day as a compromise minimum consumption rate so long as it is coupled with a CRL of 10^{-6}. 2016 Partial Approval/Disapproval p. 15.

of 10^{-6} to derive HHC for Washington addresses the potential for synergistic toxicity from exposure to multiple toxins.

Other commenters asserted that EPA's use of a 10^{-6} CRL is inconsistent with EPA's guidance and longstanding policy on acceptable risk levels. These commenters stated that EPA accepts CRLs of 10^{-6} or 10^{-5}, provided the median FCR for highly exposed populations is protected to a 10^{-4} risk level, and pointed to prior EPA actions, including EPA's 2019 approval of HHC in Idaho, 2011 HHC approval in Oregon, and EPA's Clean Water Act national recommended 304(a) criteria that pair a 10^{-6} cancer risk level with a general population fish consumption rate rather than an FCR associated with high fish consumers. Some commenters characterized a CRL of 10^{-4} as effectively zero risk to a small population such as the tribal population in Washington. Other commenters argued that the CRL is a choice for states to make and that EPA was right to accept Washington's choice of a PCB-specific CRL in 2019 because Washington's 2016 PCB criteria strike a more appropriate balance between cost and human health protection, and EPA's proposed PCB criteria are not scientifically defensible or attainable with currently available technology. Some commenters raised concerns that EPA's proposed criteria are below analytical method quantitation limits and therefore it is not clear how dischargers can comply with the criteria and this could be misleading to the public. Some commenters criticized EPA's cost estimates for the proposed rule, stating that testing methodology may improve, such that dischargers will then be out of compliance with permit limits, and stating that Washington is unlikely to adopt WQS variances to provide dischargers with relief. These commenters asserted that certain dischargers are already being pushed by EPA to use an unapproved PCB test method as the basis to design and install new treatment systems, and that EPA was wrong to assume that PCBs are not likely to be found in the effluent from minor facilities. Some commenters raised concerns that EPA and Washington State allow for the continued release of PCBs into the environment under the Toxic Substances Control Act, tribal and Federal hatchery operations in Washington, and Washington's Model Toxics Control ACT, which in turn puts an unfair burden on dischargers in Washington to meet the proposed HHC for PCBs. Commenters also raised concerns that EPA has not shared the latest science evaluating the toxicity of inadvertently generated PCBs and there is ongoing scientific uncertainty with EPA's proposed PCB criteria that EPA has not sufficiently explained.

As noted above, in this final rule EPA is maintaining its proposed CRL of 10^{-6}, which Washington used in 2016 and EPA used in its 2016 Federal rule for all pollutants. With respect to the comments regarding utilizing that same CRL for PCBs, for the reasons that EPA further explained in the proposed rulemaking, the agency has concluded that Washington's PCB HHC are not protective of Washington's designated uses because of Washington's selected chemical-specific CRL, which is not based on a sound scientific rationale. For detailed responses to all comments received, including those which reiterate prior comments that EPA received on its 2015 proposed rulemaking for Washington and previously responded to, such as comments about the intersection of the CWA and the Toxic Substances Control Act with respect to PCBs, see EPA's Response to Comment document in the docket for this rule.

d. Relative Source Contribution

EPA recommends using an RSC for non-carcinogens and nonlinear carcinogens to account for sources of exposure other than drinking water and consumption of inland and nearshore fish and shellfish (see section II.B.d of this preamble). In its 2015 304(a) criteria recommendations, after evaluating information on chemical uses, properties, occurrences, releases to the environment and regulatory restrictions, EPA developed chemical-specific RSCs for non-carcinogens and nonlinear carcinogens ranging from 0.2 (20 percent) to 0.8 (80 percent) following the Exposure Decision Tree approach described in EPA's 2000 Human Health Methodology.[67] [68]

When EPA promulgated HHC for Washington in 2016, EPA adjusted RSC values using a ratio of the national dataset characterizing all FCRs versus inland and nearshore-only FCRs derived from the NHANES dataset. EPA then applied this ratio to the proportion of the RfD reserved for inland and nearshore fish consumption in the RSC, and used this adjustment to account for double-counted potential exposure to certain chemicals in certain anadromous fish species (*e.g.,* salmon). This approach involves the following assumptions:

- The pollutant concentrations in anadromous fish are the same as those in inland and nearshore fish; and
- The ratio of all fish to inland and nearshore fish from NHANES data approximates the ratio of inland, nearshore, and anadromous fish to just inland and nearshore fish from Columbia River Inter-Tribal Fish Commission (CRITFC)[69] data (since CRITFC data were used to derive the 175 g/day FCR).

At the 90th percentile rate of consumption, the national adult consumption rate from NHANES data for all fish is 53 g/day and 22 g/day for inland and nearshore-only fish, or a ratio of 2.4. Applying this to an RSC of 0.2 yields 0.48, or 0.5 rounding to a single decimal place. Because the 175 g/day FCR includes some but not all marine species, EPA decided to use this approach to adjust the RSC values. However, EPA only adjusted RSC values to 0.5 for criteria calculations previously using an RSC between 0.2 and 0.5. Criteria derived using an RSC greater than 0.5 remained unchanged. EPA is using these same 2016 RSCs to derive HHC for Washington in this final rule, having no new data or information to support revising RSCs. The inclusion of protective RSCs in the development of HHC is a science-based decision that protects human health by ensuring that a person's exposure to multiple sources of a chemical is accounted for. See Table 1, column B2 of this preamble for a list of EPA's RSCs by pollutant.

Some commenters asserted that use of an RSC of 1 is scientifically indefensible and that returning to EPA's 2016 approach of using an RSC equal to or less than 0.8 will ensure that the HHC consider other potential exposures. Commenters stated that tribes are regularly exposed to toxins through other routes of exposure in addition to fish consumption, such as dermal exposure. Commenters agreed with EPA's statement in the proposed rule that the choice of cancer risk level (CRL) is irrelevant to the choice of RSC since these inputs are for mutually exclusive

[67] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[68] Final Updated Ambient Water Quality Criteria for the Protection of Human Health, (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC *https://www.epa.gov/wqc/human-health-water-quality-criteria.*

[69] *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

categories of pollutants (carcinogens vs. non-carcinogens).

Other commenters asserted that the RSC value is a discretionary risk management decision and there is no regulatory requirement to examine multiple exposure routes when developing HHC. Commenters also stated that the criteria are only intended to protect for risks related to surface water exposure, *i.e.,* fish and water. Some commenters asserted that it is arbitrary for EPA to use an RSC less than 1 when the FCR includes all fish. Other commenters pointed to prior EPA actions, including EPA's 2011 HHC approval in Oregon, and EPA's 2013 approval of HHC for the Spokane Tribe, to assert that EPA has approved HHC that rely on an RSC of 1. Finally, some commenters state that EPA's use of RSCs in the drinking water program under the Safe Drinking Water Act (SDWA) is different than using them for WQS since SDWA allows for consideration of cost in setting the final regulatory limits.

As explained in the proposed rulemaking, EPA determined that Washington's use of an RSC value of 1 to derive HHC is not based on sound scientific rationale as it apportioned the entire ''safe'' dose of certain chemicals to drinking water and fish consumption, ignoring other sources of those chemicals. While EPA acknowledges the comments indicating that it has previously approved WQS where states and authorized tribes utilized an RSC of 1 to develop certain HHC, in those prior actions, EPA only approved HHC that used an RSC of 1 if EPA had not yet updated its own corresponding national recommended 304(a) criteria to reflect chemical-specific RSC values following the Exposure Decision Tree approached described in the 2000 Methodology. Without updated national recommended 304(a) criteria, states and tribes did not yet have the benefit of EPA's thorough review of exposure information that now exists since EPA updated its national HHC recommendations in 2015. Since the 2015 recommended HHC updates, EPA has encouraged all states to consider the latest science reflected in EPA's 2015 HHC recommendations during the triennial review of state WQS and update their HHC to incorporate appropriate RSCs. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

e. Pollutant-Specific Bioaccumulation Factors

Where data are available, EPA uses BAFs to account for the uptake and retention of waterborne chemicals by aquatic organisms from all surrounding media and to ensure that resulting criteria are science-based and protect designated uses for human health. Consistent with the 2016 Federal rule for Washington,[70] EPA is finalizing HHC for Washington by applying the trophic level four BAF from the 2015 CWA section 304(a) recommended HHC updates in conjunction with the 175 g/day FCR.[71]

Some commenters asserted that the choice of BCFs versus BAFs is a science-based rather than risk management decision, and that EPA is appropriately following the science in applying BAFs in this rule. These commenters asserted that BCFs undercount the amount of chemicals in fish, and EPA disregarded science and its own guidance when it approved BCF-based HHC in 2019.

Other commenters asserted that Washington's choice to use BCFs rather than BAFs was a sound science policy choice. These commenters asserted that BCFs are based on sound scientific principles and state that EPA has previously approved HHC that rely on BCFs. Commenters asserted that EPA's national recommended BAFs are just guidance, that they overestimate bioaccumulation and therefore lead to overly stringent HHC, and that they are insufficiently explained such that it is not possible to determine if they are appropriate for Washington. Some commenters asserted that both BAFs and BCFs are influenced by the local environment (*e.g.,* food web structure, water temperature, dissolved carbon) and therefore cannot be based on a single set of assumptions for all waters.

Regarding the comments supporting the use of BCFs, as explained in the proposed rule, the use of BCFs rather than BAFs, where BAF data are available, to calculate the HHC is inconsistent with sound scientific rationale on the bioaccumulation of pollutants. EPA has considered the comments received on its selected BAFs and reiterates its explanation in the proposed rule that it does not have new data or information to support an alternative to its 2016 decision to use the trophic level four BAFs, given that the species commonly consumed in Washington are trophic level four fish (*e.g.,* salmon). For certain pollutants for which science-based BAFs are not currently available, EPA is finalizing HHC using the BCFs from its updated CWA section 304(a) recommended HHC for those pollutants as the best available scientific information. See Table 1, columns B4 and B5 of this preamble for a list of EPA's bioaccumulation factors by pollutant. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

C. Final Human Health Criteria for Washington

EPA is finalizing 141 HHC for 72 different pollutants (70 organism-only criteria and 71 water-plus-organism criteria) to protect the applicable designated uses of Washington's waters (see Table 1 of this preamble). The final HHC are the same criteria that EPA promulgated in 2016. The water-plus-organism criteria in column C1 of Table 1 of this preamble, are the applicable criteria for any waters that include the Domestic Water use (domestic water supply) defined in Washington's WQS (WAC 173–201A–600). The organism-only criteria in column C2 of Table 1 of this preamble, are the applicable criteria for any waters that do not include the Domestic Water use (domestic water supply) and that Washington defines at WAC 173–201A–600 and 173–201A–610 as the following:

- Fresh waters—Harvesting (fish harvesting), and Recreational Uses;
- Marine waters—Shellfish Harvesting (shellfish—clam, oyster, and mussel—harvesting), Harvesting (salmonid and other fish harvesting, and crustacean and other shellfish—crabs, shrimp, scallops, etc.—harvesting), and Recreational Uses.

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[70] *Revision of Certain Water Quality Standards Applicable to Washington,* 81 FR 85417 (November 28, 2016).

[71] Because the surveyed population upon which the 175 g/day FCR is based consumed almost exclusively trophic level four fish (*i.e.,* predator fish species), EPA used the trophic level four BAF from the 2015 CWA section 304(a) HHC updates in conjunction with the 175 g/day FCR, in order to derive protective criteria. See *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

Table 1. Final Human Health Criteria for Washington

	A		B					C	
	Chemical	**CAS Number**	**Cancer Slope Factor, CSF (per mg/kg·d) (B1)**	**Relative Source Contribution, RSC (-) (B2)**	**Reference Dose, RfD (mg/kg·d) (B3)**	**Bio-accumulation Factor (L/kg tissue) (B4)**	**Bio-concentration Factor (L/kg tissue) (B5)**	**Water & Organisms (µg/L) (C1)**	**Organisms Only (µg/L) (C2)**
1	1,1,1-Trichloroethane	71556	-	0.50	2	10	-	20,000	50,000
2	1,1,2,2-Tetrachloroethane	79345	0.2	-	-	8.4	-	0.1	0.3
3	1,1,2-Trichloroethane	79005	0.057	-	-	8.9	-	0.35	0.90
4	1,1-Dichloroethylene	75354	-	0.50	0.05	2.6	-	700	4,000
5	1,2,4-Trichlorobenzene	120821	0.029	-	-	430	-	0.036	0.037
6	1,2-Dichlorobenzene	95501	-	0.50	0.3	82	-	700	800
7	1,2-Dichloroethane	107062	0.0033	-	-	1.9	-	8.9	73
8	1,2-Diphenylhydrazine	122667	0.8	-	-	27	-	0.01	0.02
9	1,2-Trans-Dichloroethylene	156605	-	0.50	0.02	4.7	-	200	1,000
10	1,3-Dichlorobenzene	541731	-	0.50	0.002	190	-	2	2
11	1,3-Dichloropropene	542756	0.122	-	-	3.0	-	0.22	1.2
12	1,4-Dichlorobenzene	106467	-	0.50	0.07	84	-	200	200
13	2,4-Dichlorophenol	120832	-	0.50	0.003	48	-	10	10
14	2,4-Dinitrophenol	51285	-	0.50	0.002	4.4	-	30	100
15	2-Chloronaphthalene	91587	-	0.80	0.08	240	-	100	100
16	2-Methyl-4,6-Dinitrophenol	534521	-	0.50	0.0003	10	-	3	7
17	4,4'-DDD	72548	0.24	-	-	240,000	-	7.9E-06	7.9E-06
18	4,4'-DDE	72559	0.167	-	-	3,100,000	-	8.8E-07	8.8E-07
19	4,4'-DDT	50293	0.34	-	-	1,100,000	-	1.2E-06	1.2E-06
20	Acenaphthene	83329	-	0.50	0.06	510	-	30	30
21	Aldrin	309002	17	-	-	650,000	-	4.1E-08	4.1E-08
22	alpha-BHC	319846	6.3	-	-	1,500	-	4.8E-05	4.8E-05
23	alpha-Endosulfan	959988	-	0.50	0.006	200	-	6	7
24	Anthracene	120127	-	0.50	0.3	610	-	100	100
25	Antimony	7440360	-	0.50	0.0004	-	1	6	90
26	Benzo(a) Anthracene	56553	0.73	-	-	3,900	-	0.00016	0.00016
27	Benzo(a) Pyrene	50328	7.3	-	-	3,900	-	1.6E-05	1.6E-05
28	Benzo(b) Fluoranthene	205992	0.73	-	-	3,900	-	0.00016	0.00016
29	Benzo(k) Fluoranthene	207089	0.073	-	-	3,900	-	0.0016	0.0016
30	beta-BHC	319857	1.8	-	-	180	-	0.0013	0.0014
31	Bis(2-Ethylhexyl) Phthalate	117817	0.014	-	-	710	-	0.045	0.046
32	Bromoform	75252	0.0045	-	-	8.5	-	4.6	12
33	Butylbenzyl Phthalate	85687	0.0019	-	-	19,000	-	0.013	0.013
34	Chlordane	57749	0.35	-	-	60,000	-	2.2E-05	2.2E-05
35	Chlorobenzene	108907	-	0.50	0.02	22	-	100	200
36	Chlorodibromomethane	124481	0.04	-	-	5.3	-	0.60	2.2
37	Chloroform	67663	-	0.50	0.01	3.8	-	100	600
38	Chrysene	218019	0.0073	-	-	3,900	-	0.016	0.016

39	Cyanide	57125	-	0.50	0.0006	-	1	9	100
40	Dibenzo(a,h) Anthracene	53703	7.3	-	-	3,900	-	1.6E-05	1.6E-05
41	Dichlorobromomethane	75274	0.034	-	-	4.8	-	0.73	2.8
42	Dieldrin	60571	16	-	-	410,000	-	7.0E-08	7.0E-08
43	Diethyl Phthalate	84662	-	0.50	0.8	920	-	200	200
44	Dimethyl Phthalate	131113	-	0.50	10	4,000	-	600	600
45	Di-n-Butyl Phthalate	84742	-	0.50	0.1	2,900	-	8	8
46	Endosulfan Sulfate	1031078	-	0.50	0.006	140	-	9	-
47	Endrin	72208	-	0.80	0.0003	46,000	-	0.002	0.002
48	Ethylbenzene	100414	-	0.50	0.022	160	-	29	31
49	Fluoranthene	206440	-	0.50	0.04	1,500	-	6	6
50	Fluorene	86737	-	0.50	0.04	710	-	10	10
51	gamma-BHC; Lindane	58899	-	0.50	0.0047	2,500	-	0.43	0.43
52	Heptachlor	76448	4.1	-	-	330,000	-	3.4E-07	3.4E-07
53	Heptachlor Epoxide	1024573	5.5	-	-	35,000	-	2.4E-06	2.4E-06
54	Hexachlorobenzene	118741	1.02	-	-	90,000	-	5.0E-06	5.0E-06
55	Hexachlorobutadiene	87683	0.04	-	-	1,100	-	0.01	0.01
56	Hexachlorocyclopentadiene	77474	-	0.50	0.006	1,300	-	1	1
57	Hexachloroethane	67721	0.04	-	-	600	-	0.02	0.02
58	Indeno(1,2,3-cd) Pyrene	193395	0.73	-	-	3,900	-	0.00016	0.00016
59	Methyl Bromide	74839	-	0.50	0.02	1.4	-	300	-
60	Methylene Chloride	75092	0.002	-	-	1.6	-	10	100
61	Nickel	7440020	-	0.50	0.02	-	47	80	100
62	Nitrobenzene	98953	-	0.50	0.002	3.1	-	30	100
63	Pentachlorophenol (PCP)	87865	0.4	-	-	520	-	0.002	0.002
64	Phenol	108952	-	0.50	0.6	1.9	-	9,000	70,000
65	Polychlorinated Biphenyls (PCBs)		2	-	-	-	31,200	[a]7E-06	[a]7E-06
66	Pyrene	129000	-	0.50	0.03	860	-	8	8
67	Selenium	7782492	-	0.50	0.005	-	4.8	60	200
68	Tetrachloroethylene	127184	0.0021	-	-	76	-	2.4	2.9
69	Toluene	108883	-	0.50	0.0097	17	-	72	130
79	Trichloroethylene	79016	0.05	-	-	13	-	0.3	0.7
71	Vinyl Chloride	75014	1.5	-	-	1.7	-	-	0.18
72	Zinc	7440666	-	0.50	0.3	-	47	1,000	1,000

[a] This criterion applies to total PCBs (e.g., the sum of all congener or isomer or homolog or Aroclor analyses).

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D. Applicability

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their navigable waters (CWA section 303(a)–(c)). Although EPA is finalizing revised HHC for Washington, Washington continues to have the option to adopt and submit to EPA newly revised HHC for the State's waters consistent with CWA section 303(c) and EPA's implementing regulations at 40 CFR part 131. If, subsequent to this final rule, Washington adopts and submits revised HHC, EPA's federally promulgated criteria will remain applicable for purposes of the CWA until EPA withdraws the federally promulgated criteria (40 CFR 131.21(c)). EPA would undertake such a rulemaking to withdraw the Federal criteria if and when Washington adopts and EPA approves corresponding State criteria that meet the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131.

E. Alternative Regulatory Approaches and Implementation Mechanisms

The Federal WQS regulation at 40 CFR part 131 provides several tools that Washington has available to use at its discretion when implementing or deciding how to implement these HHC. Among other things, EPA's WQS regulation: (1) specifies how states and authorized tribes establish, modify, or remove designated uses (40 CFR 131.10); (2) specifies the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific

conditions (40 CFR 131.11); (3) authorizes and provides a regulatory framework for states and authorized tribes to adopt WQS variances where it is not feasible to attain the applicable WQS at that time (40 CFR 131.14); and (4) allows states and authorized tribes to authorize the use of compliance schedules in National Pollutant Discharge Elimination System (NPDES) permits to meet water quality-based effluent limits (WQBELs) derived from the applicable WQS (40 CFR 131.15). Each of these approaches is discussed in more detail in the next sections. Whichever approach a state pursues, however, all NPDES permits would need to comply with EPA's regulations at 40 CFR 122.44(d)(1)(i).

a. Designated Uses

EPA's HHC apply to waters that Washington has designated for the following:

- Fresh waters—Harvesting (fish harvesting), Domestic Water (domestic water supply), and Recreational Uses;
- Marine waters—Shellfish Harvesting (shellfish—clam, oyster, and mussel—harvesting), Harvesting (salmonid and other fish harvesting, and crustacean and other shellfish—crabs, shrimp, scallops, etc.—harvesting), and Recreational Uses (see WAC 173–201A–600 and WAC 173–201A–610).

The Federal regulation at 40 CFR 131.10(g) provides requirements for establishing, modifying, and removing designated uses when attaining the use is not feasible based on one of the six factors specified in the regulation. If Washington removes a use and adopts the highest attainable use,[72] the State must also adopt criteria to protect the newly designated highest attainable use consistent with 40 CFR 131.11. It is possible that criteria other than the federally promulgated criteria would protect the highest attainable use. If EPA found removal or modification of the designated use and the adoption of the highest attainable use and criteria to protect that use to be consistent with CWA section 303(c) and the implementing regulation at 40 CFR part 131, the agency would approve the revised WQS. EPA would then undertake a rulemaking to withdraw the corresponding Federal WQS for the relevant water(s).

b. WQS Variances

Washington's WQS provide authority to apply WQS variances when implementing federally promulgated HHC, as long as such WQS variances are adopted consistent with 40 CFR 131.14 and submitted to EPA for review under CWA section 303(c). The Federal regulation at 40 CFR 131.3(o) defines a WQS variance as a time-limited designated use and criterion, for a specific pollutant or water quality parameter, that reflects the highest attainable condition during the term of the WQS variance. A WQS variance may be appropriate if attaining the use and criterion would not be feasible during the term of the WQS variance because of one of the seven factors specified in 40 CFR 131.14(b)(2)(i)(A). These factors include a situation where NPDES permit limits more stringent than technology-based controls would result in substantial and widespread economic and social impact. WQS variances adopted in accordance with 40 CFR 131.14 (including a public hearing consistent with 40 CFR 25.5) provide a flexible but defined pathway for states and authorized tribes to issue NPDES permits with limits that are based on the highest attainable condition during the term of the WQS variance. This allows dischargers to make water quality improvements when the WQS is not immediately attainable but may be in the future. When adopting a WQS variance, states and authorized tribes specify the interim requirements of the WQS variance by identifying a quantitative expression that reflects the highest attainable condition (HAC) during the term of the WQS variance, establishing the term of the WQS variance, and describing the pollutant control activities expected to occur over the specified term of the WQS variance. WQS variances provide a legal avenue by which NPDES permit limits can be written to comply with the WQS variance rather than the underlying WQS for the term of the WQS variance. If dischargers are still unable to meet the WQBELs derived from the applicable WQS once a WQS variance term is complete, the regulation allows the State to adopt a subsequent WQS variance if it is adopted consistent with 40 CFR 131.14. EPA is finalizing HHC that apply to use designations that Washington has already established. Washington's WQS regulations currently include provisions to use WQS variances when implementing criteria (see WA 173–210A–420), as long as such WQS variances are adopted consistent with 40 CFR 131.14 and approved by EPA. Washington may use the State's EPA-approved WQS variance procedures when adopting such WQS variances.

c. NPDES Permit Compliance Schedules

EPA's regulations at 40 CFR 122.47 and 131.15 address how permitting authorities can use schedules for compliance with a limit in the NPDES permit if the discharger needs additional time to undertake actions like facility upgrades or operation changes to meet a WQBEL based on the applicable WQS. EPA's regulation at 40 CFR 122.47 allows a permitting authority to include a compliance schedule in the NPDES permit, when appropriate and where authorized by the state, to provide a discharger with additional time to meet a WQBEL implementing applicable WQS. EPA's regulation at 40 CFR 131.15 requires that a state that intends to allow the use of NPDES permit compliance schedules adopt specific provisions authorizing their use and obtain EPA approval under CWA section 303(c) to ensure that a decision to allow a permit compliance schedule is transparent and allows for public input.[73] EPA has approved Washington's State law provision authorizing the use of permit compliance schedules (see WAC–173–201A–510(4)), consistent with 40 CFR 131.15. Washington's compliance schedule authorizing provision is not affected by this rule. Washington is authorized to grant permit compliance schedules, as appropriate, based on the Federal HHC in Washington, if such permit compliance schedules are consistent with EPA's permitting regulation at 40 CFR 122.47.

IV. Economic Analysis

EPA focused its economic analysis on the potential cost impacts to current holders of individual NPDES permits (point sources) and the costs the State of Washington may bear to develop Total Maximum Daily Loads (TMDLs) for waters newly identified as impaired under CWA section 303(d) using the revised WQS. Costs might also arise to holders of general permits[74] should the State modify those permits in some manner as a result of the revised WQS. Costs might also arise to sectors whose operations are nonpoint sources of pollutants through implementation of TMDLs or through other voluntary,

[72] If a state or authorized tribe adopts a new or revised WQS based on a required use attainability analysis, then it must also adopt the highest attainable use (40 CFR 131.10(g)). The highest attainable use is the modified aquatic life, wildlife, or recreation use that is both closest to the uses specified in section 101(a)(2) of the CWA and attainable, based on the evaluation of the factor(s) in 40 CFR 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the Act and sub-categories of such a use are not attainable (see 40 CFR 131.3(m)).

[73] 80 FR 51022 (August 21, 2015).

[74] General permits typically focus on best management practices.

incentivized, or State-imposed controls. This rule does not directly regulate nonpoint sources and under the CWA states are responsible for the regulation of nonpoint sources. EPA recognizes that controls for nonpoint sources may be part of future TMDLs, but any such future decisions will be made by the State. Nonpoint sources are intermittent, variable, and occur under hydrologic or climatic conditions associated with precipitation events. Data to model and evaluate the potential cost impacts associated with nonpoint sources were not available and any estimate would be too uncertain to be informative. EPA also did not estimate potential sediment remediation costs for this analysis.

These WQS may serve as a basis for development of NPDES permit limits. Washington has NPDES permitting authority and retains considerable discretion in implementing standards. EPA evaluated the potential costs to NPDES dischargers associated with State implementation of EPA's criteria. This analysis is documented in ''Economic Analysis for Restoring Protective Human Health Criteria in Washington,'' which can be found in the record for this rule. Any NPDES-permitted facility that discharges pollutants for which the revised HHC are more stringent than the applicable aquatic life criteria (or for which HHC are the only applicable criteria) could potentially incur compliance costs. The types of affected facilities could include industrial facilities and POTWs discharging wastewater to surface waters (*i.e.,* point sources).

A. Identifying Affected Entities

EPA identified 406 point source facilities that could ultimately be affected by this rule. Of these potentially affected facilities, 73 are major dischargers and 333 are minor dischargers. EPA did not include general permit facilities in its analysis because data for such facilities are limited and requirements typically focus on best management practices. Of the potentially affected facilities, EPA evaluated a sample of 18 major facilities. Minor facilities are less likely to incur costs as a result of implementation of the rule because of the reduced potential for significant presence of toxic pollutants in their effluent. EPA did not have effluent data on toxic pollutants to evaluate minor facilities for this analysis. Table 2 summarizes these potentially affected facilities by type and category.

TABLE 2—POTENTIALLY AFFECTED FACILITIES

Category	Minor	Major	All
Municipal	169	44	213
Industrial	164	29	193
Total	333	73	406

B. Method for Estimating Costs

EPA evaluated the two major municipal facilities with design flows greater than 100 mgd and the largest industrial facility, to attempt to capture the facilities with the potential for the largest costs. For the remaining major facilities, EPA evaluated a random sample of facilities to represent discharger type and category. For all sample facilities, EPA evaluated existing baseline permit conditions, reasonable potential to exceed HHC based on the rulemaking, and potential to exceed projected effluent limitations based on the last three years of effluent monitoring data (if available). Only compliance actions and costs that would be needed above the baseline level of controls are attributable to the rulemaking.

EPA assumes that dischargers would pursue the least cost means of compliance with WQBELs. Compliance actions attributable to the rulemaking may include pollution prevention, end-of-pipe treatment, and alternative compliance mechanisms (*e.g.,* WQS variances). EPA annualizes capital costs, including study (*e.g.,* WQS variance) and program (*e.g.,* pollution prevention) costs, over 20 years using discount rates of 3 percent and 7 percent to obtain total annual costs per facility. To obtain an estimate of total costs to point sources, EPA extrapolates the annualized costs for the random sample based on the flow volume for the sample facilities and the flow volume for all facilities.

C. Results

Based on the results for 18 sample facilities across 10 industrial and municipal categories,[75] EPA did not identify any incremental costs to any major point source discharges of process wastewater from POTWs or industrial facilities attributable to EPA's criteria revisions. This does not mean that EPA anticipates there would be no costs to point sources over time to implement controls or modify processes to meet future permit limits, only that available data do not indicate the immediate need for the facilities evaluated. It would be highly speculative to attempt to estimate potential costs either based on the possibility of measuring pollutant levels at lower levels as a result of future requirements or future technology, or based on changes to facility operations or practices. Should the need to consider advanced treatment or other substantial costs arise in the future, there are mechanisms such as WQS variances in place which may consider cost and feasibility in the application of protective criteria, and alternative permit limits may be derived to avoid excessive costs. EPA will work with the State of Washington and with stakeholders on a continuing basis to assess the possibility of economically significant future costs of compliance. If such costs arise, EPA will provide guidance for applying alternative compliance mechanisms to minimize costs.

One important contributing factor to examining point source costs is the limitations of required analytical methods to measure chemical concentrations in effluents. Nearly half of pollutant parameters addressed in this rule have analytical quantitation limits that are above both the criteria currently in place and EPA's criteria. PCBs are a good example. The current criterion in place is 170 picograms per liter (pg/L) and EPA's criterion is 7 pg/L. However, the State identifies the analytical detection limit for effluent measurement as 65,000 pg/L as the means to evaluate compliance. EPA has completed a multi-laboratory validation of a new analytical method for PCBs (method 1628) that has an average analytical quantitation limit for each PCB congener of approximately 2,000

[75] Ten industrial categories (coal mining, food and kindred products, paper and allied products, chemicals and allied products, petroleum refining and related industries, primary metal industries, fabricated metal products, electric, gas and sanitary services, and national security and international affairs) and municipal POTWs.

pg/L, which is a substantial improvement over the current regulatory method, but still well above either the criterion currently in place or EPA's criterion. As a general matter, analytical methods and quantitation limits are subject to change over time. As such, it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods.

EPA also evaluated potential administrative costs to the State for developing additional TMDLs under CWA section 303(d) for any waters that are newly identified as impaired as a result of EPA's criteria. Using available ambient monitoring data, EPA compared pollutant concentrations to the baseline and revised criteria, identifying waterbodies that may be incrementally impaired (*i.e.,* impaired under EPA's criteria but not under the baseline). EPA identified 32 impairments under the baseline criteria and 61 under the revised criteria, resulting in 29 potential incremental impairments. The estimated total annual costs for TMDL development range from $100,000 to $182,000, at a 3 percent discount rate, based on single-cause single-waterbody TMDL development costs. Actual costs may be reduced if the State develops multi-cause or multi-waterbody TMDLs.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

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

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

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. While actions to implement these WQS could entail additional paperwork burden, this action does not directly contain any information collection, reporting, or record-keeping requirements. OMB has previously approved the information collection activities contained in the existing regulation at 40 CFR part 131 and has assigned OMB control number 2040–0049.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Small entities, such as small businesses or small governmental jurisdictions, are not directly regulated by this rule. EPA-promulgated WQS are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with a NPDES permit. CWA section 301(b)(1)(C) and EPA's implementing regulations at 40 CFR 122.44(d)(1) introductory text and (d)(1)(i) provide that all NPDES permits shall include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, EPA's promulgation of WQS establishes standards that the State implements through the NPDES permit process. While the State has discretion in developing discharge limits, as needed to meet the WQS, those limits, per regulations at 40 CFR 122.44(d)(1)(i), ''must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard, including [s]tate narrative criteria for water quality.'' As a result of this action, the State of Washington will need to ensure that permits it issues include any limitations on discharges necessary to comply with the WQS established in this final rule. In doing so, the State will have a number of choices associated with permit writing. While Washington's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA's action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

Under the technical requirements of Executive Order 13132, the EPA has determined that this rule may not have federalism implications but believes that the consultation requirements of the Executive order have been satisfied in any event. This rule does not alter Washington's considerable discretion in implementing these WQS, nor does it preclude Washington from adopting WQS that EPA concludes meet the requirements of the CWA after promulgation of this final rule.

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

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. This rule could affect federally recognized Indian tribes in Washington because the numeric criteria for Washington will apply to waters adjacent to (or upstream or downstream of) the tribal waters. Additionally, there are six federally recognized Indian tribes in the Columbia River Basin located in the States of Oregon and Idaho that this rule could affect because their waters could affect or be affected by the water quality of Washington's downstream or upstream waters.

EPA consulted with tribal governments under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to ensure meaningful and timely input into its development. In August 2021, EPA held coordination and consultation sessions with tribal environmental staff and leadership to share information, hear their views and answer questions on the rulemaking. Representatives from 17 tribes and two tribal consortia participated in two leadership meetings with EPA held in August 2021. Additionally, EPA conducted tribal consultation and coordination activities on the proposed rulemaking from March 29, 2022, through June 3, 2022. During these meetings, the tribes repeatedly asked EPA to reinstate the 2016 Federal HHC for Washington, which EPA is doing in this final rule.

A *Summary of EPA's Consultation, Coordination, and Outreach with Federally Recognized Tribes on the Restoration of Protective Human Heath Criteria for Washington* is available in the docket for this final rule.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in

Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section II.B of this preamble, in which EPA recommends that HHC be designed to reduce the risk of adverse cancer and non-cancer effects occurring from lifetime exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish obtained from inland and nearshore waters. EPA's HHC for Washington are similarly based on reducing the chronic health effects occuring from lifetime exposure and therefore are expected to be protective of a person's exposure during both childhood and adult years.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866. This action establishes CWA HHC for waters under the State of Washington's jurisdiction.

I. National Technology Transfer and Advancement Act of 1995

This rule does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or Indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained below.

1. Introduction

EPA defines Environmental Justice (EJ) as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations and policies.[76] Three Executive orders (E.O. 12898,[77] 13985,[78] and 14008[79]) advance EJ by calling on Federal agencies to identify and address disproportionate impacts on historically underserved, marginalized, and economically disadvantaged people. Additionally, EPA has expressed a commitment to conducting EJ analyses for rulemakings as described in the April 30, 2021, revisions to the Cross-State Air Pollution Rule (CSAPR).[80]

EPA believes that this rule is not expected to have disproportionately high and adverse human health or environmental effects on low-income populations, people of color, or tribal populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). In its economic impact analysis, EPA only estimates administrative costs to the State of Washington to develop TMDLs and no incremental costs to point source discharges based on available data, as explained above in section IV of this preamble. Therefore, EPA does not anticipate that this rule will impose any additional costs or other negative impacts on tribes or other low income or disadvantaged communities.

Instead, this action identifies and ameliorates disproportionately high and adverse human health effects on tribal communities, people of color and low-income populations in Washington by restoring HHC in Washington that are based on sound scientific rationale and protect high fish consumers.

Many groups in Washington, such as Asian, Pacific Islanders, and subsistence and recreational tribal and non-tribal fishers consume large amounts of fish and shellfish as part of traditionally influenced diets.[81] The 2019 Reconsidered HHC currently expose these high fish consumers to greater risk from toxic pollutants because the criteria do not accurately account for pollutant bioaccumulation into fish and expose fish consumers to a greater risk of cancer from PCB exposure.

Environmental impacts to tribes may be considered under the category of EJ in recognition that tribes may at times be among the disadvantaged communities disproportionately impacted by environmental degradation. Where tribal communities are part of a larger non-tribal community, many of the EJ considerations are very similar to those of other disadvantaged groups. However, there is a very unique set of EJ considerations for tribes, particularly in this context where tribes are exercising their cultural practices and treaty-reserved rights outside of their reservations on state waters.

While the overall impacts to communities with EJ concerns are improved as a result of this rule, by relying on the fish consumption rates based on tribal data, this rule helps ensure that tribal members, in particular, and their treaty-protected activities and resources are protected.[82] Specifically, this rule establishes HHC based on an FCR of 175 g/day reflective of regional tribal FCR survey data[83] to represent and protect higher fish consumers. In conjunction with the FCR, the rule uses a CRL of 10^{-6} to

[76] Fair treatment means that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental and commercial operations or programs and policies.'' Meaningful involvement occurs when ''(1) potentially affected populations have an appropriate opportunity to participate in decisions about a proposed activity [*e.g.,* rulemaking] that will affect their environment and/or health; (2) the public's contribution can influence [the EPA's rulemaking] decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) [the EPA will] seek out and facilitate the involvement of those potentially affected.'' A potential EJ concern is defined as ''the actual or potential lack of fair treatment or meaningful involvement of minority populations, low-income populations, tribes, and tribal peoples in the development, implementation and enforcement of environmental laws, regulations and policies.'' See ''Guidance on Considering Environmental Justice During the Development of an Action,'' Environmental Protection Agency, *www.epa.gov/environmentaljustice/guidanceconsidering-environmental-justice-duringdevelopment-action.* See also *https://www.epa.gov/environmentaljustice.*

[77] Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. Available at *https://www.epa.gov/environmentaljustice/federal-actions-address-environmental-justice-minority-populations-and-low,* accessed October 6, 2021.

[78] Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009, January 25, 2021). Available at *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government,* accessed October 6, 2021.

[79] Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). Available at *https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad,* accessed October 6, 2021.

[80] 86 FR 23054, 23162 (April 30, 2021) (''Going forward, EPA is committed to conducting environmental justice analysis for rulemakings based on a framework similar to what is outlined here, in addition to investigating ways to further weave environmental justice into the fabric of the rulemaking process including through enhanced meaningful engagement with environmental justice communities.'').

[81] Department of Ecology. *Fish Consumption Rates: Technical Support Document, A Review of Data and Information about Fish Consumption in Washington, Version 2.0 Final.* January 2013. Ecology Publication No. 12–09–058, p.18. *https://apps.ecology.wa.gov/publications/documents/1209058.pdf.*

[82] 80 FR 55063 (September 14, 2015) (''In Washington, many tribes hold reserved rights to take fish for subsistence, ceremonial, religious, and commercial purposes, including treaty-reserved rights to fish at all usual and accustomed fishing grounds and stations in waters under state jurisdiction, which cover the majority of waters in the state. Such rights include not only a right to take those fish, but necessarily include an attendant right to not be exposed to unacceptable health risks by consuming those fish.'').

[83] *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

derive HHC for all cancer-causing pollutants, including PCBs, a rate which is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at the 175 g/day level.

Central to working with tribes on their environmental issues and opportunities is government to government consultation, which is consistent with Executive Order 13175 (65 FR 67249, November 6, 2000). To ensure that this rule considers the interests and perspective of tribes, EPA engaged with tribes that may be affected by this action to receive meaningful and timely input from tribal officials. See section V.F of this preamble for a summary of tribal consultation.

In addition to Executive Orders 12898 and 13175, and in accordance with Title VI of the Civil Rights Act of 1964, each Federal agency shall ensure that all programs or activities receiving Federal financial assistance that affect human health or the environment do not directly, or through contractual or other arrangements, use criteria, methods, or practices that discriminate on the basis of race, color, or national origin. With that directive in mind, in August 2011 the Environmental Justice Interagency Working Group established a Title VI Committee to address the intersection of agencies' environmental justice efforts with their Title VI enforcement and compliance responsibilities. If Washington receives Federal funds for CWA implementation, they are legally prohibited from discriminating on the basis of race, color or national origin under Title VI when engaging in CWA implementation activities. Additionally, and in compliance with Executive Order 12898, EPA expects that Washington will consider disproportionately high adverse human health and environmental effects on minority and low-income populations when implementing this rule under the CWA.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

■ 2. Amend § 131.45 by revising paragraph (b) to read as follows:

§ 131.45 Revision of certain Federal water quality criteria applicable to Washington.

* * * * *

(b) *Criteria for priority toxic pollutants in Washington.* The applicable human health criteria are shown in table 1 to this paragraph (b).

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Table 1 to Paragraph (b)—Human Health Criteria for Washington

	A		B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
1	1,1,1-Trichloroethane	71556	-	0.50	2	10	-	20,000	50,000
2	1,1,2,2-Tetrachloroethane	79345	0.2	-	-	8.4	-	0.1	0.3
3	1,1,2-Trichloroethane	79005	0.057	-	-	8.9	-	0.35	0.90
4	1,1-Dichloroethylene	75354	-	0.50	0.05	2.6	-	700	4,000
5	1,2,4-Trichlorobenzene	120821	0.029	-	-	430	-	0.036	0.037
6	1,2-Dichlorobenzene	95501	-	0.50	0.3	82	-	700	800
7	1,2-Dichloroethane	107062	0.0033	-	-	1.9	-	8.9	73
8	1,2-Diphenylhydrazine	122667	0.8	-	-	27	-	0.01	0.02
9	1,2-Trans-Dichloroethylene	156605	-	0.50	0.02	4.7	-	200	1,000
10	1,3-Dichlorobenzene	541731	-	0.50	0.002	190	-	2	2
11	1,3-Dichloropropene	542756	0.122	-	-	3.0	-	0.22	1.2
12	1,4-Dichlorobenzene	106467	-	0.50	0.07	84	-	200	200
13	2,4-Dichlorophenol	120832	-	0.50	0.003	48	-	10	10
14	2,4-Dinitrophenol	51285	-	0.50	0.002	4.4	-	30	100
15	2-Chloronaphthalene	91587	-	0.80	0.08	240	-	100	100
16	2-Methyl-4,6-Dinitrophenol	534521	-	0.50	0.0003	10	-	3	7
17	4,4'-DDD	72548	0.24	-	-	240,000	-	7.9E-06	7.9E-06
18	4,4'-DDE	72559	0.167	-	-	3,100,000	-	8.8E-07	8.8E-07
19	4,4'-DDT	50293	0.34	-	-	1,100,000	-	1.2E-06	1.2E-06
20	Acenaphthene	83329	-	0.50	0.06	510	-	30	30
21	Aldrin	309002	17	-	-	650,000	-	4.1E-08	4.1E-08
22	alpha-BHC	319846	6.3	-	-	1,500	-	4.8E-05	4.8E-05
23	alpha-Endosulfan	959988	-	0.50	0.006	200	-	6	7
24	Anthracene	120127	-	0.50	0.3	610	-	100	100
25	Antimony	7440360	-	0.50	0.0004	-	1	6	90
26	Arsenic*	7440382	1.75	-	-	-	44	[a]0.018	[a]0.14

	A		B					C	
	Chemical	**CAS Number**	**Cancer Slope Factor, CSF (per mg/kg·d) (B1)**	**Relative Source Contribution, RSC (-) (B2)**	**Reference Dose, RfD (mg/kg·d) (B3)**	**Bio-accumulation Factor (L/kg tissue) (B4)**	**Bio-concentration Factor (L/kg tissue) (B5)**	**Water & Organisms (µg/L) (C1)**	**Organisms Only (µg/L) (C2)**
27	Benzo(a) Anthracene	56553	0.73	-	-	3,900	-	0.00016	0.00016
28	Benzo(a) Pyrene	50328	7.3	-	-	3,900	-	1.6E-05	1.6E-05
29	Benzo(b) Fluoranthene	205992	0.73	-	-	3,900	-	0.00016	0.00016
30	Benzo(k) Fluoranthene	207089	0.073	-	-	3,900	-	0.0016	0.0016
31	beta-BHC	319857	1.8	-	-	180	-	0.0013	0.0014
32	Bis(2-Chloro-1-Methylethyl) Ether**	108601	-	0.50	0.04	10	-	400	900
33	Bis(2-Ethylhexyl) Phthalate	117817	0.014	-	-	710	-	0.045	0.046
34	Bromoform	75252	0.0045	-	-	8.5	-	4.6	12
35	Butylbenzyl Phthalate	85687	0.0019	-	-	19,000	-	0.013	0.013
36	Chlordane	57749	0.35	-	-	60,000	-	2.2E-05	2.2E-05
37	Chlorobenzene	108907	-	0.50	0.02	22	-	100	200
38	Chlorodibromomethane	124481	0.04	-	-	5.3	-	0.60	2.2
39	Chloroform	67663	-	0.50	0.01	3.8	-	100	600
40	Chrysene	218019	0.0073	-	-	3,900	-	0.016	0.016
41	Cyanide	57125	-	0.50	0.0006	-	1	9	100
42	Dibenzo(a,h) Anthracene	53703	7.3	-	-	3,900	-	1.6E-05	1.6E-05
43	Dichlorobromomethane	75274	0.034	-	-	4.8	-	0.73	2.8
44	Dieldrin	60571	16	-	-	410,000	-	7.0E-08	7.0E-08
45	Diethyl Phthalate	84662	-	0.50	0.8	920	-	200	200
46	Dimethyl Phthalate	131113	-	0.50	10	4,000	-	600	600
47	Di-n-Butyl Phthalate	84742	-	0.50	0.1	2,900	-	8	8
48	Endosulfan Sulfate	1031078	-	0.50	0.006	140	-	9	-
49	Endrin	72208	-	0.80	0.0003	46,000	-	0.002	0.002
50	Ethylbenzene	100414	-	0.50	0.022	160	-	29	31
51	Fluoranthene	206440	-	0.50	0.04	1,500	-	6	6
52	Fluorene	86737	-	0.50	0.04	710	-	10	10
53	gamma-BHC; Lindane	58899	-	0.50	0.0047	2,500	-	0.43	0.43
54	Heptachlor	76448	4.1	-	-	330,000	-	3.4E-07	3.4E-07
55	Heptachlor Epoxide	1024573	5.5	-	-	35,000	-	2.4E-06	2.4E-06
56	Hexachlorobenzene	118741	1.02	-	-	90,000	-	5.0E-06	5.0E-06
57	Hexachlorobutadiene	87683	0.04	-	-	1,100	-	0.01	0.01
58	Hexachlorocyclopentadiene	77474	-	0.50	0.006	1,300	-	1	1
59	Hexachloroethane	67721	0.04	-	-	600	-	0.02	0.02
60	Indeno(1,2,3-cd) Pyrene	193395	0.73	-	-	3,900	-	0.00016	0.00016
61	Methyl Bromide	74839	-	0.50	0.02	1.4	-	300	-
62	Methylene Chloride	75092	0.002	-	-	1.6	-	10	100
63	Methylmercury	22967926	-	2.7E-05	0.0001	-	-	-	[b]0.03 (mg/kg)
64	Nickel	7440020	-	0.50	0.02	-	47	80	100

	A		B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
65	Nitrobenzene	98953	-	0.50	0.002	3.1	-	30	100
66	Pentachlorophenol (PCP)	87865	0.4	-	-	520	-	0.002	0.002
67	Phenol	108952	-	0.50	0.6	1.9	-	9,000	70,000
68	Polychlorinated Biphenyls (PCBs)		2	-	-	-	31,200	[c]7E-06	[c]7E-06
69	Pyrene	129000	-	0.50	0.03	860	-	8	8
70	Selenium	7782492	-	0.50	0.005	-	4.8	60	200
71	Tetrachloroethylene	127184	0.0021	-	-	76	-	2.4	2.9
72	Toluene	108883	-	0.50	0.0097	17	-	72	130
73	Trichloroethylene	79016	0.05	-	-	13	-	0.3	0.7
74	Vinyl Chloride	75014	1.5	-	-	1.7	-	-	0.18
75	Zinc	7440666	-	0.50	0.3	-	47	1,000	1,000

[a] This criterion refers to the inorganic form of arsenic only.

[b] This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See *Water Quality Criterion for the Protection of Human Health: Methylmercury* (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.

[c] This criterion applies to total PCBs (e.g., the sum of all congener or isomer or homolog or Aroclor analyses).

[*] These criteria were promulgated for Washington in the National Toxics Rule at § 131.36, and are moved into § 131.45 to have one comprehensive human health criteria rule for Washington.

[**] Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.

* * * * *

[FR Doc. 2022–25150 Filed 11–17–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0387; FRL–10030–01–OCSPP]

Cyclaniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyclaniliprole in or on multiple crops that are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 18, 2022. Objections and requests for hearings must be received on or before January 17, 2023, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0387, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0387 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before January 17, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0387, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2021 (86 FR 58239) (FRL–8792–04–OCSPP) and April 28, 2022 (87 FR 25178) (FRL–9410–12–OCSPP), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8904) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to establish tolerances for residues of the insecticide cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[(1-cyclopropylethyl)amino] carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, including its metabolites and degradates, in or on the raw agricultural commodities: Artichoke, globe at 1.5 parts per million (ppm); Pepper/eggplant subgroup 8–10B at 1.5 ppm; Sunflower subgroup 20B at 0.4 ppm; Tomato subgroup 8–10A at 0.6 ppm; Hog, meat at 0.01 ppm; Hog, fat at 0.015 ppm; Hog, meat byproducts at 0.015 ppm; Egg at 0.01 ppm; Poultry, meat at 0.01 ppm; Poultry, fat at 0.015 ppm; and Poultry, meat byproducts at 0.015 ppm. Upon the establishment of the tolerances specified above, IR–4 requested to remove the established tolerance for Vegetable, fruiting, group 8–10 at 0.20 ppm. The documents referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov.* There were no substantive comments received in response to the notices of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the commodities for which tolerances are being set.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyclaniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyclaniliprole follows.

No single or repeated dose study performed by any route of exposure produced an adverse effect following cyclaniliprole exposure at dose levels below, at, or above the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)). Although the oral toxicity studies in dogs were conducted at approximately a third of the limit dose, no adverse effects were seen. While adaptive liver effects were seen in these studies, it is unlikely that cyclaniliprole would produce adverse liver effects if tested at higher doses in dogs as a structurally related chemical, chlorantraniliprole, was tested up to the limit dose in dogs and did not demonstrate adverse liver effects. There is no evidence that cyclaniliprole produces increased susceptibility with prenatal or postnatal exposures. Cyclaniliprole is considered not likely to be carcinogenic based on no increase in treatment-related tumor incidence in carcinogenicity studies in rats and mice and no genotoxicity.

Specific information on the studies received for cyclaniliprole as well as the no-observed-adverse-effect-level (NOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document, ''Cyclaniliprole: Human Health Risk Assessment for the Proposed New Uses on Globe Artichoke and Sunflower Subgroup 20B and for new Greenhouse Uses (with Amended Tolerances) on Tomato Subgroup 8–10A and Pepper/Eggplant Subgroup 8–10B'', in docket ID number EPA–HQ–OPP–2021–0387.

Based on the review of the available cyclaniliprole toxicological studies, no toxicity endpoints or points of departure were selected for risk assessment. Based on the toxicological profile of cyclaniliprole, EPA has concluded that the FFDCA requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) requires an additional tenfold margin of safety in the case of threshold risks, which cyclaniliprole does not present. Section 408(b)(2)(D)(v) requires consideration of information concerning cumulative effects of substances that have a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of

toxicity finding as to cyclaniliprole and any other substances, and cyclaniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyclaniliprole has a common mechanism of toxicity with other substances.

Cyclaniliprole has been grouped with the pyridyl pyrazoles. As part of the ongoing process to review registered pesticides, the Agency intends to apply this framework to determine if the available toxicological data for cyclaniliprole suggests a candidate common mechanism group (CMG) may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

There is a potential for exposure to cyclaniliprole residues via food and drinking water based on existing uses and the proposed uses for cyclaniliprole application directly to growing crops. These applications can also result in cyclaniliprole reaching surface and ground water, both of which can serve as sources of drinking water. There are no existing or proposed uses in residential settings and therefore no anticipated residential exposures, although exposures resulting from spray drift from agricultural applications onto residential areas may occur. However, no quantitative risk assessment was conducted because no toxicity endpoints or points of departure were selected for risk assessment.

Determination of safety. Based on the available data indicating a lack of adverse effects from exposure to cyclaniliprole, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyclaniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry (LC–MS/MS)) is available to enforce the tolerance expression for plants and livestock commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has established MRLs for cyclaniliprole. The tolerance definitions are harmonized between the U.S. and Codex for plant and livestock commodities. There are Codex MRLs established on tomato subgroup 8–10A at 0.08 ppm for most commodities and at 0.1 ppm for tomato and on pepper/eggplant subgroup 8–10B at 0.15 ppm. For peppers (bell/non-bell) and tomatoes, the Agency is not harmonizing with the Codex MRLs because the Codex MRLs are much lower than the U.S. tolerances (0.15 vs 1.5 ppm for pepper subgroup and 0.1 vs 0.7 ppm for tomato subgroup). Harmonization could potentially result in tolerance exceedances in the U.S. and is therefore not possible.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the tolerance value for tomato subgroup 8–10A from 0.6 ppm to 0.7 ppm because EPA used different residue data to calculate the tolerance. The proposed preharvest interval (PHI) for tomato is 1 day and the petitioner used residue data from a 1-day PHI. The decline trial indicated that residues increased at higher PHIs, so EPA included the highest cyclaniliprole residue at a PHI of 7 days in the tolerance calculation to be conservative.

EPA has determined that tolerances for Hog, meat; Hog, fat; Hog, meat byproducts; Egg; Poultry, meat; Poultry, fat; and Poultry, meat byproducts are not necessary because the calculated dietary burdens for swine and poultry are very low such that there is no reasonable expectation of finite residues in these commodities as a result of eating treated feedstuff (40 CFR 180.6(a)(3)).

V. Conclusion

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops, EPA is establishing tolerances for residues resulting from direct applications to certain commodities because the petitioner requested them for international trade purposes. Therefore, tolerances are established for residues of cyclaniliprole in or on Artichoke, globe at 1.5 ppm; Pepper/eggplant subgroup 8–10B at 1.5 ppm; Sunflower subgroup 20B at 0.4 ppm; and Tomato subgroup 10A at 0.7 ppm. Additionally, the tolerance for Vegetable, fruiting, group 8–10 is removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal

Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: November 15, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.694, amend the table in paragraph (a) by:

■ a. Adding a heading;

■ b. Adding in alphabetical order the entries ''Artichoke, globe'', ''Pepper/eggplant subgroup 8–10B'', ''Sunflower subgroup 20B'', and ''Tomato subgroup 8–10A''; and

■ c. Removing the entry for ''Vegetable, fruiting, group 8–10''.

The additions read as follows:

§ 180.694 Cyclaniliprole; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Artichoke, globe	1.5
* * * * *	
Pepper/eggplant subgroup 8–10B	1.5
* * * * *	
Sunflower subgroup 20B	0.4
* * * * *	
Tomato subgroup 8–10A	0.7
* * * * *	

* * * * *

[FR Doc. 2022–25185 Filed 11–17–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

[LLORN03000.L63000000.HD0000. 22X.241A.HAG 22–0018]

Final Supplementary Rule for Public Lands in the Lower Lake Creek Falls Special Recreation Management Area, Lane County, OR

AGENCY: Bureau of Land Management, Interior.

ACTION: Final supplementary rule.

SUMMARY: The Bureau of Land Management (BLM) Oregon/Washington State Director is finalizing a supplementary rule prohibiting the use and possession of alcoholic beverages in the Lower Lake Creek Falls Special Recreation Management Area (SRMA).

DATES: This final supplementary rule is effective on December 19, 2022.

ADDRESSES: Inquiries may be directed to the BLM Northwest Oregon, Siuslaw Field Office at (541) 683–6600 or 3106 Pierce Pkwy., E Springfield, OR 97477. The final supplementary rule and accompanying environmental documents are available for inspection at the BLM Northwest Oregon, Siuslaw Field Office and on the ePlanning website at: *https://eplanning.blm.gov/eplanning-ui/project/67998/510.*

FOR FURTHER INFORMATION CONTACT: Morgan Schneider, Team Lead, Telephone: (541) 683–6407, email: *BLM_OR_NO_SIU_NEPA@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Background

The BLM Northwest Oregon District, Siuslaw Field Office manages the Lower Lake Creek SRMA. This popular recreation site contains unique waterfalls and natural water slide features that draw visitors from throughout the region. Visitors hike along a short trail to Lake Creek and enjoy swimming in natural pools and other in-water recreational activities. The consumption of alcoholic beverages in the SRMA has resulted in increased occurrences of unsafe behavior by visitors, such as wading in fast-moving and shallow sheet water flowing over natural rock formations. This final supplementary rule will ban the possession and consumption of alcoholic beverages in the area and, as a result, return the area to a safer and more family-friendly outdoor recreation opportunity for all members of the public to enjoy.

BLM law enforcement, recreation personnel, local law enforcement, and local search and rescue professionals agree that some visitors' consumption of alcohol has been a major factor in contributing to increased public safety risks at the recreation site. Such public safety issues include an increase in fatal traffic accidents involving travelers driving to and from the recreation area, as well as increased problems associated with litter, sanitation, and noise. This final supplementary rule is needed to ensure a safe recreational setting for all visitors and the local communities of Triangle Lake and Blachly, Oregon.

This final supplementary rule is established under the authority of 43 CFR 8365.1–6, which allows BLM State Directors to establish supplementary rules for ''the protection of persons, property, and public lands and resources.'' This final supplementary rule prohibits visitors of all ages from consuming, possessing, or furnishing any beverage defined as an alcoholic beverage by Oregon State Law within the boundaries of the Lower Lake Creek SRMA, including, but not limited to, the parking lot, day-use area and surrounding hillside, Lower Lake Creek Falls swimming area, and pathways leading to the swimming area and waterfalls site. Prohibited acts under this provision include the consumption,

possession, and furnishing of any alcoholic beverage within motor vehicles, tents, or other structures in the area described herein.

II. Discussion of Public Comments

On August 9, 2012, the BLM published a proposed supplementary rule (77 FR 47662) to replace an existing supplementary rule on alcohol use within the Lower Lake Creek SRMA. The existing supplementary rule, adopted in 1997, prohibits ''consumption, possession, or furnishing of any alcoholic beverage in violation of Oregon State law.'' Because of the way it is written, the existing supplementary rule does not actually ban the consumption, possession, or furnishing of alcohol in the SRMA.

The substance of the ''Prohibited Act'' in this final supplementary rule, which is the same as the substance of the proposed supplementary rule (*i.e.,* alcoholic beverages), would prohibit consumption, possession, or furnishing of ''any beverage defined as an alcoholic beverage by Oregon State law while on public lands'' within the boundaries of the Lower Lake Creek SRMA. In the proposed supplementary rule, the BLM explained that the existing supplementary rule is insufficient to control an increasing population of visitors who consume, possess, or furnish alcohol, and the proposed supplementary rule would put in place an enforceable ban on alcoholic beverages for all visitors, regardless of age.

The BLM received no comments on the proposed supplementary rule. The BLM signed a decision record on the *Proposed Rules for public land within the Lower Lake Creek SRMA Environmental Assessment* (DOI–BLM–ORWA–E050–2012–0002–EA), which was posted on the BLM's ePlanning website on October 11, 2016. The BLM received two comments during the environmental assessment's (EA) 30-day comment period. These commenters thanked the BLM for moving forward with a ban on alcoholic beverages at the Lower Lake Creek Falls SRMA.

III. Procedural Matters

Executive Order (E.O.) 12866, Regulatory Planning and Review

This supplementary rule is not a significant regulatory action and is not subject to review by the Office of Management and Budget under E.O. 12866. This supplementary rule would not have an annual effect of $100 million or more on the economy. It is not intended to affect commercial activity but imposes a rule of conduct on recreational visitors for public safety in a limited area of public lands. This supplementary rule would not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal Governments or communities. This supplementary rule would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. This supplementary rule does not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the right or obligations of their recipients, nor does it raise novel legal or policy issues; it merely strives to protect public safety.

National Environmental Policy Act

A ban on alcoholic beverages was analyzed in the EA titled ''Proposed Rules for Public Land Within the Lower Lake Creek SRMA'' (DOI–BLM–ORWA–E050–2012–0002–EA). This document was subject to a 30-day public comment period. On July 23, 2012, BLM determined that this supplementary rule did not constitute a major Federal action significantly affecting the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. On October 11, 2016, BLM signed a decision record based on the EA, which analyzed a permanent restriction on consuming alcohol. This supplementary rule merely regulates conduct on the BLM lands administered by the Siuslaw Field Office within the boundaries of the Lower Lake Creek Falls SRMA in order to protect public safety. A detailed environmental impact statement under NEPA is not required.

The BLM reviewed and signed a Determination of NEPA Adequacy (DNA) in 2018 (DOI–BLM–ORWA–N030–2017–0005–DNA) after confirming that the EA's analysis is still valid. Circumstances in the SRMA have not changed since then.

The BLM has placed the EA, the decision record, the finding of no significant impact, and the DNA on file in the BLM administrative record at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

This final supplementary rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (RFA) of 1980, 5 U.S.C. 601, *et seq.* Congress enacted the RFA to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. The supplementary rule does not pertain specifically to commercial, not-for-profit, or governmental entities of any size, but to public consumption of alcoholic beverages on specific public lands.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more;

(b) Will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local Government agencies; or geographic regions; and

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This supplementary rule does not impose an unfunded mandate on State, local, or Tribal Governments of more than $100 million per year; nor does it have a significant or unique effect on State, local, or Tribal Governments or the private sector. This supplementary rule does not impose requirements on State, local, or Tribal Governments. A statement containing the information required by the Unfunded Mandates Reform Act, 2 U.S.C. 1531 *et seq.,* is not required.

Paperwork Reduction Act

This supplementary rule does not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

This rule does not affect a taking of private property or otherwise have takings implications under E.O. 12630. This supplementary rule is not a Government action capable of interfering with constitutionally protected property rights. This supplementary rule does not address property rights in any form and does not cause the impairment of any private property rights. A takings implication assessment is not required.

Executive Order 13132, Federalism

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This supplementary rule will not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of Government. A federalism summary impact statement is not required.

Executive Order 12988, Civil Justice Reform

This rule complies with the requirements of E.O. 12988. Specifically, the following rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its Government-to-Government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in E.O. 13175 and have determined that it has no substantial direct effects on federally recognized Indian Tribes and that consultation under the Department's Tribal consultation policy is not required.

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

IV. Final Supplementary Rule

Author

The principal author of this supplementary rule is Cheryl Adcock, Field Manager for the Siuslaw Field Office, Oregon/Washington.

For the reasons stated in the preamble, and under authority for supplementary rules at 43 U.S.C. 1740 and 43 CFR 8365.1–6, the BLM Oregon/Washington State Director establishes a supplementary rule for public lands administered by the BLM in Oregon/Washington, to read as follows:

Final Supplementary Rule for Public Lands in the Lower Lake Creek Falls Special Recreation Management Area, Lane County, OR

Definitions

Alcoholic beverage uses the definition set forth in 2017 ORS 471.001(1).

Prohibited Acts

No person may consume, possess, or furnish alcoholic beverages within the boundaries of the Lower Lake Creek Falls SRMA, including, but not limited to, the parking lot, day-use area and surrounding hillside, Lower Lake Creek Falls swimming area, and pathways leading to the swimming area and falls site. Prohibited acts under this provision also include the consumption, possession, and furnishing of any alcoholic beverage within motor vehicles, tents, or other structures.

Exemptions

No persons, agencies, municipalities, or companies are exempt from the supplementary rule unless specifically authorized in writing by the BLM.

Penalties

Any person who violates this supplementary rule may be tried before a United States magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials also impose penalties for violations of Oregon law.

Barry R. Bushue,

Bureau of Land Management, State Director, Oregon/Washington.

[FR Doc. 2022–25015 Filed 11–17–22; 8:45 am]

BILLING CODE 4310–33–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 17–59, WC Docket 17–97, FCC 22–37; FR ID 113860]

Advanced Methods To Target and Eliminate Unlawful Robocalls; Call Authentication Trust Anchor

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) announces that the Office of Management and Budget (OMB) has approved the public information collection associated with a rule that requires gateway providers to block calls based on a ''reasonable Do Not Originate (DNO) list,'' and that compliance with the rule will be required. This document is consistent with the *Sixth Report and Order* in CG Docket No. 17–59, *Fifth Report and Order* in WC Docket No. 17–97, and *Gateway Provider Report and Order,* FCC 22–37 adopted on May 19, 2022 and released on May 20, 2022, which states the Commission will publish a document in the **Federal Register** announcing a compliance date for the rule section and revise the rules accordingly.

DATES:

Effective date: The amendment is effective December 19, 2022.

Compliance date: Compliance with 47 CFR 64.1200(o), published at 87 FR 42916, July 18, 2022, is required on December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Jerusha Burnett, Consumer Policy Division, Consumer and Governmental Affairs Bureau, at (202) 418–0526, or email: *Jerusha.Burnett@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the information collection requirement in § 64.1200(o) on November 3, 2022.

The Commission publishes this document as an announcement of the compliance date of the rule.

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 3.317, 45 L Street NE, Washington, DC 20554. Please include the OMB Control Number, 3060–1303, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

This document also removes § 64.1200(p) of the Commission's rules, which advised that compliance was not required until OMB approval was obtained.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files,

audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval on July 20, 2022, for the information collection requirement contained in the modification to 47 CFR 64.1200(o).

Under 5 CFR 1320.5(b), an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number for the information collection requirement in 47 CFR 64.1200(o) is 3060–1306.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Pubulic Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1306.

OMB Approval Date: November 3, 2022.

OMB Expiration Date: November 30, 2025.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents: 6,493 respondents; 77,916 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On-occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections are contained in sections 4(i), 4(j), 201, 202, 217, 227, 227b, 251(e), 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201, 202, 217, 227, 227b, 251(e), 303(r), 403.

Total Annual Burden: 77,916 hours.

Total Annual Cost: No cost.

Needs and Uses: The notification and request for comments sought to establish a new information collection as it pertains to the *Advanced Methods to Target and Eliminate Unlawful Robocalls Sixth Report and Order and Call Authentication Trust Anchor Fifth Report and Order (''Gateway Provider Report and Order'')* (87 FR 42916, July 18, 2022). Unwanted and illegal robocalls have long been the Federal Communication Commission's (''Commission'') top source of consumer complaints and one of the Commission's top consumer protection priorities. Foreign-originated robocalls represent a significant portion of illegal robocalls, and gateway providers serve as a critical choke-point for reducing the number of illegal robocalls received by American consumers. In the *Gateway Provider Report and Order,* the Commission took steps to prevent these foreign-originated illegal robocalls from reaching consumers and to help track these calls back to the source. Along with further extension of the Commission's caller ID authentication requirements and Robocall Mitigation Database filing requirements, the Commission adopted several robocall mitigation requirements, including a requirement for gateway providers to respond to traceback within 24 hours, mandatory blocking requirements, a ''know your upstream provider'' requirement, and a general mitigation requirement.

Gateway Provider Report and Order, FCC 22–37, paras. 87–91, 47 CFR 64.1200(o).

A provider that serves as a gateway provider for particular calls must, with respect to those calls, block any calls purporting to originate from a number on a reasonable do-not-originate list. A list so limited in scope that it leaves out obvious numbers that could be included with little effort may be deemed unreasonable. The do-not-originate list may include only:

- Numbers for which the subscriber to which the number is assigned has requested that calls purporting to originate from that number be blocked because the number is used for inbound calls only;
- North American Numbering Plan numbers that are not valid;
- Valid North American Numbering Plan Numbers that are not allocated to a provider by the North American Numbering Plan Administrator; and
- Valid North American Numbering Plan numbers that are allocated to a provider by the North American Numbering Plan Administrator, but are unused, so long as the provider blocking the calls is the allocatee of the number and confirms that the number is unused or has obtained verification from the allocatee that the number is unused at the time of blocking.

This document also removes § 64.1200(p) of the Commission's rules, which advised that compliance was not required until OMB approval was obtained.

List of Subjects in 47 CFR Part 64

Carrier equipment, Communications common carriers, Reporting and recordkeeping requirements, Telecommunications, Telephone.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

The Federal Communications Commission amends part 64 of title 47 of the Code of Federal Regulations as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 154, 201, 202, 217, 218, 220, 222, 225, 226, 227, 227b, 228, 251(a), 251(e), 254(k), 255, 262, 276, 403(b)(2)(B), (c), 616, 620, 716, 1401–1473, unless otherwise noted; Pub. L. 115–141, Div. P, sec. 503, 132 Stat. 348, 1091.

§ 64.1200 [Amended]

■ 2. Amend § 64.1200 by removing paragraph (p).

[FR Doc. 2022–25148 Filed 11–17–22; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 87, No. 222
Friday, November 18, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Doc. No. AMS–SC–22–0048]

Decrease of Assessment Rate for Texas Oranges and Grapefruit

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Texas Valley Citrus Committee to decrease the assessment rate established for the 2022–23 and subsequent fiscal periods. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by December 19, 2022.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments can be sent to the Docket Clerk. Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237. Comments can also be sent to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or internet: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and can be viewed at: *https://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Delaney Fuhrmeister, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Delaney.Fuhrmeister@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 906 as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. Part 906 (referred to as ''the Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Texas Valley Citrus Committee (Committee) locally administers the Order and is comprised of producers and handlers of oranges and grapefruit operating within the area of production.

The Agricultural Marketing Service (AMS) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Texas citrus handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable oranges and grapefruit for the 2022–23 fiscal period, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

This proposed rule would decrease the assessment rate for the 2022–23 and subsequent fiscal periods from $0.05 to $0.03 per 7/10-bushel carton or equivalent of oranges and grapefruit.

The Order authorizes the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are familiar with the Committee's needs and with the costs for goods and services in their local area and are able to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting, and all directly affected persons have an

opportunity to participate and provide input.

For the 2021–22 and subsequent fiscal periods, the Committee recommended, and AMS approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS. That regulatory amendment raised the assessment rate from $0.01 per 7/10-bushel carton to its current level of $0.05 per 7/10-bushel carton.

The Committee met on May 24, 2022, and recommended 2022–23 expenditures of $134,970 and an assessment rate of $0.03 per 7/10-bushel carton or equivalent. In comparison, last year's budgeted expenditures were $43,900. The assessment rate of $0.03 is $0.02 lower than the rate currently in effect. The Committee voted to decrease the assessment rate due to an increase in production. The Committee estimates production for 2022–23 fiscal period to be approximately 4 million 7/10-bushel cartons or equivalent, an increase from the 1 million cartons estimated to be produced the previous year. At the current assessment rate, assessment income would equal $200,000, exceeding the Committee's anticipated expenditures of $134,970. By decreasing the assessment rate by $0.02, assessment income would be $120,000. This amount, along with reserve funds and interest income, should provide sufficient funds to meet 2022–23 anticipated expenses.

Major expenditures recommended by the Committee for the 2022–23 year include $66,220 for management expenses, $50,000 for compliance, and $18,750 for administrative expenses. Budgeted expenses for these items in 2021–22 were $20,000, $10,000, and $13,900, respectively.

The assessment rate recommended by the Committee was derived by reviewing anticipated expenses, expected shipments of Texas oranges and grapefruit, and the level of funds in reserve. Orange and grapefruit shipments for the 2022–23 year are estimated at 4,000,000 7/10-bushel cartons or equivalent, which should provide $120,000 in assessment income (4,000,000 cartons multiplied by $0.03). Income derived from handler assessments at the proposed rate, along with reserve funds and interest income, would be adequate to cover budgeted expenses. Funds in the reserve (currently about $89,126) are expected to be kept within the maximum permitted by the Order (approximately one fiscal period's expenses as authorized in § 906.35).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. Dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS evaluates Committee recommendations and other available information to determine whether modification of the assessment rate is needed, and further rulemaking would be undertaken as necessary. The Committee's 2022–23 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by AMS.

After consideration of all relevant material presented, including the information and recommendations submitted by the Committee and other available information, AMS has determined that this proposed rule is consistent with and will effectuate the purposes of the Act.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 120 producers of oranges and grapefruit in the production area and 14 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of $3,500,000 or less, and small agricultural service firms are defined as those whose annual receipts are $30,000,000 or less (13 CFR 121.201).

According to data from the National Agricultural Statistics Service (NASS), the weighted average free-on-board price for Texas citrus for the 2019–20 season was approximately $16.20 per 7/10-bushel carton or equivalent with total shipments of around 8.2 million cartons. Based on the number of handlers and the NASS data, handlers have average annual receipts of well below $30 million ($16.20 multiplied by 8.2 million cartons equals $132,840,000, divided by 14 equals $9.5 million).

In addition, based on NASS and Committee data the reported weighted average producer price for the 2020–21 season was around $9.82 per 7/10-bushel carton of Texas citrus with total shipments of around 4.45 million cartons. Based on producer price, shipment data, and the total number of Texas citrus producers, the average annual producer revenue is significantly below $3,500,0000 ($9.82 multiplied by 4.45 million cartons equals $43,699,000 divided by 119 producers equals $367,218). Thus, the majority of Texas citrus handlers and growers may be classified as small entities.

This proposal would decrease the assessment rate established for the Committee and collected from handlers for the 2022–23 and subsequent fiscal periods from $0.05 to $0.03 per 7/10-bushel carton or equivalent of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. The Committee recommended 2022–23 expenditures of $134,970 and an assessment rate of $0.03 per 7/10-bushel carton. The proposed assessment rate of $0.03 is $0.02 less than the previous rate. The quantity of assessable Texas Citrus for the 2022–23 season is estimated at 4 million 7/10-bushel cartons. Thus, the $0.03 rate should provide $120,000 in assessment income. Income derived from handler assessments along with interest income and funds from the Committee's authorized reserve would be adequate to cover budgeted expenses.

Major expenditures recommended by the Committee for the 2022–23 fiscal period include $66,220 for management expenses, $50,000 for compliance, and $18,750 for administrative expenses. Budgeted expenses for these items in 2021–22 were $20,000, $10,000, and $13,900, respectively.

The Committee recommended decreasing the assessment rate based on the 2022–23 estimate of 4 million 7/10-bushel carton or equivalent, 3 million more than estimated for the previous year. At the current assessment rate of $0.05 and with the 2022–23 crop estimated to be 4 million 7/10-bushel

cartons, assessment income would equal $200,000 ($0.05 multiplied by 4 million cartons), an amount exceeding the Committee's anticipated expenditures of $134,970. By decreasing the assessment rate by $0.02, assessment income would be approximately $120,000 ($0.03 multiplied by 4 million cartons). This amount, along with interest income, and funds from the authorized reserve, should provide sufficient funds to meet 2022–23 anticipated expenses.

Prior to arriving at this budget and assessment rate, the Committee considered maintaining the current assessment rate of $0.05. However, leaving the assessment unchanged would generate excess revenue over the Committee's budgeted expenses for the 2022–23 and potentially cause reserve amounts to surpass the limits specified by the Order. Consequently, the Committee determined the assessment rate should be decreased to $0.03 per 7/10-bushel carton and the alternative rejected.

A review of historical information and preliminary information pertaining to the upcoming season indicates that the producer price for the 2022–23 season should be approximately $12.85 per 7/10-bushel carton or equivalent of oranges and grapefruit. The proposed assessment rate of $0.03 per 7/10-bushel carton or equivalent of oranges and grapefruit represents 0.23 percent of the $12.85 revenue for the 2022–23 fiscal period as a percentage of total producer revenue ($0.03 divided by $12.85 multiplied by 100).

This proposed rule would decrease the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers and may also reduce the burden on producers.

The Committee's meeting was widely publicized throughout the Texas citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 24, 2022, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189 Fruit Crops. No changes in those requirements would be necessary as a result of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Texas oranges and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to comment on this proposed rule. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service is proposing to amend 7 CFR part 906 as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ 1. The authority citation for 7 CFR part 906 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 906.235 is revised to read as follows:

§ 906.235 Assessment rate.

On and after August 1, 2022, an assessment rate of $0.03 per 7/10-bushel carton or equivalent is established for oranges and grapefruit grown in the Lower Rio Grande Valley in Texas.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–25123 Filed 11–17–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1474; Project Identifier MCAI–2022–00888–T]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. This proposed AD was prompted by reports from the supplier that sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill, which can result in an inability to detect hot bleed air leaks. This proposed AD would require testing of all affected overheat detection sensing elements of the bleed air leak detection system, and replacement if necessary. This proposed AD would also prohibit the installation of affected parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2023.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1474; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For service information identified in this NPRM, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* website *mhirj.com*.

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

FOR FURTHER INFORMATION CONTACT: Thomas Niczky, Aerospace Engineer, Avionics & Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7347; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1474; Project Identifier MCAI–2022–00888–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Thomas Niczky, Aerospace Engineer, Avionics & Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7347; email *9-avs-nyaco-cos@faa.gov.*

Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2022–16R1, dated July 5, 2022 (TCCA AD CF–2022–16R1) (also referred to after this as the MCAI), to correct an unsafe condition on Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. The MCAI states that MHI RJ Aviation ULC received reports from the supplier of the overheat detection sensing elements of a manufacturing quality escape. Some of the sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill, which can result in an inability to detect hot bleed air leaks and cause damage to surrounding structures and systems that can prevent continued safe flight and landing.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1474.

Related Service Information Under 1 CFR Part 51

The FAA reviewed MHI RJ Service Bulletin 601R–36–021, Revision D, dated May 25, 2022; including Appendix A, Revision B, dated March 14, 2022; and MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022; including Appendix A, Revision B, dated Mar 14, 2022; Appendix B, dated October 21, 2021; and Appendix C, dated March 14, 2022. This service information specifies procedures for testing affected bleed air leak detection system sensing elements (*i.e.,* those marked with a date code before ''A2105'' (which corresponds to January 31, 2021), with a part number defined in this service information) to determine if they are serviceable, and replacing failed sensing elements with serviceable ones. This service information also allows deferring the replacement of an affected part under certain conditions and allows operating the airplane with certain deactivated defective sensing elements. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described. This proposed AD would also prohibit the installation of affected parts.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,126 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Model	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Model CL–600–2B19 (526 airplanes)	29 work hours × $85 per hour = $2,465.	$0	$2,465	$1,296,590
Model CL–600–2C10 and CL–600–2C11, CL–600–2D15 and CL–600–2D24, and CL–600–2E25 (600 airplanes).	82 work hours × $85 per hour = $6,970.	0	6,970	4,182,000

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Model/serial No. (S/Ns)	Labor cost	Parts cost	Cost per product
CL–600–2B19, S/Ns 7002–7323	Up to 26 work-hours × $85 per hour = $2,210	Up to $113,200	Up to $115,410.
CL–600–2B19, S/Ns 7324–8113	Up to 24 work-hours × $85 per hour = $2,040	Up to $100,598	Up to $102,638.
CL–600–2C10 and CL–600–2C11, S/Ns 10002–10347.	Up to 54 work-hours × $85 per hour = $4,590	Up to $70,758	Up to $75,348.
CL–600–2D15 and CL–600–2D24, S/Ns 15001–15494.	Up to 58 work-hours × $85 per hour = $4,930	Up to $74,598	Up to $79,528.
CL–600–2E25, S/Ns 19001–19064	Up to 62 work-hours × $85 per hour = $5,270	Up to $81,478	Up to $86,748.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Docket No. FAA–2022–1474; Project Identifier MCAI–2022–00888–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC airplanes, certificated in any category, and identified in paragraphs (c)(1) through (4) of this AD.

(1) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, serial numbers 7002 through 7990 inclusive, and 8000 through 8113 inclusive.

(2) Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) and CL–600–2C11 (Regional Jet Series 550) airplanes, serial numbers 10002 through 10347 inclusive.

(3) Model CL–600–2D15 (Regional Jet Series 705) and Model CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15494 inclusive.

(4) Model CL–600–2E25 (Regional Jet Series 1000), serial numbers 19001 through 19064 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 36, Pneumatic.

(e) Unsafe Condition

This AD was prompted by reports that sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill. The FAA is issuing this AD to address insufficient salt fill, which can result in an inability to detect hot bleed air leaks, which can cause damage to surrounding structures and systems that can prevent continued safe flight and landing.

(f) Compliance

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

(g) Definitions

For the purposes of this AD, the definitions specified in paragraphs (g)(1) through (4) apply.

(1) *Group 1 airplanes:* The airplanes identified in paragraph (c)(1) of this AD.

(2) *Group 2 airplanes:* The airplanes identified in paragraphs (c)(2) through (4) of this AD.

(3) *Affected part:* A sensing element marked with a date code before A2105 and having a part number as defined in Section 1, Paragraph G(1), of MHI RJ Service Bulletin 601R–36–021, Revision D, dated May 25, 2022, for Group 1 airplanes, and in Appendix B, dated October 21, 2021, of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022, for Group 2 airplanes, unless the sensing element has been tested and found to be serviceable in accordance with paragraphs (g)(3)(i) and (ii) or paragraph (h) of this AD.

(i) Has been tested in accordance with Section 3 of the Accomplishment Instructions of Kidde Aerospace and Defense Service Bulletin CFD–26–5 and found to be serviceable; and

(ii) Has been marked on one face of its connector hex nut and is packaged in accordance with Section 3.C. of the Accomplishment Instructions—Identification Procedure of the Kidde Aerospace and Defense Service Bulletin CFD–26–5.

(4) *Serviceable part:* A sensing element that is not an affected part.

(h) Testing

Perform a test of the bleed air leak detection system sensing elements to determine if they are serviceable, in accordance with Section 2, Part A through Part F, of the Accomplishment Instructions of MHI RJ Service Bulletin 601R–36–021, Revision D, dated May 25, 2022, for Group 1 airplanes; and Section 2, Part A through Part M, of the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022, for Group 2 airplanes; within the applicable compliance time indicated in figure 1 to paragraph (h) of this AD.

Figure 1 to Paragraph (h)—Compliance Time

Airplanes	Applicable Service Bulletin Accomplishment Instructions	Compliance Time
Group 1	MHI RJ Service Bulletin 601R-36-021, Revision D, dated May 25, 2022, Part D	Within 4,400 flight hours or 24 months, whichever occurs first, after the effective date of this AD.
	MHI RJ Service Bulletin 601R-36-021, Revision D, dated May 25, 2022, Part A, Part B, Part C, Part E, and Part F	Within 6,600 flight hours or 36 months, whichever occurs first, after the effective date of this AD.
Group 2	MHI RJ Service Bulletin 670BA-36-025, Revision C, dated May 25, 2022, Part K	Within 8,400 flight hours or 48 months, whichever occurs first, after the effective date of this AD.
	MHI RJ Service Bulletin 670BA-36-025, Revision C, dated May 25, 2022, Part A, Part B, Part C, Part D, Part E, Part F, Part G, Part H, Part I, Part J, Part L, and Part M	Within 2,200 flight hours or 18 months, whichever occurs first, after the effective date of this AD.

(i) Replacement

(1) For Group 1 airplanes: If any sensing element is found not serviceable during the tests required by paragraph (h) of this AD, before further flight, replace the sensing element with a serviceable part in accordance with Section 2, Part A through Part F, as applicable, of the Accomplishment Instructions of MHI RJ Service Bulletin 601R–36–021, Revision D, dated May 25, 2022.

(2) For Group 2 airplanes: If any sensing element is found not serviceable during the tests required by paragraph (h) of this AD, before further flight, unless deferred in accordance with paragraph (j) of this AD, replace the sensing element with a serviceable part in accordance with Section 2, Part A through Part M, as applicable, of the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022.

(j) Deferred Replacement for Group 2 Airplanes

The replacement of an affected part with a serviceable part for Group 2 airplanes, as required by paragraph (i)(2) of this AD, may be deferred up to a maximum of 10 days under the conditions specified in paragraphs (j)(1) or (2) of this AD.

(1) A single bleed air leak detection loop (loop A or loop B) sensing element for a given Part (Part A through Part M of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022) is found not serviceable, provided that the conditions specified in paragraphs (j)(1)(i) through (iv) of this AD have been satisfied.

(i) The remaining operative bleed air leak detection loop (loop A or loop B) sensing elements have been tested and found to be serviceable in accordance with paragraph (h) of this AD.

(ii) The applicable maintenance procedures of Appendix C, dated March 14, 2022, of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022, to deactivate the defective sensing element are accomplished prior to operation of the airplane with the defective sensing element inoperative.

(iii) A placard has been installed on the BLEED AIR control panel in accordance with Section 2, Part A through Part M, as applicable, of the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022.

(iv) All flightcrew have been advised that the airplane is dispatched with one out of two bleed air leak detection loops inoperative.

(2) Both bleed air leak detection loop A and loop B sensing elements for a given part (Part A through Part M of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022) are found not serviceable, provided that the conditions specified in paragraphs (j)(2)(i) through (iv) of this AD have been satisfied.

(i) The applicable maintenance procedures of Appendix C, dated March 14, 2022, of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022, to deactivate the defective sensing elements are accomplished prior to operation of the airplane with the defective sensing elements inoperative.

(ii) The applicable instructions and limitations of the operator's existing FAA-approved Minimum Equipment List (MEL) item 36–21–06, sub-item 1, 2, or 3, as applicable, in accordance with Section 2, Part A through Part M, of the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022, are accomplished prior to operation of the airplane with the defective sensing elements inoperative.

(iii) A placard has been installed on the BLEED AIR control panel in accordance with Section 2, Part A through Part M, as applicable, of the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022.

(iv) All flightcrew have been advised that the airplane is dispatched with both bleed air leak detection loops inoperative.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install an affected part on any airplane.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (h), (i), and (j) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (l)(1) and (2) of this AD. For performing the actions specified in the service information for the Group 1 airplanes: If the sensing element was found not serviceable, replacement is required before further flight; deferred replacement of an affected part is prohibited. For performing the actions specified in the service information for the Group 2 airplanes: If the sensing element was found not serviceable, deferred replacement of the affected part is acceptable, as specified in paragraph (j) of this AD.

(1) For Group 1 airplanes:

(i) MHI RJ Service Bulletin 601R–36–021, dated July 5, 2021.

(ii) MHI RJ Service Bulletin 601R–36–021, Revision A, dated October 21, 2021.

(iii) MHI RJ Service Bulletin 601R–36–021, Revision B, dated December 2, 2021.

(iv) MHI RJ Service Bulletin 601R–36–021, Revision C, dated March 14, 2022.

(2) For Group 2 airplanes:

(i) MHI RJ Service Bulletin 670BA–36–025, dated July 5, 2021.

(ii) MHI RJ Service Bulletin 670BA–36–025, Revision A, dated October 21, 2021.

(iii) MHI RJ Service Bulletin 670BA–36–025, Revision B, dated March 14, 2022.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the New York ACO Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (n)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or MHI RJ Aviation ULC's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(n) Additional Information

(1) Refer to Transport Canada Civil Aviation (TCCA) AD CF–2022–16R1, dated July 5, 2022, for related information. This TCCA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1474.

(2) For more information about this AD, contact Thomas Niczky, Aerospace Engineer, Avionics & Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7347; email *9-avs-nyaco-cos@faa.gov.*

(o) Material Incorporated by Reference

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

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

(i) MHI RJ Service Bulletin 601R–36–021, Revision D, dated May 25, 2022.

(ii) MHI RJ Service Bulletin 670BA–36–025, Revision C, dated May 25, 2022.

(3) For service information identified in this AD, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* website *mhirj.com.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 9, 2022.

Christina Underwood,

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

[FR Doc. 2022–25117 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1473; Project Identifier MCAI–2022–00902–T]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020–21–20, which applies to certain Dassault Aviation Model FALCON 900EX airplanes. AD 2020–21–20 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and/or airworthiness limitations. Since the FAA issued AD 2020–21–20, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require the actions in AD 2020–21–20 and would require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2023.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–

30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1473; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at regulations.gov under Docket No. FAA–2022–1473.

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

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3226; email *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1473; Project Identifier MCAI–2022–00902–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3226; email *tom.rodriguez@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020–21–20, Amendment 39–21293 (85 FR 69144, November 2, 2020) (AD 2020–21–20), for certain Dassault Aviation Model FALCON 900EX airplanes. AD 2020–21–20 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2020–0117, dated May 20, 2020 (EASA AD 2020–0117) (which corresponds to FAA AD 2020–21–20), to correct an unsafe condition.

AD 2020–21–20 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and/or airworthiness limitations. The FAA issued AD 2020–21–20 to address among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane. AD 2020–21–20 specifies that accomplishing the actions required by paragraph (g) or (i) of that AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) for Dassault Aviation Model FALCON 900EX airplanes, serial number (S/N) 97 and S/Ns 120 and higher. This proposed AD would therefore continue to allow that terminating action.

Actions Since AD 2020–21–20 Was Issued

Since the FAA issued AD 2020–21–20, EASA superseded EASA AD 2020–0117 and issued EASA AD 2022–0141, dated July 7, 2022 (EASA AD 2022–0141) (referred to after this as the MCAI), for certain Dassault Aviation Model FALCON 900EX airplanes. The MCAI states that new or more restrictive airworthiness limitations have been developed.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after November 15, 2021 must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The FAA is proposing this AD to address, among other things, fatigue cracking and damage in principal structural elements. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1473.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022–0141. This service information specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2020–0117, dated May 20, 2020, which the Director of the Federal Register approved for incorporation by reference as of December 7, 2020 (85 FR 69144, November 2, 2020).

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop

in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2020–21–20. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2022–0141 already described, as proposed for incorporation by reference. Any differences with EASA AD 2022–0141 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (n)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the IBR of EASA AD 2020–0117 and incorporate EASA AD 2022–0141 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0141 and EASA AD 2020–0117 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0141 or EASA AD 2020–0117 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0141 or EASA AD 2020–0117. Service information required by EASA AD 2022–0141 and EASA AD 2020–0117 for compliance will be available at regulations.gov by searching for and locating Docket No. FAA–2022–1473 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 191 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2020–21–20 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–21–20, Amendment 39–21293 (85 FR 69144, November 2, 2020); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2022–1473; Project Identifier MCAI–2022–00902–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

(1) This AD replaces AD 2020–21–20, Amendment 39–21293 (85 FR 69144, November 2, 2020) (AD 2020–21–20).

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05).

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 900EX airplanes, serial number (S/N) 97 and S/Ns 120 and higher, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 15, 2021.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Terminating Action

This paragraph restates the requirements of paragraph (i) of AD 2020–21–20, with a new terminating action. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 2, 2019: Except as specified in paragraph (h) of this AD, comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0117, dated May 20, 2020 (EASA AD 2020–0117). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2020–0117 With No Changes

This paragraph restates the exceptions specified in paragraph (j) of AD 2020–21–20, with no changes.

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0117 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2020–0117 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (3) of EASA AD 2020–0117 within 90 days after December 7, 2020 (the effective date of AD 2020–21–20).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0117 is at the applicable ''associated thresholds'' specified in paragraph (3) of EASA AD 2020–0117, or within 90 days after December 7, 2020 (the effective date of AD 2020–21–20), whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2020–0117 do not apply to this AD.

(5) The ''Remarks'' section of EASA AD 2020–0117 does not apply to this AD.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (k) of AD 2020–21–20, with a new exception. Except as required by paragraph (j) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0117.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0141, dated July 7, 2022. Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2022–0141

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0141 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2022–0141 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0141 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0141, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0141 do not apply to this AD.

(5) The ''Remarks'' section of EASA AD 2022–0141 does not apply to this AD.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0141.

(m) Terminating Action for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (j) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model FALCON 900EX airplanes, S/N 97 and S/Ns 120 and higher only.

(n) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (o) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(o) Additional Information

For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3226; email *tom.rodriguez@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on [DATE 35 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2022–0141, dated July 7, 2022.

(ii) [Reserved]

(4) The following service information was approved for IBR on December 7, 2020 (85 FR 69144, November 2, 2020).

(i) European Union Aviation Safety Agency (EASA) AD 2020–0117, dated May 20, 2020.

(ii) [Reserved]

(5) For EASA ADs 2020–0117 and 2022–0141, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 9, 2022.

Christina Underwood,

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

[FR Doc. 2022–25112 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1477; Project Identifier MCAI–2022–00632–E]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Pratt & Whitney Canada Corp. (P&WC) PT6E–67XP model turboprop engines with serial number HP0194 and earlier. This proposed AD was prompted by multiple reports of engines failing to achieve required power (torque) during high power applications due to internal leaks in the bleed-off valves (BOVs). This proposed AD would require replacement of the compressor BOV assembly, replacement of the BOV orifice feed air tube assembly, and installation of a redesigned P3 probe snorkel, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 3, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1477; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material that is proposed for IBR in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663–3639; email: *AD-CN@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1477; Project Identifier MCAI–2022–00632–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2022–26, dated May 26, 2022 (Transport Canada AD CF–2022–26) (referred to after this as ''the MCAI''), to address an unsafe condition for P&WC PT6E–67XP model turboprop engines with serial number HP0194 and earlier. The MCAI states that there have been reports of multiple incidents in which engines were unable to achieve the required power (torque) during high power applications. A manufacturer

investigation found that contamination from the glass beads used in the manufacturing process during the gas generator casing (GGC) production caused internal leaks in the BOVs, preventing the BOVs from fully closing at high power settings. The FAA is issuing this AD to prevent internal leaks in the BOVs, and to prevent the failure of the engine to achieve the required power (torque) during high power applications.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1477.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Transport Canada AD CF–2022–26, which specifies procedures for the replacement of the compressor BOV assembly, replacement of the BOV orifice feed air tube assembly, and installation of a redesigned P3 probe snorkel.

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

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the Transport Canada AD above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2022–26, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between This Proposed AD and the MCAI.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and CAAs to use this process. As a result, the FAA proposes to incorporate by reference Transport Canada AD CF–2022–26 in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2022–26 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the Transport Canada AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''Compliance,'' compliance with this AD requirement is not limited to the section titled ''Corrective Actions'' in Transport Canada AD CF–2022–26. Service information required by the Transport Canada AD for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2022–1477 after the FAA final rule is published.

Differences Between This Proposed AD and the Transport Canada AD

Where Transport Canada AD CF–2022–26 refers to hours air time, this proposed AD requires using flight hours.

Where Transport Canada AD CF–2022–26 specifies compliance from its effective date, this proposed AD would require using the effective date of this proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 100 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace compressor BOV assembly	5 work-hours × $85 per hour = $425	$13,102	$13,527	$1,352,700
Replace BOV orifice feed air tube assembly with P3 probe snorkel and BOV orifice feed air tube assembly.	6 work-hours × $85 per hour = $510	22,000	22,510	2,251,000

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Pratt & Whitney Canada Corp.: Docket No. FAA–2022–1477; Project Identifier MCAI–2022–00632–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pratt & Whitney Canada Corp. (P&WC) PT6E–67XP model turboprop engines with serial number HP0194 and earlier, as identified in Transport Canada AD CF–2022–26, dated May 26, 2022 (Transport Canada AD CF–2022–26).

(d) Subject

Joint Aircraft Service Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by reports of multiple incidents in which engines were unable to achieve the required power (torque) during high power applications due to internal leaks in the bleed-off valves (BOVs) caused by glass bead contamination. The FAA is issuing this AD to prevent internal leaks in the BOVs, and to prevent the failure of the engine to achieve the required power (torque) during high power applications. The unsafe condition, if not addressed, could result in loss of thrust control and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, Transport Canada AD CF–2022–26.

(h) Exceptions to Transport Canada AD CF–2022–26

(1) Where Transport Canada AD CF–2022–26 refers to hours air time, this AD requires using flight hours.

(2) Where Transport Canada AD CF–2022–26 specifies compliance from its effective date, this AD requires using the effective date of this AD.

(i) No Reporting Requirement

Although the service information referenced in Transport Canada AD CF–2022–26 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2022–26, dated May 26, 2022.

(ii) [Reserved]

(3) For Transport Canada AD CF–2022–26, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663–3639; email: *AD-CN@tc.gc.ca;* website: *tc.canada.ca/en/aviation.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 10, 2022.

Christina Underwood,

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

[FR Doc. 2022–25019 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1421; Project Identifier MCAI–2022–01088–G]

RIN 2120–AA64

Airworthiness Directives; Stemme AG Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–01–09, which applies to certain Stemme AG Model Stemme S 10–VT and Model Stemme S 12 gliders. AD 2022–01–09 requires removing the affected freewheel clutch from service and prohibits the installation of affected parts. Since the FAA issued AD 2022–01–09, the European Union Aviation Safety Agency (EASA) superseded its mandatory continuing airworthiness information (MCAI) to amend the definition of an affected part. This proposed AD would retain the requirements of AD 2022–01–09 for removing the affected freewheel clutch from service and continue to prohibit the installation of an affected part, and would amend the definition of an affected part and clarify the part installation prohibition. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 3, 2023.

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

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

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–1421; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the MCAI, any comments received, and other

information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1421; Project Identifier MCAI–2022–01088–G'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–01–09, Amendment 39–21897 (87 FR 1666, January 12, 2022) (AD 2022–01–09), for all Stemme AG Model Stemme S 10–VT and Model Stemme S 12 gliders with a freewheel clutch part number (P/N) 12AK with a serial number starting with ''12-'' installed. AD 2022–01–09 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA Emergency AD 2021–0278–E, dated December 15, 2021 (EASA AD 2021–0278–E), to correct an unsafe condition identified as unintended slipping of the freewheel clutch with overheating (burnishing) of the friction pads inside of the clutch.

AD 2022–01–09 requires removing the affected freewheel clutch from service and prohibits installing an affected part on any glider. The FAA issued AD 2022–01–09 to address unintended slipping of the freewheel clutch with overheating (burnishing) of the friction pads inside of the clutch, which if not addressed, could result in a loss of thrust and consequent loss of glider control.

Actions Since AD 2022–01–09 Was Issued

Since the FAA issued AD 2022–01–09, EASA superseded EASA AD 2021–0278–E and issued EASA AD 2021–0278R1, dated August 11, 2022 (referred to after this as ''the MCAI''), to correct an unsafe condition on all Stemme AG Model Stemme S 10–VT and Stemme S 12 gliders. The MCAI states that the definition of affected part was amended to exclude certain modified and re-identified freewheel clutches.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2022–1421.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Proposed AD Requirements in this NPRM

This proposed AD would retain the requirements of AD 2022–01–09 for removing the affected freewheel clutch from service and continue to prohibit the installation of an affected part, and would amend the definition of an affected part and clarify the part installation prohibition.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 63 gliders of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove freewheel clutch from service	4 work-hours × $85 per hour = $340	$500	$840	$52,920

The new requirements of this proposed AD add no additional economic burden over that already required by AD 2022–01–09.

Authority for This Rulemaking

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

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

develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify that the proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2022–01–09, Amendment 39–21897 (87 FR 1666, January 12, 2022); and

■ b. Adding the following new airworthiness directive:

Stemme AG: Docket No. FAA–2022–1421; Project Identifier MCAI–2022–01088–G.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

This AD replaces AD 2022–01–09, Amendment 39–21897 (87 FR 1666, January 12, 2022).

(c) Applicability

This AD applies to Stemme AG Model Stemme S 10–VT and Model Stemme S 12 gliders, all serial numbers, certificated in any category, with a freewheel clutch having part number 12AK with a serial number starting with ''12-'' installed, except those which have been modified by following the instructions of Stemme Service Bulletin Doc. No. P062–980058, Revision 02, dated April 19, 2022, and have been re-identified with ''M'' at the end of the serial number.

(d) Subject

Joint Aircraft System Component (JASC) Code 7100, Powerplant System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as unintended slipping of the freewheel clutch with overheating (burnishing) of the friction pads inside of the clutch. The FAA is issuing this AD to ensure removal of the affected freewheel clutch from service. The unsafe condition, if not addressed, could result in a loss of thrust and consequent loss of glider control.

(f) Compliance

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

(g) Required Action and Compliance

(1) Before further flight after the effective date of this AD, remove the freewheel clutch from service.

(2) As of the effective date of this AD, do not install a freewheel clutch part number 12AK with a serial number starting with 201F;12-'' on any glider, unless it has been modified by following the instructions of Stemme Service Bulletin Doc. No. P062–980058, Revision 02, dated April 19, 2022, and has been re-identified with ''/M'' at the end of the serial number.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (i)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov*. If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. AMOCs approved for AD 2022–01–09 are approved as AMOCs for the corresponding provisions of this AD.

(i) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2021–0278R1, dated August 11, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1421.

(2) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov*.

(3) For service information identified in this AD that is not incorporated by reference, contact Stemme AG, Flugplatzstrasse F2, Nr. 6–7, D–15344 Strausberg, Germany; phone: +49 (0) 3341 3612–0; fax: +49 (0) 3341 3612–30; email: *airworthiness@stemme.de;* website: *stemme.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(j) Material Incorporated by Reference

None.

Issued on November 9, 2022.

Christina Underwood,

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

[FR Doc. 2022–25020 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1412; Project Identifier MCAI–2022–00805–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A300 B2K–3C, B2–203, B4–2C, and B4–203 airplanes. This proposed AD was prompted by a determination that internal system pollution can occur, most likely due to corroded unions in the pressurization lines, with an associated risk of contamination of the check valves. This proposed AD would require repetitive inspections (functional checks) of the pressurization of the hydraulic system reservoirs, and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR

11.43 and 11.45, by any of the following methods:

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1412; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website *atad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–1412.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1412; Project Identifier MCAI–2022–00805–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0116, dated June 21, 2022 (EASA AD 2022–0116) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A300 B2–203, A300 B2K–3C, A300 B4–203, A300 B4–2C, A300C4–203, and A300F4–203 airplanes. Model A300C4–203 and A300F4–203 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The MCAI states that internal system pollution can occur, most likely due to corroded unions at the pressurization lines, with an associated risk of contamination of the check valves. The three hydraulic system reservoirs are pressurized by air coming from the engine or the auxiliary power unit bleed air duct or from the ground connection. Air tightness of the pressurization system of the reservoirs is achieved by check valves that are located on the respective pressurization lines and on top of each hydraulic reservoir. The FAA is proposing this AD to address check valve contamination, which could lead to hydraulic reservoir pressurization issues and, if combined with an air pressurization line rupture, could lead to loss of hydraulic systems and possibly result in loss of control of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0116 specifies procedures for repetitive detailed inspections by performing functional checks for air leakage of the hydraulic system reservoirs and corrective actions. Corrective actions include a fault isolation to identify the source of depressurization and replacement of the check valves. EASA AD 2022–0116 also specifies procedures for reporting the inspection findings.

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

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2022–0116 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with

requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0116 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0116 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0116 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0116. Service information required by EASA AD 2022–0116 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2022–1412 after the FAA final rule is published.

Costs of Compliance

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
4 work-hours × $85 per hour = $340	$0	$340	$680
1 work-hour × $85 per hour = $85 (reporting)	0	85	170

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

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2022–1412; Project Identifier MCAI–2022–00805–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A300 B2K–3C, B2–203, B4–2C, and B4–203 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Unsafe Condition

This AD was prompted by a determination that internal system pollution can occur, most likely due to corroded unions at pressurization lines level, with an associated risk of contamination of the check valves. The FAA is issuing this AD to address check valve contamination, which could lead to hydraulic reservoir pressurization issues and, if combined with an air pressurization line rupture, could lead to loss of hydraulic systems and possibly result in loss of control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0116, dated June 21, 2022 (EASA AD 2022–0116).

(h) Exceptions to EASA AD 2022–0116

(1) Where EASA AD 2022–0116 refers to its effective date, this AD requires using the effective date of this AD.

(2) Paragraph (3) of EASA AD 2022–0116 specifies to report the first functional check (test) results to Airbus within a certain compliance time. For this AD, report the first functional check (test) results at the applicable time specified in paragraph (h)(2)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(3) The ''Remarks'' section of EASA AD 2022–0116 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

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

(j) Related Information

(1) For EASA AD 2022–0116, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website *atad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–1412.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

Issued on November 2, 2022.

Christina Underwood,

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

[FR Doc. 2022–24987 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1480; Project Identifier MCAI–2022–00548–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–100–1A10 airplanes. This proposed AD was prompted by reports of cracks found in the tailcone upper firewall where the auxiliary power unit (APU) muffler electrical bonding strap is attached. This proposed AD would require a detailed visual inspection of the tailcone upper firewall for defects, rework by replacement of the APU electrical bonding strap, and repair if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2023.

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

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

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–1480; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Yaser Osman, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1480; Project Identifier MCAI–2022–00548–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the

following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Yaser Osman, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2022–19, dated April 19, 2022 (TCCA AD CF–2022–19) (also referred to after this as the MCAI), to correct an unsafe condition on certain Bombardier, Inc., Model BD–100–1A10 airplanes. The MCAI states that cracks were found in the tailcone upper firewall where the APU muffler electrical bonding strap is attached. Crack initiation is related to the rigid electrical bonding strap. A crack in this area, if not addressed, could result in a breach of the firewall, which could allow a fire to propagate; reduced lightning strike protection, which could affect the airplane's grounding and potentially cause a fire; and increased radio interference during flight, which could reduce the ability of the flightcrew to maintain the safe flight and landing of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1480.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Bombardier Service Bulletin 100–53–35, dated December 6, 2021; and Service Bulletin 350–53–004, dated December 6, 2021. This service information specifies procedures for doing a detailed visual inspection of the tailcone upper firewall for defects including cracking, reworking the APU electrical bonding strap by replacing it with a new flexible APU muffler jumper cable assembly, and repairing the tailcone upper firewall. These documents are distinct since they apply to different airplane configurations.

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

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 691 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$36	$121	$83,611

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
24 work-hours × $85 per hour = $2,040	*$0	$2,040

*The FAA has received no definitive data on which to base the cost estimates for the parts specified in this proposed AD.

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and

procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2022–1480; Project Identifier MCAI–2022–00548–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category, serial numbers 20003 through 20500 inclusive and 20501 through 20916 inclusive.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of cracks found in the tailcone upper firewall where the auxiliary power unit (APU) muffler electrical bonding strap is attached. The FAA is issuing this AD to address cracking in the tailcone upper firewall. The unsafe condition, if not addressed, could result in a breach of the firewall, which could allow a fire to propagate; reduced lightning strike protection, which could affect the airplane's grounding and potentially cause a fire; and increased radio interference during flight, which could reduce the ability of the flightcrew to maintain the safe flight and landing of the airplane.

(f) Compliance

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

(g) Inspection, Replacement, and Corrective Actions

Within 48 months after the effective date of this AD: Do a detailed visual inspection of the tailcone upper firewall for defects including cracking, rework the APU electrical bonding strap by replacing with a new flexible APU muffler jumper cable assembly, and repair the tail cone upper firewall, as applicable, in accordance with paragraphs 2.B., 2.C., and 2.D., of the Accomplishment Instructions of the applicable service information specified in figure 1 to paragraph (g) of this AD. Do all applicable repairs before further flight.

Figure 1 to paragraph (g) – *Service Information*

Airplane Serial Number–	Bombardier Service Bulletin–
20003 through 20500 inclusive	100-53-35, dated December 6, 2021
20501 through 20916 inclusive	350-53-004, dated December 6, 2021

(h) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the New York ACO Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (i)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Additional Information

(1) Refer to TCCA AD CF–2022–19, dated April 19, 2022, for related information. This TCCA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1480.

(2) For more information about this AD, contact Yaser Osman, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD that is not incorporated by reference, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website bombardier.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(i) Bombardier Service Bulletin 100–53–35, dated December 6, 2021.

(ii) Bombardier Service Bulletin 350–53–004, dated December 6, 2021.

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 10, 2022.

Christina Underwood,

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

[FR Doc. 2022–25113 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1475; Project Identifier MCAI–2022–00823–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–06–02, which applies to all Airbus SAS Model A318–111, and –112 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2022–06–02 requires new repetitive inspections of the 80 view unit (80VU) rack lower lateral fittings, lower central support, upper fittings, central post, and shelves attachments for discrepancies, and corrective actions if necessary. This AD was prompted by a determination that the compliances times must be revised to address the unsafe condition. This proposed AD would continue to require the actions in AD 2022–06–02 with revised compliance times, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 3, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1475; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2022–1475.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1475; Project Identifier MCAI–2022–00823–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–06–02, Amendment 39–21968 (87 FR 16094, March 22, 2022) (AD 2022–06–02), for all Airbus SAS Model A318–111, and –112 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214,

–216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2022–06–02 requires new repetitive inspections of the 80VU rack lower lateral fittings, lower central support, upper fittings, central post, and shelves attachments for discrepancies, and corrective actions if necessary. The FAA issued AD 2022–06–02 to address damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane.

Actions Since AD 2022–06–02 Was Issued

Since the FAA issued AD 2022–06–02, it's been determined that the compliance times must be revised to address the unsafe condition.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0120R1, dated June 30, 2022 (EASA AD 2022–0120R1) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, A318–112, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232, A320–233, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports of damaged lower lateral fittings of the 80VU rack and a determination that the compliance times must be revised. The FAA is proposing this AD to address damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2022–06–02, this proposed AD would retain all of the requirements of AD 2022–06–02. Those requirements are referenced in EASA AD 2022–0120R1, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0120R1 specifies procedures for repetitive special detailed inspections of the 80VU rack lower lateral fittings, lower central support, upper fittings, central post, and shelves attachments for discrepancies (referred to as damaged, or parts not found in good condition in the service information) (including broken fittings, missing bolts, an electronics rack FIN 80VU that is in contact with structure, any bush that has migrated, burred material, and cracks), and corrective action if necessary. Corrective actions include modification, repair, and replacement. EASA AD 2022–0120R1 also describes procedures for reporting inspection results to Airbus.

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

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would retain all of the requirements of AD 2022–06–02. This proposed AD would require accomplishing the actions specified in EASA AD 2022–0120R1 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD. This proposed AD would also revise the compliance times.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0120R1 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0120R1 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0120R1 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0120R1. Service information required by EASA AD 2022–0120R1 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2022–1475 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,528 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2022-06-02	Up to 8 work-hours × $85 per hour = Up to $680.	$0	Up to $680	Up to $1,039,040.

* Table does not include estimated costs for reporting.

The FAA estimates that it would take about 1 work-hour per product to comply with the reporting requirement in this proposed AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $129,880, or $85 per product.

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Repair	122 work-hours × $85 per hour = $10,370	$4,150	$14,520.
Replacement	Up to 189 work-hours × $85 per hour = Up to $16,065	Up to $6,928	Up to $22,993.
Modification	189 work-hours × $85 per hour = $16,065	$7,407	$23,472.

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–06–02, Amendment 39–21968 (87 FR 16094, March 22, 2022); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2022–1475; Project Identifier MCAI–2022–00823–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2023.

(b) Affected ADs

This AD replaces AD 2022–06–02, Amendment 39–21968 (87 FR 16094, March 22, 2022) (AD 2022–06–02).

(c) Applicability

This AD applies to all Airbus SAS airplanes, certificated in any category, identified in paragraphs (c)(1) through (4) of this AD.

(1) Model A318–111 and –112 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of damaged lower lateral fittings of the 80VU rack and a determination that the compliance times must be revised. The FAA is issuing this AD to address damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0120R1, dated June 30, 2022 (EASA AD 2022–0120R1).

(h) Exceptions to EASA AD 2022–0120R1

(1) Where EASA AD 2022–0120R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2022–0120R1 refers to the effective date of EASA AD 2021–0172,

this AD requires using April 26, 2022 (the effective date of AD 2022–06–02).

(3) Where paragraph (2) of EASA AD 2022–0120R1 specifies ''any discrepancy,'' for this AD ''any discrepancy'' includes broken fittings, missing bolts, an electronics rack FIN 80VU that is in contact with structure, any bush that has migrated, burred material, and cracks.

(4) Where the service information referenced in EASA AD 2022–0120R1 specifies to ''replace the damaged parts with new parts,'' this AD allows replacing damaged parts with new or serviceable parts.

(5) The ''Remarks'' section of EASA AD 2022–0120R1 does not apply to this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the inspections and corrective actions required by paragraph (g) of this AD if those actions were accomplished prior to the effective date of this AD using Airbus Service Bulletin A320–25–1BKJ, Revision 02, dated April 9, 2020, with corrections referenced in the Airbus Technical Adaptation 80827186/024/2020, Issue 1, dated September 18, 2020.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

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

(k) Additional Information

(1) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(2) For Airbus service information identified in this AD that is not incorporated by reference, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* website airbus.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0120R1, dated June 30, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0120R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 9, 2022.

Christina Underwood,

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

[FR Doc. 2022–25114 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1478; Project Identifier MCAI–2022–00668–E]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2004–04–09, which applies to certain Pratt & Whitney Canada Corp. (P&WC) JT15D–1, JT15D–1A, and JT15D–1B model turbofan engines. AD 2004–04–09 requires a one-time borescope inspection (BSI) of the rear face of certain impellers for evidence of a machined groove or step, and repair or replacement of the impeller if a groove or step is found. Since the FAA issued AD 2004–04–09, the FAA was notified of an uncontained failure of an impeller installed on a P&WC JT15D–1A engine during takeoff and subsequent investigation by the manufacturer that discovered machining marks on the impeller. This proposed AD would require borescope fluorescent penetrant inspection (FPI) of the rear face of certain impellers for evidence of machining witness lines and, depending on the results of the inspection, replacement of the impeller, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 3, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1478 or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For material that is proposed for IBR in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663–3639; email: *AD-CN@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.*

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

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1478; Project Identifier MCAI–2022–00668–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2004–04–09, Amendment 39–13490 (69 FR 9520, March 1, 2004) (AD 2004–04–09), for certain P&WC JT15D–1, JT15D–1A, and JT15D–1B model turbofan engines. AD 2004–04–09 was prompted by three reports of uncontained failure of the impeller. AD 2004–04–09 requires a one-time borescope inspection of the rear face of certain impellers for evidence of a machined groove or step, and repair or replacement of the impeller if a groove or step is found. The FAA issued AD 2004–04–09 to prevent uncontained failure of the impeller and possible damage to the airplane.

Actions Since AD 2004–04–09 Was Issued

Since the FAA issued AD 2004–04–09, Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2022–27, dated June 2, 2022 (Transport Canada AD CF–2022–27), to address an unsafe condition for P&WC JT15D–1, JT15D–1A, and JT15D–1B model turbofan engines. The MCAI states that there has been one recent in-service event of a JT15D–1A engine uncontained failure during a takeoff roll of the airplane. An investigation by P&WC has determined that a crack originated from machining marks on the back face of the impeller and subsequently propagated until the impeller fractured. There is evidence that the event engine had been previously inspected in accordance with P&WC Service Bulletin (SB) No. JT15D–72–7590, dated May 23, 2003 (mandated by Transport Canada AD CF–2003–17, dated June 23, 2003), but it appears that the machining marks were not detected. P&WC, therefore, published P&WC SB JT15D–72–7655, Original Issue, dated April 14, 2022, to inspect the rear face of the impeller using a new borescope FPI procedure. As a result, Transport Canada issued AD CF–2022–27 to require accomplishment of the borescope FPI at the next hot section inspection until the impeller, part number (P/N) 3020365, is replaced at the next scheduled engine overhaul.

This proposed AD was prompted by three prior reports of uncontained failure of the impeller, and one additional recent report of an in-service uncontained failure event. The FAA is proposing this AD to address uncontained failure of the impeller. This condition, if not addressed, could result in fracture of the impeller, subsequent uncontained failure of the engine, and damage to the airplane. See Transport Canada AD CF–2022–27 for additional background information.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1478.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the Transport Canada AD. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Transport Canada AD CF–2022–27. Transport Canada AD CF–2022–27 specifies instructions for performing a one-time inspection of the rear face of the impeller and replacing the impeller if unacceptable machining witness lines or crack indications are found. Transport Canada AD CF–2022–27 also specifies instructions for replacing the impeller at the next scheduled engine overhaul.

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

Proposed AD Requirements in This NPRM

This proposed AD would retain none of the requirements of AD 2004–04–09. This proposed AD would require

accomplishing the actions specified in Transport Canada AD CF–2022–27, described previously.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and CAAs to use this process. As a result, the FAA proposes to incorporate by reference Transport Canada AD CF–2022–27 in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2022–27 in its entirety through that incorporation. Using common terms that are the same as the heading of a particular section in the Transport Canada AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''Compliance,'' compliance with this AD requirement is not limited to the section titled ''Corrective Actions'' in Transport Canada AD CF–2022–27. Service information required by the Transport Canada AD for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2022–1478 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 100 engines installed on airplanes of U.S. Registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect impeller	6 work-hours × $85 per hour = $510	$0	$510	$51,000
Replace impeller	30 work-hours × $85 per hour = $2,550	75,000	77,550	7,755,000

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2004–04–09, Amendment 39–13490 (69 FR 9520, March 1, 2004); and

■ b. Adding the following new airworthiness directive:

Pratt & Whitney Canada Corp.: Docket No. FAA–2022–1478; Project Identifier MCAI–2022–00668–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by January 3, 2023.

(b) Affected ADs

This AD replaces AD 2004–04–09, Amendment 39–13490 (69 FR 9520, March 1, 2004) (AD 2004–04–09).

(c) Applicability

This AD applies to Pratt & Whitney Canada Corp. JT15D–1, JT15D–1A, and JT15D–1B model turbofan engines as identified in Transport Canada AD CF–2022–27, dated June 2, 2022 (Transport Canada AD CF–2022–27).

(d) Subject

Joint Aircraft Service Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by three prior reports of uncontained failure of the impeller, and one additional recent report of an in-service uncontained failure event. The FAA is issuing this AD to prevent uncontained failure of the impeller. The unsafe condition, if not addressed, could result in fracture of the impeller, subsequent uncontained failure of the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, Transport Canada AD CF–2022–27.

(h) No Reporting Requirement

Although the service information referenced in Transport Canada AD CF–2022–27 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD,

if requested using the procedures found in § 39.19. In accordance with § 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD and email it to: *ANE-AD-AMOC@faa.gov.*

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

(j) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov*.

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2022–27, dated June 2, 2022.

(ii) [Reserved]

(3) For Transport Canada AD CF–2022–27, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663–3639; email: *AD-CN@tc.gc.ca;* website: *tc.canada.ca/en/aviation.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 10, 2022.

Christina Underwood,

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

[FR Doc. 2022–25016 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 221115–0239]

RIN 0625–AB23

Determining the Existence of a Particular Market Situation That Distorts Costs of Production

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: Enforcement and Compliance (E&C), of the Department of Commerce (Commerce), administers the antidumping duty (AD) and countervailing duty (CVD) AD/CVD trade remedy laws of the Tariff Act of 1930, as amended (the Act). Section 773(e) of the Act provides for Commerce to address, in its antidumping calculations, the existence of a particular market situation (PMS), such that the cost of materials and fabrication do not accurately reflect the cost of production in the ordinary course of trade. Commerce seeks public comments as it considers revisiting its PMS methodology and issuing a new regulation that would identify information that Commerce should take into consideration and should not take into consideration in determining whether a PMS exists that distorts the cost of production. Commerce also seeks comments as it considers adjustments to calculations when the amount of distortion in the cost of production caused by a PMS cannot be quantified based on the record before it.

DATES: Comments must be received no later than December 18, 2022.

ADDRESSES: Submit electronic comments only through the Federal eRulemaking Portal at *https://www.Regulations.gov*, Docket No. ITA–2022–0012. Comments may also be submitted by mail or hand delivery/courier, addressed to Lisa W. Wang, Assistant Secretary for Enforcement and Compliance, Room 18022, Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230. An appointment must be made in advance with the APO/Dockets Unit at (202) 482–4920 to submit comments in person by hand delivery or courier. All comments submitted during the comment period permitted by this document will be a matter of public record and will generally be available on the Federal eRulemaking Portal at *https://www.Regulations.gov*. Commerce will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive or protected information.

Any questions concerning the process for submitting comments should be submitted to Enforcement & Compliance Communications office at (202) 482–0063 or *ECCommunications@trade.gov*.

FOR FURTHER INFORMATION CONTACT: Scott McBride at (202) 482–6292 and Hendricks Valenzuela at (202) 482–4750.

SUPPLEMENTARY INFORMATION:

Background on Particular Market Situation

In 2015, pursuant to the Trade Preferences Extension Act (TPEA), section 771(15) of the Act was amended to provide that Commerce consider sales to be outside the ''ordinary course of trade'' when there are situations in which Commerce ''determines that the particular market situation prevents a proper comparison with the export price or constructed export price.'' Further, section 773(e) of the Act was amended to provide that in determining the ''costs of material and fabrication or other processing of any kind employed in producing the merchandise, during a period which would ordinarily permit the production of the merchandise in the ordinary course of trade,'' for determining constructed value, ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade,'' Commerce ''may use another calculation methodology under this subtitle or any other calculation methodology.'' The Act does not (1) define a particular market situation (''PMS''), (2) identify the information which Commerce should consider in determining the existence of a PMS that ''does not accurately reflect the costs of production in the ordinary course of trade,'' or (3) provide Commerce with guidance as to the information which Commerce should consider in determining if a market situation is, or is not, ''particular.''

The legislative history of the cost-based particular market situation reflects that Congress intended for Commerce to not only identify such situations, but to also effectively address them in its calculations. For example, in advocating for the TPEA language, one

member of the House of Representatives argued that the legislation would ''empower'' Commerce ''to be able to disregard prices or costs of inputs that foreign producers purchase if the Department of Commerce'' determined that those input values were ''subsidized'' or otherwise outside the ordinary course of trade.[1] Likewise, on the United States Senate floor, a Senator explained that the proposed legislation would ''guarantee that Americans can find a more level playing field as we compete in the world economy. . . .'' [2] The Senator emphasized that this legislation would help stop United States workers and manufacturers from ''being cheated'' by foreign industries that were not playing fair and ''illegally subsidizing'' the production of certain products.[3]

Since the Act was amended, Commerce has in certain instances identified a PMS and adjusted its calculations in response, which has been challenged before both the U.S. Court of International Trade and the U.S. Court of Appeals for the Federal Circuit (CAFC). One matter which has been at issue before the courts is the information Commerce should consider in determining the existence of a PMS. That matter came before the CAFC this past year in *Nexteel* v. *United States,* in which the CAFC held that Commerce's finding that a PMS existed in Korea during the period of review was unsupported by substantial evidence.[4] In analyzing Commerce's PMS determination, the CAFC appeared to reach at least four conclusions. First, a PMS which distorts costs, as referenced in the Act, must cause costs to deviate from what they would have otherwise been in the ordinary course of trade.[5] Second, a PMS must be particular to certain producers or exporters, inputs, or the market where the inputs are manufactured.[6] Third, if there is a claim of a subsidy or government interference, there should be evidence that the producer or seller of the input at issue received, or should have received, that subsidy or government assistance, and that there is some form of impact on the price of the input as a result of that subsidy or government interference.[7] Finally, Commerce is not required to quantify a distortion in costs by the PMS to find the existence of a PMS, but if Commerce is able to quantify the distortion, such a quantification may help support a finding of the existence of a PMS.[8]

In light of the CAFC's holding and analysis in *Nexteel,* as well as our experience in administering the PMS provision over the past several years, we have determined it is appropriate to revisit Commerce's approach in certain instances to analyzing and determining the existence of a PMS that distorts costs of production. In revisiting Commerce's approach, we have considered that the public and Commerce may benefit from the issuance of a regulation that addresses the information which Commerce should consider, or need not consider, in determining if a PMS exists that distorts costs of production. We also believe that a regulation that addresses the adjustments Commerce may make to its calculations if it determines the existence of a PMS that distorts costs of production might prove beneficial. We are therefore soliciting public comments on certain aspects of our PMS analysis pursuant to that exercise.

Request for Comments

We are issuing this advanced notice of proposed rulemaking to inform the public that Commerce is considering issuing a PMS regulation and to invite comments on that new regulation. Specifically, Commerce is inviting parties to provide comments on three issues: (1) identify information which they believe Commerce should consider in determining if a PMS exists which distorts the costs of production if that information is reasonably available and relevant to the PMS allegation; (2) identify information which they believe Commerce should not be required to consider when determining if a PMS exists, regardless of the PMS allegation; and (3) provide comments on adjustments which Commerce may make to its calculations when it determines the existence of a PMS, but the record before it does not allow for the quantification of cost distortions.

Dated: November 15, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–25216 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See* Congressional Record-House, H4666, H4690 (June 25, 2015).

[2] *See* Congressional Record-Senate, S2899, S2900 (May 14, 2015).

[3] *Id.*

[4] *See Nexteel Co.* v. *United States,* 28 F.4th 1226 (Fed. Cir. 2022).

[5] *Id.* at 1234.

[6] *Id.* at 1234, 1236.

[7] *Id.* at 1235–36.

[8] *Id.* at 1234.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO–P–2022–0008]

RIN 0651–AD60

Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: The United States Patent and Trademark Office (USPTO) is reopening the comment period for the proposed rule titled ''Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements'' that was published in the **Federal Register** on July 12, 2022. The proposed rule's comment period, which ended on September 12, 2022, is extended until December 2, 2022. In addition, the USPTO will treat as timely any comment that was received between September 12, 2022, and November 18, 2022.

DATES: The USPTO is reopening the comment period for the proposed rule that published at 87 FR 41267 on July 12, 2022, and that requested comments by July 12, 2022. Comments on this proposed rule must be received on or before December 2, 2022. The USPTO will also treat as timely any comments received between September 12, 2022, and November 18, 2022.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, enter docket number PTO–P–2022–0008 on the homepage and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this document and click on the ''Comment'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted as various file types, including Adobe® portable document format (PDF) and Microsoft Word® format. Because comments will be made available for public inspection, information the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing

comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below (at **FOR FURTHER INFORMATION CONTACT**) for special instructions.

FOR FURTHER INFORMATION CONTACT: Kery Fries, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7757. You can also send inquiries to *patentpractice@uspto.gov.*

SUPPLEMENTARY INFORMATION: On July 12, 2022, the USPTO published a proposed rule, ''Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements,'' to revise the rules of practice pertaining to patent term adjustment to require that the patent term adjustment statement regarding information disclosure statements be submitted on a USPTO form (87 FR 41267, July 12, 2022). After the comment deadline for the proposed rule closed, USPTO became aware of some continued stakeholder interest in submitting comments on the proposal. Therefore, the USPTO is reopening the written comment period for the proposed rule to ensure that all stakeholders have a sufficient opportunity to submit comments on the proposal. The USPTO will also treat as timely any comments received between the original comment period deadline of September 12, 2022, and November 18, 2022.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–25156 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–16–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3030

[Docket No. RM2020–5; Order No. 6325]

RIN 3211–AA27

Market Dominant Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes amendments to its regulations concerning rate incentives for Market Dominant products and republishes additional rules. The Commission invites public comment.

DATES: *Comments are due:* December 19, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Background
II. Basis for Proposed Rule Change
III. Proposed Rule

I. Background

In its general Market Dominant rate adjustment filings, the Postal Service routinely proposes to offer rate incentives in the form of promotions that reduce rates by providing discounts, rebates, or credits to participating mailers of certain types of mailpieces. Typically, such promotions are offered for several months during a particular calendar year for certain mailpieces in the First-Class Mail and USPS Marketing Mail classes. If the Commission approves, then the promotion may be offered again, with or without modifications, in the next calendar year. Each rate incentive offered by the Postal Service is either a rate of general applicability or a rate not of general applicability. A rate incentive of general applicability may be eligible for inclusion in the percentage change in rates calculation (provided that it satisfies all the applicable criteria under the Commission rules), which will allow for the Postal Service to generate price cap authority for the applicable class of mail. By contrast, a rate incentive not of general applicability is ineligible for inclusion in the percentage change in rates calculation; it may not be used to generate price cap authority for the applicable class of mail.

The Commission previously adopted regulations concerning rate incentives for Market Dominant products.[1] However, in connection with an appeal, the Commission stated that it would reconsider Order No. 5510 and that it ''does not intend to enforce Order No. 5510 during the reconsideration period.'' [2] Having reconsidered, the Commission proposes modifying certain of those rules as well as republishing and enforcing certain other of those rules.

II. Basis for Proposed Rule Change

The Commission proposes to clarify its rules by making one revision and by beginning to enforce two revisions that it made in Order No. 5510. First, the Commission proposes to amend § 3030.101(j) to clarify that to qualify as a rate of general applicability, a rate incentive cannot be based on historical mail volumes or prior participation in a rate incentive or promotion. Second, the Commission proposes to begin enforcing the changes that it made to § 3030.128(f)(2) in Order No. 5510 (including the additional criterion that a rate incentive must be made available to all mailers equally on the same terms and conditions to be eligible for inclusion in the percentage change in rates calculation). Third, the Commission proposes to begin enforcing the changes that it made to § 3030.123(j), including additional requirements intended to ensure that the Postal Service provides sufficient information at the outset of a Market Dominant rate adjustment proceeding.

The proposed revision of the definition of ''rate of general applicability'' in § 3030.101(j) is designed to clarify what rate incentives may qualify for inclusion in the percentage change in rates calculation as rates of general applicability. Under the Commission's existing rules ''[a] rate is not a rate of general applicability if eligibility for the rate is dependent on factors other than the characteristics of the mail to which the rate applies[.]'' 39 CFR 3030.101(j). A characteristic of the mail is a feature of the mail sent, not of the mailer sending the mail. Thus, the proposed rule adds an additional sentence to clarify that a rate incentive is not a rate of general applicability if eligibility for the rate is dependent in whole or in part on the volume of mail sent by a mailer in a past year or years or on the participation by a mailer in a rate incentive or promotion in a past year or years. Revising the Commission's definition of ''rate of general applicability'' will provide other benefits. These other benefits include promoting fairness, avoiding unharmonious situations in the application of the Commission's rules, limiting situations in which the Postal Service could obtain undue rate authority, and maintaining streamlined calculations.

The Commission also proposes republishing and beginning to enforce the requirement of § 3030.128(f)(2)(iv) that rate incentives included in the percentage change in rates calculation

[1] Docket No. RM2020–5, Order Adopting Final Rules Regarding Rate Incentives for Market Dominant Products, May 15, 2022 (Order No. 5510).

[2] Docket No. RM2020–5, Notice of Intent to Reconsider, August 26, 2020, at 2 (Order No. 5655); *see U.S. Postal Serv.* v. *Postal Reg. Comm'n,* Joint Motion for Voluntary Dismissal and Vacatur, No. 20–1208 (D.C. Cir. Sept. 11, 2020).

be ''available to all mailers equally on the same terms and conditions.'' Enforcing this provision will enhance fairness. The Postal Service has the pricing flexibility generally to set individual Market Dominant rate cells as it chooses, subject to the class-level application of the price cap. When a rate incentive is not made available to all mailers equally on the same terms and conditions, the discounts received by eligible mailers could be offset in part by higher rates paid by non-eligible mailers. This situation could lead to the non-eligible mailers effectively paying higher rates as a result of the rate incentive without having an opportunity to receive its benefits. Enforcing the requirement of § 3030.128(f)(2)(iv) that rate incentives included in the percentage change in rates calculation be ''available to all mailers equally on the same terms and conditions'' will prevent such situations from arising.

To clarify the specific information necessary to determine whether rate incentives should be included in the percentage change in rates calculation, the Commission proposes republishing and beginning to enforce the requirements for the contents of the Postal Service's notice of rate adjustment related to Market Dominant rate incentives. These more detailed initial filing requirements will require the Postal Service to provide sufficient information at the outset of a Market Dominant rate adjustment proceeding to ensure that any rate incentive included in a percentage change in rates calculation meets the criteria of § 3030.128(f)(2).

III. Proposed Rule

Proposed § 3030.101(j). Proposed § 3030.101(j) is revised to state clearly that the definition of ''rate of general applicability'' within the context of a Market Dominant rate adjustment proceeding does not include a rate incentive that is dependent on the volume of mail sent by a mailer in a past year or years or the participation by a mailer in a rate incentive or promotion in a past year or years.

Current § 3030.123(j). Current § 3030.123(j) is republished to identify clearly what information the Postal Service must file to support its claim that a rate incentive meets the necessary criteria to be included in a percentage change in rates calculation. Current § 3030.123(j) will be enforced in its entirety.

Current § 3030.128(f)(2)(iv). Current § 3010.128(f)(2)(iv) is republished to include a criterion for a Market Dominant rate incentive to be included in a percentage change in rates calculation that the incentive be available to all mailers equally on the same terms and conditions. Current § 3010.128(f)(2)(iv) will be enforced in its entirety.

List of Subjects in 39 CFR Part 3030

Administrative practice and procedure, Postal Service.

For the reasons stated in the preamble, the Commission proposes to amend chapter III of title 39 of the Code of the Federal Regulations as follows:

PART 3030—REGULATION OF RATES FOR MARKET DOMINANT PRODUCTS

■ 1. The authority citation for part 3030 continues to read as follows:

Authority: 39 U.S.C. 503; 3622.

■ 2. Amend § 3030.101 by revising paragraph (j) to read as follows:

§ 3030.101 Definitions.

* * * * *

(j) *Rate of general applicability* means a rate applicable to all mail meeting standards established by the Mail Classification Schedule, the Domestic Mail Manual, and the International Mail Manual. A rate is not a rate of general applicability if eligibility for the rate is dependent on factors other than the characteristics of the mail to which the rate applies. A rate incentive is not a rate of general applicability if eligibility for the rate is wholly or partially dependent on the volume of mail sent by a mailer in a past year or years or on the participation by a mailer in a rate incentive or promotion in a past year or years. A rate is not a rate of general applicability if it benefits a single mailer. A rate that is only available upon the written agreement of both the Postal Service and a mailer, a group of mailers, or a foreign postal operator is not a rate of general applicability.

* * * * *

■ 3. Republish § 3030.123 paragraph (j) to read as follows:

§ 3030.123 Supporting technical documentation.

* * * * *

(j) Whenever the Postal Service includes a rate incentive with its planned rate adjustment, it must include with its filing:

(1) Whether the rate incentive is being treated under § 3030.128(f)(2) or under § 3030.128(f)(1) and (g);

(2) If the Postal Service seeks to include the rate incentive in the calculation of the percentage change in rates under § 3030.128(f)(2), whether the rate incentive is available to all mailers equally on the same terms and conditions; and

(3) If the Postal Service seeks to include the rate incentive in the calculation of the percentage change in rates under § 3030.128(f)(2), sufficient information to demonstrate that the rate incentive is a rate of general applicability, which at a minimum includes: The terms and conditions of the rate incentive; the factors that determine eligibility for the rate incentive; a statement that affirms that the rate incentive will not benefit a single mailer; and a statement that affirms that the rate incentive is not only available upon the written agreement of both the Postal Service and a mailer, or group of mailers, or a foreign postal operator.

* * * * *

■ 4. Republish § 3030.128 paragraph (f)(2) to read as follows:

§ 3030.128 Calculation of percentage change in rates.

* * * * *

(f) * * *

(2) A rate incentive may be included in a percentage change in rates calculation if it meets the following criteria:

(i) The rate incentive is in the form of a discount or can be easily translated into a discount;

(ii) Sufficient billing determinants are available for the rate incentive to be included in the percentage change in rate calculation for the class, which may be adjusted based on known mail characteristics or historical volume data (as opposed to forecasts of mailer behavior);

(iii) The rate incentive is a rate of general applicability; and

(iv) The rate incentive is made available to all mailers equally on the same terms and conditions.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–25157 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–FW–P

Notices

Federal Register
Vol. 87, No. 222
Friday, November 18, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–FTPP–22–0077]

Information Collection Renewal for Country of Origin Labeling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval, from the Office of Management and Budget, for an extension of and revision to the currently approved information collection for Country of Origin Labeling.

DATES: Comments on this notice must be received by January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments concerning this notice by using the electronic process available at *https://www.regulations.gov*. Comments may also be filed with the Docket Clerk, 1400 Independence Ave. SW, Room 2069-South, Washington, DC 20250; Fax: (202) 260–8369. All comments should reference the docket number AMS–FTPP–22–0077, the date, and the page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be posted without change, including any personal information provided, at *https://www.regulations.gov* and will be included in the record and made available to the public.

FOR FURTHER INFORMATION CONTACT: Kenneth Becker, Branch Chief of Research and Rulemaking, Food Disclosure and Labeling Division, Agricultural Marketing Service, U.S. Department of Agriculture; Telephone (202) 720–4486, Email: *kenneth.becker@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Information Collection Renewal for Country of Origin Labeling.

OMB Number: 0581–0250.

Expiration Date of Approval: March 31, 2023.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The 2002 (Pub. L. 107–171) and 2008 (Pub. L. 110–234), Farm Bills and the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of muscle cuts and ground lamb, chicken, and goat meat; wild and farm-raised fish and shellfish; perishable agricultural commodities; peanuts, pecans, and macadamia nuts; and ginseng. An interim final rule for mandatory Country of Origin Labeling (COOL) for fish and shellfish became effective on April 4, 2005. An interim final rule for the remaining covered commodities became effective on September 30, 2008. On January 15, 2009, a final rule was published for all covered commodities which became effective March 16, 2009. On May 23, 2013, a final rule was published to amend the definition of retailer and labeling requirements for meat muscle cut commodities derived from animals slaughtered in the United States. With the Consolidated Appropriations Act, 2016, Congress amended the Agricultural Marketing Act of 1946 to remove muscle cut beef and pork, and ground beef and pork commodities from COOL requirements. On March 2, 2016, AMS issued a final rule to remove mandatory COOL requirements for beef, pork, ground beef and ground pork to conform with the statute. Mandatory COOL requirements remain in full force and effect for all remaining covered commodities. Enforcement activities have been conducted since 2006 utilizing cooperative agreements established with State agencies as authorized by the statute. The previously approved information collection request expires on March 31, 2023.

Estimate of Burden: Public reporting burden for recordkeeping storage and maintenance is estimated to average 56.9 hours per response.

Recordkeepers: Importers, food manufacturers, and food retailers.

Estimated Number of Recordkeepers: 349,598.

Estimated Total Annual Responses: 349,598.

Estimated Number of Responses per Recordkeeper: 1.

Estimated Total Annual Burden on Respondents: 19,879,947.

Comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be submitted using the electronic process available at *https://www.regulations.gov.* All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–25079 Filed 11–17–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–SC–22–0047]

Pecans Grown in Multiple States; Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this

notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved information collection for Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas, Marketing Order No. 986.

DATES: Comments on this notice must be received by January 17, 2023.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice. Comments must be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *https://www.regulations.gov.* Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *https://www.regulations.gov.* All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made available to the public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Pushpa Kathir, Market Development Division, Specialty Crop Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone:(202) 720–2491 Fax:(202) 720–8938, or Email: *Pushpa.Kathir@usda.gov.*

Small businesses may request information on this notice by contacting Richard Lower, Assistant to the Director, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Room 1406–S, Washington, DC, 20250–0237; Telephone (202) 720–2491; Fax: (202) 720–8938; or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Pecans Grown in Multiple States, Marketing Order No. 986.

OMB Number: 0581–0291.

Expiration Date of Approval: December 31, 2022

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruits, vegetables, and specialty crops, in a specified production area, to work together to solve marketing problems that cannot be solved individually. Marketing order regulations help ensure adequate supplies of high-quality product and adequate returns to producers. Marketing orders are authorized by the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601–674). The Secretary of Agriculture oversees these operations and issues regulations recommended by a committee of representatives from the respective commodity industry.

The purpose of this notice is to solicit public comments on the 14 forms in this OMB package which are described below. Two ballot forms for committee nominations (SC–307 and SC–308), two grower and sheller nomination forms (SC–309 and SC–310) as well as two background and acceptance statements forms for growers and shellers and public members (SC–8 and SC–9) and a grower referendum ballot (SC–313). Two Marketing Agreements (SC–242 and SC–242A) are also included. In addition, this package includes five reporting forms the American Pecan Council uses to track shipments and inventory. The Summary Report/U.S. Pecans Received for Your Account (Form 1); Pecans Purchased Outside of the United States (Form 2); Exports by Country of Destination (Form 3); Annual Agreement of Inter-Handler Transfer (Form 4); and Year-End Inventory Report(Form 5). The number of producers has changed from 2,500 to 4,380 since the last renewal. Now that the marketing order has been in place for a few years, the industry has a better understanding of the actual numbers of producers in the industry.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.3 hours per response (rounded).

Respondents: Pecan producers, handlers, shellers and public members.

Estimated Number of Respondents: 4,512.

Estimated Total Annual of Responses: 5,225.

Estimated Number of Responses per Respondent: 1.2 (rounded).

Estimated Total Annual Burden on Respondents: 1,587 (rounded).

Comments are invited on: (1) Whether the proposed collection of the information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–25076 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 19, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to

the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program Employment and Training Program Performance Measurement, Monitoring and Reporting Requirements.

OMB Control Number: 0584–0614.

Summary of Collection: This is an extension, without change, of a currently approved collection. In accordance with Section 16(h)(5) of the Food and Nutrition Act (FNA), as amended by section 4022 of the Agriculture Act of 2014, and 7 CFR 273.7(c)(17) the Department requires that State agencies report outcome data for the Supplemental Nutrition Employment Program (SNAP) Employment and Training (E&T) programs. In order for FNS to monitor the effectiveness of E&T programs State agencies are required to report outcome data on five separate reporting measures: (1) the number and percentage of E&T participants who retain employment 2 quarters and 4 quarters after completing E&T; (2) the median wages for participants with earnings 2 quarters after completion of E&T; (3) the number and percentage of participants that completed a training, education, work experience or on-the-job training component; (4) certain unique characteristics of SNAP E&T participants; and (5) additional reporting requirements for State agencies that pledge to serve all at-risk Able-bodied Adults without Dependents (ABAWDs). State agencies are also required to identify appropriate reporting measures for each proposed component that serves a threshold number of participants of at least 100 a year. State agencies identify the reporting measures for these components in State agencies' E&T plans and report the outcome data to the Food and Nutrition Service (FNS) through State agencies' annual reports. State agencies are required to report outcome data annually.

Need and Use of the Information: With this information, FNS is able to identify more, and less, successful E&T practices and provide technical assistance to State agencies to improve their E&T programs.

Description of Respondents: State, Local, or Tribal Governments.

Number of Respondents: 53.

Frequency of Responses: Reporting; annually.

Total Burden Hours: 9,459.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–25146 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 19, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Emergency Relief Program (ERP) Phase 1.

OMB Control Number: 0560–0309.

Summary of Collection: The Extending Government Funding and Delivering Emergency Assistance Act, (Division B, Title I, Pub. L. 117–43) provided $10,000,000,000 for necessary expenses related to losses of crops (including milk, on-farm stored commodities, crops prevented from planting in 2020 and 2021, and harvested adulterated wine grapes), trees, bushes, and vines, as a consequence of droughts, wildfires, hurricanes, floods, derechos, excessive heat, winter storms, freeze, including a polar vortex, smoke exposure, quality losses of crops, and excessive moisture occurring in calendar years 2020 and 2021. USDA has directed FSA to use part of this funding to provide assistance to producers of eligible crop, tree, bush, and vine losses through ERP.

ERP Phase 1 will use a streamlined application process for losses for which data is already on file with FSA and RMA. Producers will certify on the application that the loss was due, in whole or in part, to a qualifying disaster event and indicate that they agree to obtain crop insurance or NAP coverage for the next two available crop years, which is a statutory requirement for payment eligibility.

Need and Use of the Information: The information submitted by respondents will be used by FSA to determine eligibility and issue payments to eligible applicants under ERP.

Applicants complete the following forms to apply for ERP payments:

FSA–520, Emergency Relief Program (ERP) Phase 1 Application;

AD–2047, Customer Data Worksheet;

CCC–901, Member Information for Legal Entities;

CCC–902, Farm Operating Plan;

AD–1026 Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) Certification PRA for any FSA programs but is included in the burden hours for information;

Form CCC–860, Socially Disadvantaged, Limited Resource, Beginning and Veteran Farmer or Rancher Certification; and

Form FSA–510, Request for an Exception to the $125,000 Payment Limitation for Certain Programs.

Failure to solicit applications will result in failure to provide payments to eligible applicants as intended by the Extending Government Funding and Delivering Emergency Assistance Act.

Description of Respondents: Farms.

Number of Respondents: 305,000.

Frequency of Responses: Reporting; On Occasion.

Total Burden Hours: 92,310.

Farm Service Agency

Title: Commodity Container Assistance Program (CCAP).

OMB Control Number: 0560–0310.

Summary of Collection: Applicants will receive payments under section 5(e) of the CCC Charter Act (15 U.S.C. 714c(e)) to assist owners of U.S. agricultural products with ongoing market disruptions and facilitate the recovery of shipping and other logistical services required to bring domestically produced agricultural products to their markets.

The CCAP payments continues to be issued after an applicant certifies, as applicable, the number of containers picked up or stored each month or group of months at the designated port. The applicant must certify to the total number of containers picked up or stored by January 31, 2023. If any supporting documentation is requested, the documentation must be submitted to FSA within 30 days from the request.

Need and Use of the Information: To determine whether an applicant is eligible for a CAWA payment, an applicant is required to submit:

- FSA–862, Commodity Container Assistance Program Application that includes applicant information, SAM UEI, and number of containers by port, type, and month.
- If requested by FSA, the applicant must provide supporting documentation to verify the accuracy of information provided on the application, including to substantiate the number and type of shipping containers, ownership of the commodities, or authority to act as a designated marketing agent.

If the eligible participants fail to apply, FSA will result in failure to provide payments to eligible applicants as intended.

Description of Respondents: Farms.

Number of Respondents: 200.

Frequency of Responses: Reporting; On Occasion.

Total Burden Hours: 528.

Farm Service Agency

Title: Food Safety Certification for Specialty Crops Program (FSCSC).

OMB Control Number: 0560–0311.

Summary of Collection: The Farm Service Agency (FSA) is issuing payments under the Coronavirus Aid, Relief, and Economic Stability (CARES) Act of up to $200 million to assist eligible specialty crop operations with on-farm food safety certification and related expenses. The development, implementation, and maintenance of on-farm food safety programs resulted in unforeseen costs for many specialty crop operations who sought alternate markets for their products during the pandemic, as demand from traditional markets such as restaurants and food service diminished or disappeared.

Need and Use of the Information: In order to determine whether a producer is eligible for FSCSC and to calculate a payment, an applicant is required to submit form FSA–888, Food Safety Certification for Specialty Crops Program (FSCSC). Applicants must also have the following forms on file with FSA: AD–2047, Customer Data Worksheet, and SF–3881, ACH Vendor/Miscellaneous Payment Enrollment Form.

The information submitted by respondents are used by FSA to determine eligibility and issue payments to eligible applicants under FSCSC.

Failure to solicit applications will result in failure to provide payments to eligible applicants as intended by the CARES Act.

Description of Respondents: Farms.

Number of Respondents: 22,000.

Frequency of Responses: Reporting; On Occasion.

Total Burden Hours: 25,652.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–25143 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 19, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function

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Food Safety and Inspection Service

Title: Electronic Import Inspection.

OMB Control Number: 0583–0159.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U. S.C. 601 et. seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et. seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031). These statues mandate that FSIS protect the public by verifying that meat and poultry products are safe, wholesome, and properly labeled and packaged.

Need and Use of the Information: FSIS requires foreign governments to submit additional information when submitting both the foreign establishment certificate and the foreign inspection certificate to FSIS for foreign establishments to be permitted to import product to the United States. The information that is required with the Foreign Establishment Certificate includes: the type of operation(s) conducted at the establishment (*e.g.,* slaughter, processing, storage, exporting warehouse); the establishment's eligibility status (*e.g.,* new or relisted (if previously delisted)); and, slaughter and processing establishment certifications that address the species and type of product(s) produced at the establishment and the process category.

Additional information that is required with the Foreign Inspection Certificate includes: the species used to produce the product and the source country and foreign establishment number; whether the source materials originate from a country other than the exporting country; the product's description, including the process category, the product category, and the product group; the address of the consignor; the address of the consignee; the name and address of the exporter; the name and address of the importer;

and, any additional information the Administrator requests to determine whether the product is eligible to be imported into the U.S.

To conduct the information collections less frequently would inhibit the ability of FSIS to ensure that imported product is safe, wholesome, and not adulterated.

Description of Respondents: Business or other for-profit.

Number of Respondents: 939.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Annually.

Total Burden Hours: 49,385.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–25171 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID FSA–2022–0015]

Information Collection Request; Organic Certification Cost Share Program

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a current information collection request associated with the Organic Certification Cost Share Program (OCCSP). OCCSP provides cost share assistance to producers and handlers of agricultural products who are obtaining or renewing their certification under the National Organic Program (NOP). Certified operations may receive up to 50 percent of their certification costs paid, up to a maximum of $500 for each of the following scopes: crops, wild crops, livestock, processing/handling, and State organic program fees. Certain State agencies also submit applications to FSA to administer OCCSP in their States.

DATES: We will consider comments that we receive by January 17, 2023.

ADDRESSES: We invite you to submit comments on the notice. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://regulations.gov* and search for docket ID FSA–2022–0015. Follow the online instructions for submitting comments.
- *Mail:* Farm Service Agency, USDA, Chris Vazquez, 1400 Independence Avenue, Mail Stop 0517, SW, Washington, DC 20250–0517.

Comments will be available for inspection online at *http://www.regulations.gov*. Copies of the information collection may be requested by contacting Chris Vazquez (see **FOR FURTHER INFORMATION CONTACT** below). You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Chris Vazquez, (202) 690–0013; email: *christopher.vazquez@usda.gov*. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Description of Information Collection Request

Title: Organic Certification Cost Share Program.

OMB Number: 0560–0289.

Expiration Date of Approval: 04/30/2023.

Type of Request: Extension.

Abstract: FSA is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection request associated with OCCSP. Producers and handlers will apply for cost share payments, and State Agencies will establish agreements to get funds and to disburse payments to qualified producers or handlers.

There are no changes to the burden hours since the last OMB approval. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses hours multiplied by the estimated total annual responses.

Estimate of Annual Burden: Public reporting burden for this collection of information is estimated to average 1.0015 hours per response.

Type of Respondents: Individuals, and State.

Estimated Number of Respondents: 15,565.

Estimated Annual Number of Responses per Respondent: 5.0455.

Estimated Total Annual of Responses: 78,533.

Estimated Average Time per Responses: 1.0015 hours.

Estimated Total Annual Burden on Respondents: 78,650 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected;

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice, including names and addresses when provided, will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

William Marlow,

Acting Administrator, Farm Service Agency.

[FR Doc. 2022–25086 Filed 11–17–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2010–0023]

Expansion of FSIS Shiga Toxin-Producing Escherichia coli (STEC) Testing to Additional Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that on February 1, 2023, the Agency will expand its routine verification testing for six Shiga toxin-producing *Escherichia coli* that are adulterants (non-O157 STEC; O26, O45, O103, O111, O121, or O145), in addition to the adulterant *Escherichia coli* (*E. coli*) O157:H7, to ground beef, bench trim, and other raw ground beef components in addition to raw beef manufacturing trimmings in official establishments. The raw ground beef components to be tested for these six non-O157 STEC, hereafter ''other raw ground beef components,'' are: head meat, cheek meat, weasand (esophagus) meat, product from advanced meat recovery (AMR) systems, partially defatted

chopped beef and partially defatted beef fatty tissue, low temperature rendered lean finely textured beef, and heart meat. Currently, FSIS tests only its beef manufacturing trimmings samples for these six non-O157 STEC and *E. coli* O157:H7. Otherwise, all other raw beef products are tested only for *E. coli* O157:H7 and *Salmonella.* FSIS also will begin testing for these non-O157 STEC in ground beef samples that it collects at retail stores and in applicable samples it collects of imported raw beef products. Additionally, FSIS is responding to comments regarding the STEC testing expansion and the costs and benefits analysis (CBA), as well as its updated STEC laboratory testing criteria for determining whether a result is positive.

DATES: Beginning February 1, 2023, FSIS will implement routine verification testing for the six additional STECs discussed in this document (O26, O45, O103, O111, O121, and O145) in raw ground beef, bench trim, and other raw ground beef components. At this time, FSIS also will implement testing for these non-O157 STEC in ground beef samples that it collects at retail stores and in applicable samples it collects of imported raw beef products.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2020, FSIS announced in the **Federal Register** its plans to expand its routine verification testing for six non-O157 STEC (O26, O45, O103, O111, O121, or O145) that are adulterants in applicable raw beef products, in addition to the adulterant *E. coli* O157:H7, to ground beef, bench trim, and other raw ground beef components for samples collected at official establishments (85 FR 34397). FSIS also announced that it would test for these non-O157 STEC in ground beef samples that it collects at retail stores and in applicable samples it collects of imported raw beef products. FSIS stated that it would announce the date for implementation of the new testing in a subsequent **Federal Register** notice. Additionally, FSIS responded to comments on the November 19, 2014, **Federal Register** notice titled, ''Shiga Toxin-Producing *Escherichia coli* (STEC) in Certain Raw Beef Products (79 FR 68843).'' FSIS also made available its updated CBA on the implementation of its non-O157 STEC testing on raw beef manufacturing trimmings and the costs and benefits associated with the expansion of its non-O157 STEC testing to ground beef, bench trim, and other raw ground beef components.[1]

Recent Changes to FSIS' Laboratory Testing Criteria for Determining Positives

On April 16, 2021, FSIS announced in the *Constituent Update* changes to the laboratory testing criteria for *E. coli* O157:H7.[2] FSIS explained that it had fully aligned the testing criteria for *E. coli* O157:H7 with that for non-O157 STEC. FSIS also explained that identifying specific bacterial genes associated with human illness is important for detecting STECs in food. Under the updated method, consistent with laboratory testing for non-O157 STEC, an *E. coli* O157:H7 isolate is confirmed positive if it has a *stx* gene, an *eae* gene, and is identified by the laboratory as O157. Further, under the new method, FSIS no longer performs H7 gene testing for certain O157:H7 isolates. Harmonizing STEC laboratory testing creates a more efficient FSIS laboratory workflow where all regulated STECs are treated the same from initial laboratory screening to full isolate characterization. This update did not affect current FSIS laboratory protocols leading to the reporting of potential and presumptive positive results. To implement this change, FSIS updated the Microbiology Laboratory Guidebook (MLG) Chapter 5C, ''*Detection, Isolation, and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STECs) from Meat Products and Carcass and Environmental Sponges,*'' [3] and began using the updated STEC method on samples received on or after May 17, 2021.

Aligning the criteria for identifying positives for the top seven STECs of public health interest does not affect FSIS' public health priorities, will not require establishments, or public health partners, or equivalent countries that ship beef to the United States to change their existing STEC laboratory methods that met the previous two separate STEC definitions, and may facilitate commercial test kit technology development.

Implementation

Currently, the only raw beef products FSIS routinely tests for non-O157 STEC are beef manufacturing trimmings. On February 1, 2023, FSIS plans to implement its expansion of its routine verification testing for the six non-O157 STEC that are adulterants to ground beef, bench trim, and other raw ground beef components for samples collected at official establishments. Once FSIS expands its non-O157 sampling to all raw beef products, for any positive results during routine verification testing, FSIS will conduct follow-up testing. FSIS will analyze all follow-up samples for all seven adulterant STEC and *Salmonella.*

Responses to Comments

In response to a request from multiple industry associations for more time to submit comments on the June 4, 2020 **Federal Register** notice, FSIS extended the comment period by an additional 30 days to September 3, 2020.[4] FSIS received 10 comments. Specifically, FSIS received comments from a small establishment owner and an industry organization opposed to the expanded testing; while a food industry group, a consumer group coalition, and a college organization supported the expansion of testing. A foreign country and a laboratory testing representative also commented on the proposal. Two comments were outside the scope of this document.

In response to comments, FSIS added clarification on the new laboratory method, and a new table showing the additional cost of the expansion; but made no fundamental changes to the CBA. The Agency still plans to expand STEC testing to ground beef, bench trim, and other raw ground beef components. A summary of the issues raised by commenters and the Agency's responses follows.

Cost and Benefits Analysis

Comment: An industry organization stated that the Agency did not adequately explain how it calculated an annual savings of $51.6 million from reduced non-O157 STEC outbreak-related recalls. Also, the commenter stated that the Agency did not provide data to support that the proposal will prevent two outbreak-related recalls per year because, according to the commenter, there were only a few non-O157 STEC outbreak-related recalls before 2012 and they are still rare.

The industry organization argued that FSIS' contention in the CBA that detection can prevent recalls does not include supporting data. According to the commenter, the Agency started

[1] The CBA is available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf.*

[2] *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-16-2021.*

[3] *https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/MLG-5C.01.pdf.*

[4] *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-june-19-2020.*

testing beef manufacturing trimmings for non-O157 STECs in 2012; therefore, FSIS should compare the number of non-O157 STEC outbreak related recalls before and after implementing this testing program to determine whether the theory has merit.

Response: In the 2020 CBA, FSIS explained how it determined that the proposed policy was likely to prevent, on average, two recalls per year at an estimated cost of $25.6 million per recall. It described the reasoning in detail in section 3.b ''Benefits from reduced outbreak-related recalls'' and section 4 ''Net benefit'' (pp. 19–23). FSIS clarified that the estimate was based on Public Health Information System (PHIS) data related to non-O157 STEC contamination and prevalence (*i.e.,* Agency sampling data), not solely on the historical number of non-O157 STEC outbreak-related recalls.

Before 2012, FSIS did not routinely test raw beef products for non-O157 STEC, so it is not possible to make the proposed comparison between the number of recalls associated with beef products contaminated with non-O157 STEC versus recalls caused by *E. coli* O157:H7. The first non-O157 STEC investigation that led to a recall of ground beef product in the U.S. occurred in 2010. Once the Agency began testing for non-O157 STEC in raw beef manufacturing trimmings, the Agency prevented contaminated raw beef products from entering commerce. Beginning February 8, 2013, FSIS began to withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received (77 FR 73401). A substantial number of recalls (93 recalls) of raw beef products adulterated with STEC occurred between August 2012 and December 2020. Of these recalls approximately 20.0 percent (19 recalls) were caused by non-O157 STEC. Six of the 19 recalls were a result of outbreak investigations and seven were from routine FSIS verification testing. The remaining six recalls were results of: establishment-product testing (four), Agricultural Marketing Service (AMS) testing (one), and a notification from U.S. Food and Drug Administration (FDA) about contaminated flour used to produce a USDA regulated product (one).

As is stated above, currently, the only raw beef products FSIS routinely tests for non-O157 STEC are beef manufacturing trimmings. However, of the 19 non-O157 STEC recalls, 15 of them involved raw non-intact and ground beef products containing non-O157 STEC. Five of the 15 beef products recalled occurred as a result of FSIS routine and follow-up sampling of beef manufacturing trimmings and follow-up sampling verification programs. FSIS may have detected the other ten if FSIS had sampled the product through a routine verification sampling project. Analysis of the Agency's historical testing data indicates that the number of beef manufacturing trimming samples positive for non-O157 STEC (0.71 percent) exceeded samples positive for *E. coli* O157:H7 (0.23 percent). Therefore, other beef samples subject to FSIS testing for *E. coli* O157:H7 may contain non-O157 STEC. As such, we believe it is reasonable to derive the estimate of prevented outbreak-related recalls from the detected prevalence of the pathogen.

Comment: An industry organization commented that the proposed expansion would not contribute to overall lower numbers of positive non-O157 test results. The commenter stated that there have been only two outbreaks of non-O157 STEC attributed to raw beef products since 2006 that resulted in recalls. In the same timeframe, the commenter stated that there have been eight *E. coli* O157:H7 outbreaks. In addition, the commenter stated that from 2006 to present, there have been 129 recalls for O157, compared to 20 for non-O157 STEC. Finally, the commenter stated that the vast majority of recalls for STEC are not associated with illnesses, because the presence of the pathogen is only part of the equation. Virulence, consumer health, handling, and preparation all play a part.

Response: The STEC pathogen must be present for an individual to show symptoms of the disease caused by that pathogen. FSIS has previously determined that raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, that are contaminated with STEC are adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011). Virulence, consumer health, handling, and preparation may play a part in causing illness, but the key point is that the pathogen must be present.

Between August 2012 and December 2020 approximately 45 million pounds of contaminated raw beef products were prevented from entering commerce by FSIS because of STEC adulteration. Over this timeframe, FSIS tested a total of 167,073 raw beef samples for *E. coli* O157:H7 and 220 (0.13 percent) of these samples were positive. Analysis of the data tested for O157:H7 and non-O157 STEC by FSIS between August 2012 and December 2020 showed that non-O157 STEC were more frequently recovered from verification beef manufacturing trimming samples.

Specifically, FSIS tested 44,457 samples over the same timeframe as above. See table 1 below for the percent of positive samples for the different STEC.

TABLE 1—PERCENT OF POSITIVE SAMPLES IN VARIOUS SEROGROUPS

Serogroup	Percent of positive samples
Non-O157	.71
O103	.42
O157:H7	.23
O26	.15
O111	.11
O145	.022
O45	.020
O121	.016

FSIS raw beef verification testing has been effective in helping to protect the public by detecting *E. coli* O157:H7 and non-O157 STEC adulterants and preventing these products from entering commerce.

As mentioned, in response to a previous comment, between August 2012 and December 2020, there were 19 recalls of FSIS regulated products that were caused by adulteration of product by non-O157 STEC serogroups. These recalls show that non-O157 STEC can be present in products intended for commerce and represents a threat to public health.

According to the CDC, the number of culture-confirmed illnesses caused by non-O157 STEC have increased, and outpaced illnesses caused by O157:H7 STEC.[5] Surveillance data presented by the CDC revealed that the percentage change in incidence of STEC infections in 2019 compared with the annual average incidence from 2016 to 2018 showed that O157:H7 decreased by 20 percent and non-O157 STEC increased by 35 percent.

Comment: An industry organization commented that the CBA relies on the outdated 2013 *Pathogen Controls in Beef Operations Survey* to evaluate the potential costs from expanded industry sampling in response to the proposal. According to the commenter, this survey may not accurately represent industry sampling practices, and, therefore, costs to industry may be underestimated due to outdated data. The commenter stated that the Agency should conduct an updated survey, with specific questions related to the proposal, and update the CBA before

[5] Ibid.

finalizing any changes to its STEC sampling program.

Response: FSIS does not require industry testing for STEC. Under the Hazard Analysis and Critical Control Point (HACCP) regulations, the establishment is required to identify the intended use of the product (9 CFR 417.2(a)(2)), conduct the hazard analysis (9 CFR 417.2(a)), determine the hazard(s) reasonably likely to occur (9 CFR 417.2(a)(1)), and support the decision(s)made (9 CFR 417.5(a)(1)). Also, all establishments are required to conduct on-going verification activities to ensure that their HACCP plans are effectively implemented (9 CFR 417.4(a)(2)). Establishments are required to conduct ongoing verification activities to ensure that any critical control point (CCP) is adequately addressing STEC, or that purchase specifications continue to prevent the pathogen from entering the facility. FSIS recommends that establishments' verification activities include testing for STEC (67 FR 62325, 62331).

Lastly, the HACCP regulations in 9 CFR part 417 require that establishments validate the HACCP plan's adequacy to control the food safety hazards identified by the hazard analysis (9 CFR 417.4(a)). These regulations prescribe requirements for the initial validation of an establishment's HACCP plan and require that establishments ''conduct activities designed to determine that the HACCP plan is functioning as intended.'' Validation under 9 CFR 417.4(a)(1) requires that establishments assemble two types of data: (1) The scientific or technical support for the judgments made in designing the HACCP system, and (2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support. Thus, validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis (80 FR 27557).

In 2012, FSIS explained in a **Federal Register** notice (77 FR 31979) how *E. coli* O157:H7 results can be used for non-O157 STEC HACCP decision-making. FSIS considers controls for *E. coli* O157:H7 to be effective against non-O157 STEC when implemented appropriately (85 FR 34397). How each establishment designs and supports their unique HACCP system can vary, and in-plant testing may or may not be conducted. When employed, testing can be conducted for different reasons, including to establish microbiological independence between lots, fulfill customer purchase specifications for specific products, validate HACCP controls, verify the HACCP system is functioning as intended, or other reasons. The frequency of sampling, products sampled, lot size, sampling method used, and laboratory testing methodology can vary from establishment to establishment based on the purpose sampling serves in each establishment's HACCP system.

In 2013, FSIS conducted a survey of industry practices of STEC controls to evaluate the potential costs to industry of expanding sampling in response to the 2012 change. Since that survey in 2013, the above HACCP requirements have not changed, the Agency's method of verification has not changed, and the Agency's policy regarding the use of *E. coli* O157:H7 as an indicator for STEC has not changed. Though an establishment may conduct STEC testing for a variety of reasons as noted above, FSIS does not have reason to believe the data obtained in the 2013 survey is no longer reliable nor indicative (on the aggregate) of industry practices. Further, innovations in testing methodology have since occurred that can reduce the costs of STEC analysis (see Section of Recent Changes to FSIS' Laboratory Method (85 FR 34397, 34399)). If FSIS assumes establishments do not adopt these cost-saving innovations, the results of the 2013 survey remain valid for cost estimations.

In response to the comments regarding the use of *E. coli* O157:H7 testing results for non-O157 STEC decision-making, under HACCP, establishments may be able to support using a single STEC serogroup (*e.g., E. coli* O157:H7) as an ''indicator'' of all STEC as one component for demonstrating overall process control over STEC. If this approach is used, the decision-making for how *E. coli* O157:H7 results indicate control over non-O157 STEC is to be included in the hazard analysis and appropriately supported. Testing for *E. coli* O157:H7 as an indicator of STEC control may be acceptable for validation, verification, and process control because often the same controls address all STEC.

However, as explained in the **Federal Register** notice referenced above, both *E. coli* O157:H7 and non-O157 STECs occur in raw beef at low levels and at low prevalence, and positive tests for these pathogens are not likely to be highly correlated. For this reason, testing for a single STEC serogroup alone cannot serve as an ''index'' organism for any other STEC, meaning an *E. coli* O157:H7 result alone does not provide direct evidence about the actual presence or absence of any other STEC serogroups in a specific lot. If an establishment produces 2 lots of product from the same source material and if one lot is positive for a non-O157 STEC serogroup, then an *E. coli* O157:H7 negative test in the second lot of product would not be sufficient to show microbiological independence even with additional process control information. Such microbiological independence determination would include consideration of numerous other factors, including commonalities in the source materials used, sanitation practices employed, antimicrobial interventions applied, any process control information, other sample results, and illness reports. *E. coli* O157:H7 testing results alone are not sufficient evidence for microbiological independence following a non-O157 positive.

In addressing corrective actions after a positive STEC result, FSIS personnel are to consider the impact one or more non-O157 STEC positives may have on the adequacy of the HACCP system to control STEC but should not automatically expect establishments to begin non-O157 STEC testing. When a product tests positive for non-O157 STEC, it is important for the establishment to recognize that even though the *E. coli* O157:H7 results and other processing CCP records may indicate process control was maintained, identification of non-O157 STEC contamination in the production process questions whether design or implementation of the establishment's unique food safety system is sufficient to control STEC. In response to one or more non-O157 STEC positives, establishments must ensure any additional testing conducted includes non-O157 as part of the validation, verification, and reassessment requirements of 9 CFR 417.4 and supporting documentation requirements of 9 CFR 417.5(a)(1), until the establishment is able to demonstrate control over STEC in their unique HACCP system, or the HACCP system may be deemed inadequate (9 CFR 417.6). For example, it is particularly important in veal establishments to demonstrate control over STEC because FSIS data and other peer-reviewed research shows a higher incidence of

non-O157 STEC as compared to *E. coli* O157:H7.[6]

Comment: An industry organization stated that after FSIS starts testing for non-O157 STEC in additional raw beef products, AMS will likely similarly expand its purchase program requirements as it has done in the past in response to FSIS sampling programs, which could increase industry costs.

Response: AMS has a Federal Purchase Program and vendors that choose to participate in that program must comply with AMS's requirements, including any testing requirements. The requirements of AMS's Federal Purchase Program are outside the scope of this **Federal Register** notice about FSIS' non-O157 STEC testing program.

Response to Positive Test Result

Comment: An industry organization commented that the proposal should not affect practices that have proven successful in the industry's continued improvement on STEC control. These practices have predominantly applied to beef manufacturing trimmings but should be accepted for any additional products that FSIS samples and tests when it implements expanded testing.

Response: If an establishment uses the same controls for STEC on beef manufacturing trimmings as it does on its other raw beef products, even if the other raw beef products were not slaughtered on-site, it should be able to support the decisions made in the use of such controls. How each establishment designs and supports their HACCP system may vary depending on the establishment and its hazard analysis, HACCP plan and the decisions made to support them.

Comment: A consumer group and a college organization commented that they did not support the use of *E. coli* O157:H7 testing results for non-O157 STEC decision-making and encouraged FSIS to amend its instructions to inspection personnel to require establishment non-O157 STEC testing to the same degree as *E. coli* O157:H7 testing. However, an industry organization's comments did support using *E. coli* O157:H7 testing results for non-O157 STEC process control decision-making.

Additionally, an industry organization commented that the Agency and industry must appropriately understand and respond to positive STEC results, regardless of the serovar.

Response: FSIS does not require industry testing for STEC. Under the Hazard Analysis and Critical Control Point (HACCP) regulations, the establishment is required to identify the intended use (9 CFR 417.2(a)(2)), conduct the hazard analysis (9 CFR 417.2(a)), determine the hazard(s) reasonably likely to occur (9 CFR 417.2(a)(1)), and support the decision(s)-made (9 CFR 417.5(a)(1)). To be clear: this notice announces the expansion of non-O157 STEC testing by FSIS when it conducts routine verification testing. It does not impose testing requirements on industry.

As is stated above, FSIS considers controls for *E. coli* O157:H7 to be effective against non-O157 STEC when implemented appropriately (85 FR 34397). As mentioned above, in 2012, FSIS explained in a **Federal Register** notice (77 FR 31979) how *E. coli* O157:H7 results can be used for non-O157 STEC HACCP decision-making.

International

Comment: A foreign government questioned whether FSIS would provide a reasonable interval between the publication of the final **Federal Register** notice and when foreign countries would be required to implement new testing for non-O157 STEC.

Response: After FSIS expands its non-O157 STEC verification sampling and testing, FSIS will require foreign countries that ship beef product to the United States to implement equivalent government verification testing for non-O157 STEC in the same products included in FSIS' new expanded verification testing program. FSIS acknowledges that foreign countries will need additional time to implement changes to their testing requirements and to provide applicable supporting documentation. FSIS will continue to use the existing equivalence process[7] to ensure that foreign countries implement a government microbiological sampling and testing program equivalent to FSIS' verification testing program for raw beef products within a reasonable time period. In addition, FSIS will begin testing imported ground beef, bench trim, and other raw ground beef components for non-O157 STEC at the same time as FSIS implements its domestic non-O157 STEC testing program (*i.e.,* on this notice's effective date).

Test Only for Other Raw Ground Beef Components at Slaughter

Comment: Two industry organizations commented that FSIS should only expand testing to other raw ground beef components produced in slaughter establishments because STEC are introduced, and therefore most effectively controlled, at slaughter. Also, conducting the testing at slaughter establishments allows establishments to identify positive product before it enters commerce. The commenters argued that testing other raw ground beef components for non-O157 STEC at slaughter would prevent recalls and allow establishments to address the underlying cause at the source.

The commenters also stated that sampling and testing at further processing establishments makes it more difficult to identify the cause of the positive result and may increase the amount of product implicated in a recall. Also, according to the commenters, sampling ground beef does not provide feedback to either the processing establishments or slaughter establishments on process control. The commenters stated that the Agency should not include ground beef in the Agency's expanded non-O157 STEC testing.

Also, one commenter disagreed with the Agency's argument that by sampling bench trim, the Agency is verifying the product is not adulterated before it is ground. The commenter argued that instead of sampling for non-O157 STEC, FSIS should consider verification tasks at grinding establishments to ensure they maintain effective programs, such as purchase specifications or validated antimicrobial interventions.

Response: FSIS agrees that slaughter establishments are in the best position to prevent non-O157 STEC contamination because the introduction of the contaminant to the exterior surface of beef products can occur during the slaughter and dressing operation. However, processing establishments that receive product for grinding also have an important role in addressing non-O157 STEC. As explained above, the HACCP regulations require establishments to conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur in their processes and to identify the preventive measures they can apply to control those hazards in the production of particular products (see 9 CFR 417.2(a)). Consistent with the HACCP regulations, processing establishments can control or reduce non-O157 STEC to below detectable levels by using preventive measures, including validated antimicrobial interventions. Processing establishments can also establish as a preventive measure a purchase specification that requires suppliers to provide source materials with no detectable STEC.

[6] *https://ask.usda.gov/s/article/When-an-establishment-only-conducts-product-testing-for-E-coli-what-factors-does-the-establi.*

[7] *https://www.fsis.usda.gov/inspection/import-export/equivalence.*

Processing establishments can then verify that these control measures are working as intended through their own product testing (*see* 67 FR 62325).

As stated earlier in the document, currently, the only raw beef products routinely tested for non-O157 STEC by the Agency are beef manufacturing trimmings, and beef manufacturing trimmings are produced at the slaughter establishment. However, of the 19 non-O157 STEC recalls, 15 of them were a result of raw non-intact and ground beef products containing non-O157 STEC. These 15 recalls support that expansion of routine non-O157 testing to other raw beef products, such as ground beef and other raw ground beef components, is necessary so that adulterated products do not reach the consumer.

Testing Based on Production Volume

Comment: An industry organization commented that FSIS should conduct sampling and testing for non-O157 STEC in applicable product in all establishments, regardless of production volume, for at least one year, and then FSIS should evaluate the data to determine whether continued sampling is warranted. This approach would allow additional components to be tested for non-O157 STECs at all establishment sizes for all products used as components for ground beef.

Response: Currently, per FSIS Directive 10,010.1, all establishments that produce raw beef products are subject to FSIS sampling and testing for STEC and *Salmonella,* regardless of establishment size. Consistent with the sampling frequency set in the directive, FSIS will sample each establishment that produces raw ground beef products at least three times per year. FSIS also samples establishments that produce bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product. FSIS will continue to assess results and make necessary changes to its sampling and testing program. However, FSIS anticipates that it will continue this sampling and testing on an ongoing basis beyond one year of sampling and testing.

Testing Methods

Comment: One individual commented that STEC testing is much more sensitive than *E. coli* O157:H7 testing. The commenter stated that the STEC test is a presence or absence test that will show positive results with just a couple of cells. The commenter also stated that test results showing low numbers for Aerobic Plate Count (APC) and generic *E. coli* would also test positive for STEC.

Response: As discussed earlier in the document, FSIS updated its laboratory method in 2019 to use a single, combined workflow to screen samples for the presence of *E. coli* O157:H7 and the six non-O157 STEC that FSIS considers adulterants (O26, O45, O103, O111, O121, or O145). The technology used for screening samples allows all seven STEC serogroups to be screened identically. FSIS utilizes the following performance criteria and definitions when evaluating the suitability of an alternative laboratory method for a given analyte and sampling matrix pair: [8]

- Sensitivity of 90 percent or greater,
- Specificity of 90 percent or greater,
- Accuracy of 90 percent or greater,
- Positive Predictive Value of 90 percent or greater, and
- Negative Predictive Value of 90 percent or greater. FSIS' internal verification work during the selection of new technologies in 2018 found a sensitivity of 92 percent in STEC samples inoculated with approximately 1 CFU in a 325g sample for that technology.[9] The manufacturer determined the average limit of detection (LOD_{50}) of the iQ-Check STEC VIrX and SerO II method was 0.7 (range: 0.4–1.2) CFU/sample for O157 and other adulterant STEC.[10] There is no difference in sensitivity for *E. coli* O157 and other non-O157 adulterant STEC serogroups. Additional information for using this method may be found in Chapter 5C of the MLG and associated appendices.[11]

Testing Results

Comment: An industry organization commented that follow-up sampling conducted by the Agency in response to an *E. coli* O157:H7 positive in products only subject to *E. coli* O157:H7 testing should continue to be tested for all STEC, but the results should not be included in baseline and routine verification data (prevalence). According to the commenter, the Agency also incorrectly included follow-up sampling as part of the aggregated prevalence data in the proposed expansion of products tested for STEC. The commenter noted that FSIS previously reported follow-up sampling independently from routine sampling data and, according to the commenter, should consistently do so moving forward. According to the commenter, follow-up samples should never be included in overall prevalence calculations of O157 or non-O157 STEC. According to the commenter, follow-up sampling is conducted in response to a positive sampling result, which may indicate issues with process control at that establishment and can therefore skew the data.

Response: FSIS collects follow-up samples as a result of a positive from a routine verification sample. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC. As mentioned above, once FSIS expands its non-O157 sampling to all raw beef products, FSIS will analyze all follow-up samples for all 7 adulterant STEC and *Salmonella.* FSIS posts the follow-up sampling results separately on its website.

When calculating prevalence, FSIS does not use follow-up sampling in its prevalence calculations. Also, FSIS does not typically use follow-up samples in its baseline studies.

Reallocating Resources

Comment: Two organizations commented that the Agency should explain its reasoning for changing its allocation of resources for sampling STECs. According to the commenters, the Agency intends to sample once per week in higher volume establishments, a slight increase from four samples per month, by reallocating resources from lower-volume establishments. The commenters argued that the slight increase will likely not cause significant issues in high volume establishments, but there is not enough information about the reallocation to understand the potential impact of decreased sampling at lower volume establishments. The commenters argued that the shift in sampling may represent a significant reduction or elimination of sampling in lower volume establishments. According to the commenters, the data should be analyzed by volume to determine whether a decrease in sampling frequency at lower volume establishments will inhibit the Agency from identifying establishments that may have issues with STEC control.

A college organization noted that diverting current testing resources from lower-volume establishments will result in extending the time required for determining establishment performance, potentially increasing the risk of contaminated products entering the marketplace. According to the commenter, until FSIS has demonstrated that reallocating samples

[8] MLG 1.01- *https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/MLG-1.01_0.pdf.*

[9] *https://www.fsis.usda.gov/sites/default/files/media_file/2021-09/Molecular-Screen-Evaluation-2018-White-Paper.pdf.*

[10] *https://www.bio-rad.com/sites/default/files/2021-08/Bulletin_3213.pdf.*

[11] *https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/MLG-5C.01.pdf.*

among beef processors will not negatively impact public health, the Agency should focus on requesting additional resources from Congress for sampling and laboratory testing. The commenter encouraged FSIS to consider how microbial distribution within a product and/or false-positive test results may affect Agency verification results.

Response: FSIS may address allocating resources for sampling in a future **Federal Register** document, but FSIS believes the Agency has sufficient resources to conduct sampling and testing for STEC, ensuring that the nation's commercial supply of raw beef products, whether domestic or imported, is safe, wholesome and unadulterated.

After implementation, the Agency may adjust the numbers of samples collected and tested +/− by approximately 10 percent. FSIS has a set minimum sampling frequency for each establishment. FSIS will sample each establishment that produces raw ground beef products at least three times per year. FSIS also samples establishments that produce bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product.

Sampling Methodology

Comment: An industry organization noted that FSIS is evaluating alternatives to its sampling procedures (*e.g.,* assessing sampling using a surface swabbing with a cloth vs. N60 incision sampling). According to the commenter, methodology often has a significant impact on baseline results, which are used to inform the public health decisions of local, state, and federal bodies and other private entities, and support Agency decisions. The commenter argued that the Agency should conduct a short-term, targeted baseline sampling program after a change in methodology and make the new information public with explanations. According to the commenter, this approach will help provide context to preclude public uncertainty if prevalence seemingly increases because the new methodology increases sensitivity and detectability.

Additionally, the same commenter argued that potential changes to sampling methodology for pathogen sampling should be available for public comment. According to the commenter, the industry and other interested parties need time to consider impacts of the new methodology and provide information to the Agency to inform its decision-making. Also, an industry association and an individual commented that FSIS should continue to explore rapid and accurate methods to test for all pathogens of concern. One commenter encouraged FSIS to continue to work with industry and academia to develop rapid tests using the latest technology available to identify STEC and other pathogens in FSIS regulated products.

Response: FSIS continues to update its laboratory criteria and posts changes to its laboratory method in the MLG Chapter 5C titled ''*Detection, Isolation, and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STECs) from Meat Products and Carcass and Environmental.*'' FSIS also usually announces these changes in the *Constituent Update.*

FSIS recognizes the importance of keeping abreast of the latest scientific endeavors as well as its role in promoting research in areas important to the FSIS mission. FSIS food safety research priorities [12] are presented as suggestions for researchers interested in pursuing food safety objectives that are relevant to FSIS regulated products. This list of research areas of interest may be useful to researchers who are preparing grants for submission to agencies that fund food safety research (*e.g.,* USDA National Institute of Food and Agriculture (*https://www.nifa.usda.gov*), National Institutes of Health (*https://www.nih.gov/*), *Grants.gov* (*https://www.grants.gov*), or researchers with resources to conduct such research. In 2021 FSIS added a study titled, ''Develop a method to detect Shiga toxin-producing *Escherichia coli* (STEC) based on virulence factors,'' to the Food Safety Research Priority list.

As mentioned in its June 4, 2020 **Federal Register** notice (85 FR 34397), FSIS is conducting an in-field surface sampling study to determine the feasibility of a non-destructive surface sample collection method to collect raw beef manufacturing trimmings verification samples. FSIS will announce any changes to the sample collection method for the beef manufacturing trimmings project in a future **Federal Register** notice.

Data for Agency Policy

Comment: An industry organization commented that FSIS should use relevant scientific data for Agency policy. Specifically, the aggregated data by calendar year publicly available on FSIS' website incorrectly includes sample results from multiple slaughter classes of cattle, different sampling categories, and is not appropriately stratified. In the aggregated data, the commenter stated that the Agency does not separate samples attributed to different slaughter classes of cattle, such as veal. The commenter stated that different slaughter classes of cattle have varying risks of O157 and non-O157 STEC contamination, and FSIS should evaluate the risk of these different slaughter classes separately.

Response: In the discussion regarding aggregated data, FSIS stated the sampling results from FSIS verification testing programs includes data from veal establishments and follow-up sampling results.[13] Using aggregated sampling results is appropriate because FSIS is not proposing any changes to sampling allocations by slaughter class as part of the lab testing change. Therefore, the portion of samples collected from each slaughter class and the overall aggregate sampling is expected to remain consistent. The information showed that FSIS was finding non-O157 positive results in its verification sampling programs across all slaughter classes.

USDA's Non-Discrimination Statement

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Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, *USDA*

[12] *https://www.fsis.usda.gov/science-data/research-priorities.*

[13] *https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-escherichia-coli.*

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

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

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

(3) *Email: program.intake@usda.gov.*

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Done at Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2022–25140 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

The Northwest Forest Plan Area Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to establish an advisory committee and call for nominations.

SUMMARY: The Forest Service intends to establish the Northwest Forest Plan Area Advisory Committee (the Committee), subject to the Secretary of Agriculture's approval. In accordance with provisions of the Federal Advisory Committee Act (FACA), the Committee is being established to provide advice and recommendations on landscape management approaches that promote sustainability, climate change adaptations, and wildfire resilience while providing for increasing use of and demands from National Forest System lands in the Northwest Forest Plan area. The Committee is necessary and in the public interest. Therefore, the Secretary of Agriculture is also seeking nominations for individuals to be considered as committee members. DATES: Written nominations must be submitted electronically or post-marked by January 17, 2023. Nominations must contain a completed application packet that includes the cover letter, resume, references, and completed form AD–755 (Advisory Committee Membership Background Information). The form AD–755 may be obtained from the Forest Service contact person or from the following website: *https://www.usda.gov/sites/default/files/documents/ad-755.pdf.* The package must be sent to either the email address or mailing address listed in the ADRESSESS. Electronic submission is preferred.

ADDRESSES: Please submit nominations and applications to Glenn Casamassa, Regional Forester, Pacific Northwest Region at *sm.fs.NWFP_FACA@usda.gov* and include the phrase 'FACA Nomination' in the subject line. If sending by express mail, overnight courier service, or the U.S. Postal Service, use the following address: Regional Forester Glenn Casamassa, c/o NWFP FACA Team, 1220 SW 3rd Avenue, Portland, OR 97204.

FOR FURTHER INFORMATION CONTACT: Mark Brown, U.S. Department of Agriculture, Forest Service at 971–712–4369; Nick Goldstein, Forest Service at 503–347–1765; or email the NWFP FACA team at *sm.fs.NWFP_FACA@usda.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800 877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app. 2), with the concurrence of the General Services Administration (GSA), and subject to the approval of the Secretary of Agriculture, the Forest service intends to establish the Federal Advisory Committee for sustainable, climate-adapted, wildfire-resilient landscapes across the Northwest Forest Plan Area. The Committee will be a discretionary advisory committeeand will operate under the provisions of the FACA and report to the Secretary of Agriculture through the Chief of the Forest Service.

The purpose of the Committee is to provide advice and recommendations on landscape management approaches that promote sustainability, climate change adapations, and wildfire resilience while providing for increasing use of and demands from National Forest System lands in the Northwest Forest Plan area. Accordingly, the Committee will be asked to perform the following duties or fulfill other requests made by the Secretary of Agriculture or the Chief of the Forest Service by offering recommendations on:

1. Planning options that complement the national Wildfire Crisis Strategy to assist the U.S. Forest Service transition to greater proactive wildfire risk reduction and related vegetation management.

2. Approaches to address the dynamic nature of ecosystems, utilize adaptive management, monitoring, and integration of future uncertainty into land management planning.

3. Application of the best available science regarding the following primary issues: (a) the ecological importance of mature and old growth forests; (b) climate change, fire, and associated disturbance processes; (c) terrestrial and aquatic reserved land use allocations and the relationship between the two; (d) the climatic diversity of forests encompassed by the NWFP area; and, (e) habitat connectivity at multiple scales in light of changed conditions.

4. Incorporation of traditional ecological knowledge and indigenous perspectives and values into federal forest planning and management.

5. Communication tools and strategies to: (a) help provide greater understanding of landscape or programmatic level planning options

and requirements and (b) enhance outreach efforts, public engagement, meaningful Tribal consultation and participation, targeted outreach to underserved communities, and stakeholder collaboration within the scope of the Committee.

6. Issue preliminary discrete recommendations in sequence with Forest Service NWFP planning timelines.

The Committee is expected to need two years to carry out its objectives. All deliverables will be submitted to the Designated Federal Official (DFO) according to planning schedule needs. The Committee will meet approximately 4 to 6 times annually or as often as necessary and at such times as designated by the DFO. Subcommittees may meet more frequently. Attendance may be in-person, by telephone, or by other electronic means. Meetings of the Committee whether in person, by telephone or electronic means shall be announced 15 calendar days in advance in the **Federal Register** as required by the FACA.

The Committee will hold open meetings unless the Secretary determines that a meeting or a portion of a meeting should be closed to the public in accordance with subsection C of section 522(b) of title 5, United States Code. All proceedings and relevant documents will be posted and made accessible to the public. No individual who is currently registered as a federal lobbyist is eligible to serve as a member of the Committee.

Overview and Memberships

The committee will be comprised of 20 members approved by the Secretary of Agriculture with each member serving a two-year term. The Committee membership will be balanced in terms of the points of view represented and functions to be performed. Members of the Committee will serve without compensation but may be reimbursed for travel expenses while performing duties on behalf of the Committee, subject to approval by the DFO and the Department. The Committee should represent to the extent possible, a balance across the three states covered by the NWFP (Oregon, Washington, California) and reflect the demographic diversity of the NWFP area. The Committee shall include representation from experts in the following interest areas:

(1) Science: Up to 9 members who represent the scientific community, and have an understanding in the following disciplines and how they relate to the NWFP area:

(a) Forest ecology

(b) Vegetation management

(c) Fire ecology

(d) Terrestrial wildlife ecology

(e) Aquatic and riparian ecosystems and species

(f) Climate change

(e) Social science

(g) Adaptive management and planning

(h) Indigenous traditional ecological knowledge (ITEK) practitioners.

(2) Organizations: Up to 7 members who represent a broad array of organizations with an interest in NWFP forests:

(a) National, regional, or local conservation organizations with staff and active programs in the Pacific Northwest

(b) Forest products industry

(c) Recreation organization

(d) Organization involved in outreach with underserved communities

(e) Forest collaborative groups

(f) Wildlife organization

(g) Watershed organization.

(3) Government and public: Up to 4 members who represent governmental entities or the public at-large:

(a) Member of the affected public at large

(b) Represent state governments

(c) Represent counties

(d) Represent American Indian Tribes.

Nomination and Application Information

The appointment of members to the Committee will be made by the Secretary of Agriculture. Any individual or organization may nominate one or more qualified persons to serve on the Federal Advisory Committee for sustainable, climate-adapted, wildfire-resilient landscapes across the Northwest Forest Plan Area. Individuals may also nominate themselves. To be considered for membership, nominees must submit a:

1. Cover letter identifying what interest area group(s) listed above the nominee would represent, how they are qualified to represent that interest group, and why they want to serve on the Committee.

2. Three references that may be contacted about the nominee's application.

3. A resume describing in detail the nominee's qualifications for membership to the Committee.

4. A completed form AD–755, Advisory Committee Membership Background Information. The form AD–755 may be obtained from the Forest Service contact person or from the following website: *https://www.usda.gov/sites/default/files/documents/ad-755.pdf.*

5. Letters of recommendation are welcome. All nominations will be vetted by the Agency and the Secretary of Agriculture will appoint committee members from the list of qualified applicants. Members serve at the pleasure of the Secretary.

Submit nominations and applications to the addressee listed in this notice.

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Equal opportunity practices in accordance with USDA policies shall be followed in all membership appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDA, membership shall, to the extent practicable, include individuals with demonstrated ability to represent all racial and ethnic groups, gender diversity, and persons with disabilities.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English. USDA is an equal opportunity provider, employer, and lender.

Dated: November 15, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–25184 Filed 11–17–22; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, November 18, 2022, 10 a.m. EST.

ADDRESSES: Meeting to take place telephonically and is open to the public via the Commission's YouTube page at: *www.youtube.com/usccr.*

FOR FURTHER INFORMATION CONTACT: Angelia Rorison: 202–376–8371; *publicaffairs@usccr.gov*.

SUPPLEMENTARY INFORMATION: In accordance with the Government in Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, November 18, 2022, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
- A. Presentations by State Advisory Committee Chairs on Released Reports and Memorandums
- B. Discussion and Vote on Advisory Committee Appointments
- C. Discussion and Vote on Advisory Committee (SAC) Report
- D. Discussion and Vote on FY 2023 Crime Victims Report Timeline and Discovery Materials
- E. Management and Operations
- Staff Director's Report

Adjourn Meeting

Dated: November 16, 2022.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2022–25275 Filed 11–16–22; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–50–2022]

Foreign-Trade Zone (FTZ) 196—Fort Worth, Texas; Notification of Proposed Production Activity; Prairie Industries Holdings, Inc. DBA Truvant (Construction Toy Sets); Haslet, Texas

Prairie Industries Holdings, Inc. DBA Truvant submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Haslet, Texas within FTZ 196. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 10, 2022.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products are LEGO® construction toy sets (duty rate is duty-free).

The proposed foreign-status materials and components include: packaging components (decorative plastic ribbons; laminated packaging sheeting; paper liners; tissue wrapping paper; corrugated and non-corrugated folding cartons; rigid paperboard boxes; printed labels; molded paper pulp containers; paper pulp trays; printed gift cards); toy set components (auto-adhesive stickers; electric motors; alkaline batteries; radio remote controls; motion sensor switches); packaging insert components (building instructions; advertising material catalogs); and, plastic, molded, interlocking bricks of various colors (duty rate ranges from duty-free to 6.7%). The request indicates that certain materials/components are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 28, 2022.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Juanita Chen at *juanita.chen@trade.gov.*

Dated: November 14, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–25149 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Voluntary Self-Disclosure of Violations of the EAR

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at *mark.crace@bis.doc.gov* or to *PRAcomments@doc.gov*). Please reference OMB Control Number 0694–0058 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202–482–8093 or by email at *mark.crace@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is needed to detect violations of the Export Administration Act and Regulations and determine if an investigation or prosecution is necessary and to reach a settlement with violators. Voluntary self-disclosure of EAR violations strengthens BIS's enforcement efforts by allowing BIS to conduct investigations of the disclosed incidents faster than would be the case if BIS had to detect the violations without such disclosures. BIS evaluates the seriousness of the violation and either (1) Informs the person making the disclosure that no

action is warranted; (2) issues a warning letter; (3) issues a proposed charging letter and attempts to settle the matter; (4) issues a charging letter if settlement is not reached; and/or (5) refers the matter to the U.S. Department of Justice for criminal prosecution.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0694–0058.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 488.

Estimated Time per Response: 10 hours.

Estimated Total Annual Burden Hours: 4,880.

Estimated Total Annual Cost to Public: 0.

Respondent's Obligation: Voluntary.

Legal Authority: EAR Sections 764.5, and 764.7.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–25208 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–813]

Polyethylene Terephthalate Sheet From the Sultanate of Oman: Notice of Initiation of Changed Circumstances Review and Consideration of Revocation of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on a request from Advanced Extrusion, Inc., Good Natured Products, IL dba Ex-Tech Inc., and Multi-Plastics Extrusions, Inc. (collectively, the petitioners), the U.S. Department of Commerce (Commerce) is initiating a changed circumstances review (CCR) to consider the possible revocation of the antidumping duty (AD) order on polyethylene terephthalate (PET) sheet from the Sultanate of Oman (Oman).

DATES: Applicable November 18, 2022.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2020, Commerce published an AD order on PET sheet from Oman.[1] On October 26, 2022, the petitioners (*i.e.,* domestic producers of subject merchandise) requested, through a CCR, the revocation of the *Order* pursuant to section 751(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.222(g)(1).[2]

Scope of the Order

The merchandise covered by the *Order* is raw, pretreated, or primed polyethylene terephthalate sheet, whether extruded or coextruded, in nominal thicknesses of equal to or greater than 7 mil (0.007 inches or 177.8 μm) and not exceeding 45 mil (0.045 inches or 1143 μm) (PET sheet). The scope includes all PET sheet whether made from prime (virgin) inputs or recycled inputs, as well as any blends thereof. The scope includes all PET sheet meeting the above specifications regardless of width, color, surface treatment, coating, lamination, or other surface finish.

The merchandise subject to the *Order* is properly classified under statistical reporting subheading 3920.62.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope is dispositive.

Initiation of CCR and Consideration of Revocation of the Order

Pursuant to section 751(b) of the Act, Commerce will conduct a CCR upon receipt of a request from an interested party [3] that shows changed circumstances sufficient to warrant a review of the order. In accordance with 19 CFR 351.216(d), Commerce determines that the information submitted by the petitioners, *i.e.,* their statement of no interest in the continued maintenance of the *Order,* constitutes a sufficient basis to conduct a CCR of the *Order.*

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that Commerce may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. In its administrative practice, Commerce has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[4]

The petitioners stated that they were the sole petitioners in the original investigation, but that they did not

[1] *See Polyethylene Terephthalate Sheet from the Republic of Korea and the Sultanate of Oman: Antidumping Duty Orders,* 85 FR 55824 (September 10, 2020) (*Order*).

[2] *See* Petitioners' Letter, ''Request for a ''No Interest'' Changed Circumstances Review and Revocation of the Order,'' dated October 26, 2022.

[3] The petitioners reported, in their request for a CCR, that they are U.S.-based producers of PET sheet. As such, the petitioners are an interested party within the meaning of section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v).

[4] *See, e.g., Certain Cased Pencils from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent to Revoke Order in Part,* 77 FR 42276 (July 18, 2012), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination to Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

know whether they account for substantially all of the U.S. production of the domestic like product covered by the *Order.* Accordingly, we are not combining this notice of initiation with a preliminary determination, pursuant to 19 CFR 351.221(c)(3)(ii). Rather, we will provide interested parties with an opportunity to address the issue of domestic industry support with respect to the revocation of the *Order,* as explained below. After examining comments, if any, concerning domestic industry support for revocation, we will issue the preliminary results of this CCR.

Public Comment

Interested parties are invited to provide comments and/or factual information regarding this CCR, including comments on industry support. Any comments and factual information must be submitted to Commerce no later than ten days after the date of publication of this notice. Rebuttal comments and rebuttal factual information must be filed with Commerce no later than seven days after the initial comments and/or factual information submissions.[5] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[6] An electronically filed document must be received successfully in its entirety by ACCESS, by 5:00 p.m. Eastern Time on the due dates set forth in this notice. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[7]

Preliminary and Final Results of the CCR

Commerce intends to publish in the **Federal Register** a notice of the preliminary results of this CCR in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice. Unless extended, Commerce will issue the final results of this CCR is accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act and 19 CFR 351.221(b)(1).

[5] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2).

[6] *See generally* 19 CFR 351.303.

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

Dated: November 14, 2022.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2022–25200 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC561]

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will meet December 5, 2022, through December 14, 2022.

DATES: The meetings will be held Monday, December 5, 2022, through Wednesday, December 14, 2022.

ADDRESSES: The meetings will be a hybrid conference. The in-person component of the meeting will be held at the Hilton Hotel, 500 W 3rd Ave, Anchorage, AK 99501, or join the meeting online through the links at *https://www.npfmc.org/upcoming-council-meetings.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via web conference are given under Connection Information below.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; email: *diana.evans@noaa.gov;* telephone: (907) 271–2809. For technical support, please contact our Council administrative staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Council's Scientific and Statistical Committee (SSC) will begin at 8 a.m. in the Aleutian room on Monday, December 5, 2022, and continue through Wednesday, December 7, 2022. The Council's Advisory Panel (AP) will begin at 8 a.m. in the Denali room on Tuesday, December 6, 2022, and continue through Friday, December 9, 2022. The Council will begin at 8 a.m. in the Aleutian room on Thursday, December 8, 2022, and continue through Wednesday, December 14, 2022. The Bering Sea FEP LKTK Subsistence Taskforce (LKTKS) will meet on Monday, December 5, 2022, from 8:30 a.m. to 5 p.m. in the Denali room. The Charter Halibut Committee will meet Wednesday, December 7, 2022, from 8 a.m. to 1 p.m. at the North Pacific Fishery Management Council's Conference Room; 1007 W 3rd Ave, Suite 400, Anchorage, AK 99501–2252. All times listed are Alaska Time.

Agenda

Monday, December 5, 2022, Through Wednesday, December 7, 2022

The SSC agenda will include the following issues:

(1) Administrative Issues;

(2) Snow crab rebuilding analysis—Initial Review;

(3) Bering Sea Aleutian Islands (BSAI) Groundfish—(a) Bering Sea (BS) and Aleutian Islands (AI) Ecosystem Status Reports, (b) Stock Assessment and Fishery Evaluation (SAFE) report, (c) adopt Acceptable Biological Catch (ABC)/Over Fishing Limits (OFLs); (d) Plan Team report;

(4) Gulf of Alaska (GOA) Groundfish—(a) GOA Ecosystem Status Report, (b) SAFE report, (c) adopt ABC/OFLs, (d) Plan Team report.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2963* prior to the meeting, along with meeting materials.

In addition to providing ongoing scientific advice for fishery management decisions, the SSC functions as the Council's primary peer review panel for scientific information, as described by the Magnuson-Stevens Act section 302(g)(1)(e), and the National Standard 2 guidelines (78 FR 43066). The peer-review process is also deemed to satisfy the requirements of the Information Quality Act, including the Office of Management and Budget (OMB) Peer Review Bulletin guidelines.

Tuesday, December 6, 2022, Through Friday, December 9, 2022

The Advisory Panel agenda will include the following issues:

(1) Administrative Issues;

(2) Snow crab rebuilding analysis—Initial Review;

(3) Cook Inlet Salmon Fishery Management Plan (FMP) amendment—Initial Review;

(4) Salmon bycatch: Review—(a) Salmon findings of State of Alaska Bycatch Taskforce; (b) Chum salmon bycatch discussion paper; (c) Salmon Bycatch Committee report;

(5) BSAI Groundfish—(a) BS and AI Ecosystem Status Reports, (b) SAFE report, (c) adopt ABC/OFLs; (d) Plan Team report;

(6) GOA Groundfish—(a) GOA Ecosystem Status Report, (b) SAFE report, (c) adopt ABC/OFLs, (d)Plan Team report;

(7) 2023 Charter halibut management measures—Final action;

(8) Staff Tasking.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2964* prior to the meeting, along with meeting materials.

Thursday, December 8, 2022, Through Wednesday, December 14, 2022

The Council agenda will include the following issues. The Council may take appropriate action on any of the issues identified.

(1) B Reports (Executive Director, NMFS Management, NOAA General Counsel (GC), NOAA Enforcement Report, Alaska Department of Fish and Game (ADF&G), United States Coast Guard (USCG), United States Fish and Wildlife Service (USFWS), SSC report, AP report);

(2) Red King Crab Savings Area (RKCSA) emergency rule request—Review;

(3) Snow crab rebuilding analysis—Initial Review;

(4) Crab conservation workplan—Review;

(5) Cook Inlet Salmon FMP amendment—Initial Review;

(6) BSAI Groundfish—(a) BS and AI Ecosystem Status Reports, (b) SAFE report, (c) adopt ABC/OFLs; (d) Plan Team report;

(7) GOA Groundfish—(a) GOA Ecosystem Status Report, (b) SAFE report, (c) adopt ABC/OFLs, (d)Plan Team report;

(8) 2023 Charter halibut management measures—Final action;

(9) Salmon bycatch: Review—(a) Salmon findings of State of Alaska Bycatch Taskforce; (b) Chum salmon bycatch discussion paper; (c) Salmon Bycatch Committee report;

(10) Staff Tasking.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2964* prior to the meeting, along with meeting materials.

Monday, December 5, 2022

The LKTKS Taskforce agenda will include (a) receive an overview of Taskforce work products, namely the LKTKS protocol which includes the primary guidelines and onramps for identifying, analyzing, and including LKTKS information and expertise in the Council's decision-making process; (b) further develop the protocol and recommendations for LKTKS onramps; (c) discuss the timeline for remaining work to meet the Council's objectives for the Taskforce; and (d) other business. The Agenda is subject to change, and the latest version will be posted at: *https://meetings.npfmc.org/Meeting/Details/2954.*

Wednesday, December 7, 2022

The Charter Halibut Committee agenda will include (a) begin with introductions (b) review the ADF&G analysis for 2023, (c) have a committee discussion, (d) have committee recommendations, (e) have an electronic logbook discussion, (f) discuss upcoming meetings and other business.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2957* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://www.npfmc.org/upcoming-council-meetings.* For technical support, please contact our administrative staff, email: *npfmc.admin@noaa.gov.*

If you are attending the meeting in-person, please refer to the COVID avoidance protocols on our website, *https://www.npfmc.org/upcoming-council-meetings/.*

Public Comment

Public comment letters will be accepted and should be submitted electronically through the links at *https://www.npfmc.org/upcoming-council-meetings.* The Council strongly encourages written public comment for this meeting to avoid any potential for technical difficulties to compromise oral testimony. The written comment period is open from November 18, 2022, to December 2, 2022, and closes at 12 p.m. Alaska Time on Friday, December 2, 2022.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 2022.

Diane M. DeJames-Daly,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–25188 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC543]

New England Fishery Management Council; Public Meeting; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of correction of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, December 1, 2022, beginning at 1:30 p.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/3900671858064240652*.

ADDRESSES:

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on November 15, 2022 (87 FR 68440). The original notice stated the time of the meeting was to begin at 12:30 p.m. This notice corrects the time of the meeting to begin at 1:30 p.m. All other previously published information remains the same.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 2022.

Diane M. DeJames-Daly,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–25203 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC560]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council, NEFMC) will hold a four-day in-person meeting with an option for remote participation to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). The Council continues to follow all public safety measures related to COVID–19 and intends to do so for this meeting.

DATES: The meeting will be held on Monday, December 5, 2022 through Thursday, December 8, 2022, beginning at 1 p.m. on Monday and 9 a.m. on Tuesday, Wednesday, and Thursday.

ADDRESSES:

Meeting address: The meeting will be held at the Hotel Viking, One Bellevue Avenue, Newport, RI 02840; telephone: (401) 847–3300; online at *https://www.hotelviking.com/.* Join the webinar at *https://attendee.gotowebinar.com/register/8990407940060984847.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone: (978) 465–0492; *www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492, ext. 113.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, December 5, 2022

After brief announcements, the Council will receive reports on recent activities from its Chair and Executive Director, the Greater Atlantic Regional Fisheries Office (GARFO) Regional Administrator, the Northeast Fisheries Science Center (NEFSC) Director, the NOAA Office of General Counsel, the Mid-Atlantic Fishery Management Council liaison, staff from the Atlantic States Marine Fisheries Commission (ASMFC), and representatives from the U.S. Coast Guard, NOAA's Office of Law Enforcement, and the Northeast Trawl Advisory Panel. Next, the Council will receive a briefing from NOAA General Counsel on disclosure of financial interests and voting recusal regulations for Regional Fishery Management Council members. This will be followed by an introduction to the Chief of the Bureau of Ocean Energy Management's (BOEM) Office of Renewable Energy Programs, who will provide comments on the responsibilities of this position and take questions. Then, the Habitat Committee will provide its report, which will cover: (1) an update on a framework adjustment to facilitate offshore Atlantic salmon aquaculture; (2) a discussion on the retention of the Georges Bank Dedicated Habitat Research Area; and (3) an update on offshore energy issues and other habitat-related work. As the last item of business for the day, the Council will have a discussion on policies for preventing harassment of Council staff and all other Council process participants.

Tuesday, December 6, 2022

The Council will begin the second day of its meeting with a Northeast Fisheries Science Center presentation on the peer-reviewed results of the September 2022 Monkfish Management Track Stock Assessment. Next, the Council will receive a presentation on the peer-reviewed September 2022 Management Track Stock Assessments for numerous groundfish stocks. The Council then will receive a report from its Scientific and Statistical Committee (SSC), which will cover SSC recommendations for overfishing limits (OFLs) and acceptable biological catches (ABCs) for: (1) Georges Bank cod and Georges Bank yellowtail flounder for fishing years 2023–24, as well as 14 other groundfish stocks for fishing years 2023–25; (2) monkfish for fishing years 2023–25; and (3) Atlantic sea scallops for fishing year 2023 and defaults for fishing year 2024.

After the lunch break, members of the public will have the opportunity to speak during an open comment period on issues that relate to Council business but are not included on the published agenda for this meeting. The Council asks the public to limit remarks to 3–5 minutes. These comments will be received both in person and through the webinar. A guide for how to publicly comment through the webinar is available on the Council website at *https://s3.amazonaws.com/nefmc.org/NEFMC-meeting-remote-participation_generic.pdf.* Next, the Council will take up the Groundfish Committee report, which is focused on final action for Framework Adjustment 36 to the Northeast Multispecies Fishery Management Plan (FMP). The framework includes: (1) 2023–24 total allowable catches (TACs) for U.S./Canada shared resources on Georges Bank; (2) 2023–24 specifications for Georges Bank cod and Georges Bank yellowtail flounder; (3) 2023–25 specifications for 14 additional groundfish stocks; (4) revised rebuilding plan for Gulf of Maine cod; (5) additional measures to promote Georges Bank and Gulf of Maine cod stock rebuilding; and (6) acceptable biological catch (ABC) control rule revisions for groundfish. At the conclusion of this discussion, the Council will adjourn for the day.

Wednesday, December 7, 2022

The Council will lead off the third day of its meeting discussing Atlantic sturgeon. First, GARFO will provide a presentation on the final action plan for Atlantic sturgeon, which will be followed by a Council discussion on next steps to reduce sturgeon bycatch in federal large-mesh gillnet fisheries. Next, the Council will take up final action on Framework Adjustment 13 to the Monkfish FMP, which contains 2023–25 fishery specifications and other measures. The Council will move into the Scallop Committee report, which will focus on final action for Framework Adjustment 36 to the Atlantic Sea Scallop FMP. The framework includes specifications for the 2023 fishing year, default specifications for the 2024 fishing year, and other measures.

Following the lunch break, the Council will engage in an afternoon-long discussion as a next step under the East Coast Climate Change Scenario Planning initiative. This will be a facilitated discussion to identify main takeaways and potential actions across four thematic areas—management and governance, data and science, alternative ocean uses, and adaptability—developed through the East Coast Climate Change Scenario Planning initiative. The Council will recommend and prioritize actions for evaluation at a February 2023 Summit to assist East Coast fishery management organizations in adapting to climate change. At the conclusion of this discussion, the Council will adjourn for the day.

Thursday, December 8, 2022

The Council will lead off the fourth day of its meeting with the Ecosystem-Based Fishery Management (EBFM) Committee report, which will include: (1) a preliminary summary of the in-person EBFM Public Information Workshops conducted in October and November; (2) an overview of the

Prototype Management Strategy Evaluation (MSE) scoping meetings for EBFM and the Georges Bank example Fishery Ecosystem Plan (eFEP); and (3) a short overview of the November 2022 Council Member Ongoing Development (CMOD) meeting in Denver, CO. The Council then will receive a spiny dogfish presentation and approve specifications for the 2023 spiny dogfish fishing year. Next on the agenda, the Council will receive the 2022 Small-Mesh Multispecies (Whiting) Annual Monitoring Report covering the 2021 fishing year. The Council then will review and approve a comment letter on NOAA's updated Saltwater Recreational Fisheries Policy.

Following the lunch break, the Council will discuss and take final action on 2022 Council Priorities for all fishery management plans and other Council responsibilities. Finally, the Council will close out the meeting with other business.

Although non-emergency issues not contained on this agenda may come before the Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 2022.

Diane M. DeJames-Daly,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–25191 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC541]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Availability; Receipt of a proposed Habitat Conservation Plan (HCP); Incidental Take Permit (ITP) application; announcement of public meeting; request for comments.

SUMMARY: We, the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS) have received separate ITP applications from the Oregon Department of State Lands (ODSL; applicant), associated with the Elliott State Research Forest HCP. The applications, including the HCP, have been submitted pursuant to Section 10 of the Endangered Species Act of 1973, as amended. The applicant is seeking authorization from FWS and NMFS (together, the Services) for the incidental take of three species expected to result from research and management-related activities on the Elliott State Forest in Coos and Douglas Counties, Oregon. These research and management activities include timber removal and infrastructure maintenance. FWS is the lead Federal agency under the National Environmental Policy Act (NEPA), and NMFS is a cooperating agency. The availability of the Draft Environmental Impact Statement was announced separately by FWS. NMFS is seeking public comments on the HCP.

DATES: We will accept online or hardcopy comments. Hardcopy comments must be received or postmarked on or before December 19, 2022 (See **ADDRESSES**). Comments submitted online at *https://www.regulations.gov/* must be received by 11:59 p.m. Eastern Time on December 19, 2022.

Public Meetings: FWS is hosting a public meeting during the public comment and review period. A meeting link will be posted to the FWS project web page (*https://www.fws.gov/project/elliott-state-research-forest-habitat-conservation-plan*) prior to the meeting. The public meeting will be held virtually at the following time:

- December 13, 2022, from 2 p.m. to 3:30 p.m. Pacific Time.

ADDRESSES:

Written Comments: Written comments on the proposed HCP will be accepted via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter FWS–R1–ES–2022–0029 in the Search Box. Follow instructions for submitting comments on Docket FWS–R1–ES–2022–0029. When commenting, please refer to the specific section and/or page number and the subject of your comment.

Instructions: Written comments submitted though any other method, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov.* All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Kathleen Wells, NMFS, 503–230–5437, *Kathleen.Wells@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Species covered by NMFS:

- Coho salmon (*Oncorhynchus kisutch*): Threatened.

Species covered by FWS:

- Northern spotted owl (*Strix occidentalis*): Threatened.
- Marbled murrelet (*Brachyramphus marmoratus*): Threatened.

Background

Section 9 of the ESA and Federal regulations prohibit the taking of a species listed as endangered or threatened. The ESA defines ''take'' to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS and FWS may issue permits, under limited circumstances, to take listed species incidental to, and not the purpose of, otherwise lawful activities. Section 10(a)(1)(B) of the ESA and implementing regulations (50 CFR 222.307 for NMFS and 50 CFR 17.22(b) and 17.32(b) for FWS) provide for authorizing incidental take of listed species.

NMFS and FWS received separate ITP applications from ODSL on October 10, 2022, pursuant to the ESA. ODSL prepared the HCP in support of both ITP applications and is seeking authorization from NMFS and FWS for

incidental take of the species described above.

The ITPs, if issued, would authorize take of the covered species that may occur incidental to ODSL's research and forest management activities (the covered activities). The plan area includes a total of 93,432 acres (378.11 km²), which includes School Lands and Board of Forestry Lands managed by ODSL and the Oregon Department of Forestry (ODF). The covered activities include the foundational research design of the Elliott State Research Forest proposal including; forest research treatments; operation standards, by research treatment designation; projected harvest timing, amount, and amount of harvest types, and methods; supporting management activities; supporting infrastructure, including roads and facilities; potential research projects; and implementation of the HCP's conservation strategy.

The HCP specifies the impacts that will likely result from the taking of covered species and describes the steps that ODSL will take to minimize and offset such impacts. The HCP also describes the covered species' life history and ecology, as well as biological goals and objectives of the HCP, adaptive management, monitoring, and funding assurances.

NMFS is seeking public input on the HCP. We specifically request information on the following:

1. Biological information, analysis, and relevant data concerning the covered species, other wildlife, and ecosystems.
2. Potential effects that the proposed permit actions could have on the covered species, and other endangered or threatened species and their habitats, including the interaction of the effects of the project with climate change and other stressors.
3. Alternatives to the proposed action.
4. Adequacy of the conservation strategy to minimize and mitigate the impact of the taking on covered species.
5. Other information relevant to the HCP.

The Services will each make their permit decision on the statutory and regulatory criteria of the ESA. Their decisions will also be informed by the data, analyses, and public comments received on the Draft EIS and HCP. The Services will each document their determinations independently in an ESA Section 10 findings document, and an ESA section 7 biological opinion. It is NMFS' intent to adopt the EIS and issue its own record of decision to complete the NEPA process. If the Services find that all requirements for issuance of the ITPs are met, they will issue the requested permits, subject to terms and conditions deemed necessary or appropriate to carry out the purposes of ESA Section 10.

Authority: Section 10(c) of the ESA and its implementing regulations (50 CFR 222.307, 17.22, and 17.32).

Dated: November 9, 2022.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–24883 Filed 11–17–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice is Given of the Names of Members of the Performance Review Board for the Department of the Air Force

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice.

SUMMARY: Notice is given of the names of members of the 2022 Performance Review Board for the Department of the Air Force.

FOR FURTHER INFORMATION CONTACT: Please direct any written comments or requests for information to Mr. Christopher Whitener, Air Force Civilian Senior Executive Management Office, SAF/MRL, 1660 Air Force Pentagon, Washington, DC, 20330–1040, (PH: 703–695–7323; or via email at *christopher.whitener@us.af.mil*).

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4314(c) (1–5), the Department of the Air Force announces the appointment of members to the Air Force's Senior Executive Service Performance Review Board. Appointments are made by the authorizing official. Each board member shall review and evaluate performance scores provided by the Senior Executive's rater/immediate supervisor. Performance standards must be applied consistently across the Air Force. The board will make final recommendations to the authorizing official relative to the performance of the executive.

The members of the 2022 Performance Review Board for the Air Force are:

1. Honorable Alex Wagner (Chair), Assistant Secretary of the Air Force for Manpower and Reserve Affairs
2. General Duke Richardson (Vice Chair), Commander for Air Force Materiel Command Commander
3. General David Allvin, Vice Chief of Staff of the Air Force
4. General David Thompson, Vice Chief of Space Operations for U.S. Space Force
5. Major General Brook Leonard, Chief of Staff for U.S. Space Command
6. Mr. John Fedrigo, Principal Deputy Assistant Secretary of the Air Force for Manpower and Reserve Affairs
7. Mr. Anthony Reardon, Administrative Assistant to the Secretary of the Air Force
8. Ms. Gwendolyn DeFilippi, Assistant Deputy Chief of Staff for Manpower, Personnel and Services
9. Ms. Katharine Kelley, Deputy Chief of Space Operations for Human Capital, U.S. Space Force
10. Ms. Darlene Costello, Principal Deputy Assistant Secretary of the Air Force Acquisition, Technology & Logistics
11. Mr. Steven Herrera, Principal Deputy Assistant Secretary of the Air Force for Financial Management and Comptroller
12. Ms. Lorna Estep, Executive Director, Air Force Materiel Command
13. Mr. Craig Smith, Principal Deputy General Counsel of the Air Force
14. Mr. John Salvatori, Director, Concepts, Development, and Management Office
15. Ms. Shannon McGuire (Legal Advisor), Deputy General Counsel for Fiscal Ethics and Administrative Law
16. Mr. Richard Desmond (Legal Advisor), Associate General Counsel of the Air Force
17. Ms. Laura Megan-Posch (Legal Advisor), Associate General Counsel of the Air Force

The following Tier 3 Career SES members will serve as alternates:

1. Mr. Douglas Bennett, Auditor General of the Air Force
2. Mr. Richard Lombardi, Deputy Chief Management Officer
3. Ms. Kelli Seybolt, Deputy Under Secretary of the Air Force, International Affairs
4. Mr. Daniel Fri, Assistant Deputy Chief of Staff, Logistics, Engineering and Force Protection
5. Mr. Douglas Sanders, Deputy Administrative Assistant to the Secretary of the Air Force
6. Mr. Thomas Lawhead, Assistant Deputy Chief of Staff, Strategy Integration and Requirements
7. Mr. Michael Shoults, Assistant Deputy Chief of Staff for Strategic Deterrence and Nuclear Integration
8. Mr. Edwin Oshiba, Acting Assistant Secretary of the Air Force for Installations, Environment and Energy
9. Ms. Lauren Knausenberger, Chief Information Officer

10. Mr. Joseph McDade, Assistant Deputy Chief of Staff for Strategic Plans and Programs
11. Mr. Rowayne Schatz Jr., Director for Studies and Analysis, Office of the Secretary of the Air Force
12. Ms. Lisa Costa, Deputy Chief of Space Operations for Technology and Innovation
13. Ms. Wanda Jones-Heath, Principal Cyber Advisor
14. Ms. Jennifer Miller, Director of Staff, Office of the Secretary of the Air Force
15. Mr. Andrew Cox, Director for Space Protection Program Office
16. Ms. Marianne Malizia, Director for Office of Diversity and Inclusion

Adriane Paris,

Air Force Federal Register Liaison Officer.

[FR Doc. 2022–25121 Filed 11–17–22; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Grant a Partially Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant a partially exclusive patent license to UES Inc., a small business, having a place of business at 4401 Dayton-Xenia Road, Dayton, OH 45432–1894. Such license is partially exclusive as it is limited to the field of electronics.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to James F. McBride, Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Area B, Building 11, Wright-Patterson AFB, OH 45433–7109; Facsimile: (937) 255–9318; or Email: *afmclo.jaz.tech@us.af.mil.* Include Docket ARX–210727A–PL in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: James F. McBride, Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Area B, Building 11, Wright-Patterson AFB, OH 45433–7109; Telephone: (937) 713–0229; Facsimile: (937) 255–9318; or Email: *afmclo.jaz.tech@us.af.mil.*

Abstract of Patents and Patent Application(s)

I. Articles comprising a resistor comprising core shell liquid metal encapsulates and methods of detecting an impact on an article using a resistor comprising core shell liquid metal encapsulates are disclosed. Such core shell liquid metal encapsulates enable simple but robust impact sensors as such encapsulates comprise a highly electrically resistant metal oxide shell that prevents such encapsulates from coalescing. Yet when such shell is ruptured, the highly conductive bulk liquid metal is released. Such liquid metal changes electrical properties of a sensor comprising core shell liquid metal encapsulates which in turn is evidence of the aforementioned impact.

Intellectual Property

U.S. Patent No. 10,900,848 B2, that issued on January 26, 2021, and entitled ''*Articles comprising a resistor comprising core shell liquid metal encapsulates and method of detecting an impact.*''

II. The present invention relates to core shell liquid metal encapsulates comprising multi-functional ligands, networks comprising such encapsulates and processes of making and using such encapsulates and networks. When subjected to strain, such network's conductivity is enhanced, thus allowing the network to serve as a healing agent that restores at least a portion of the conductivity in an adjacent conductor.

Intellectual Property

U.S. Patent No. 11,100,223 B2, that issued on August 24, 2021, and U.S. Patent Application Serial No. 17/376,644, that was filed on July 15, 2021. Such patent and patent application being entitled ''*Core shell liquid metal encapsulates comprising multi-functional ligands and networks comprising same*''

III. The present invention relates to articles comprising core shell liquid metal encapsulate networks and methods of using core shell liquid metal encapsulate networks to control AC signals and power. Such method permits the skilled artisan to control the radiation, transmission, reflection and modulation of an AC signal and power. As a result, AC system properties such as operation frequency, polarization, gain, directionality, insertion loss, return loss, and impedance can be controlled under strain.

Intellectual Property

U.S. Patent Application Serial No. 16/580,652, that was filed on September 24, 2019, and entitled ''*Articles comprising core shell liquid metal encapsulate networks and method to control alternating current signals and power*''.

IV. The present invention relates to substrates comprising a network comprising core shell liquid metal encapsulates comprising multi-functional ligands and processes of making and using such substrates. The core shell liquid metal particles are linked via ligands to form such network. Such networks volumetric conductivity increases under strain which maintains a substrate's resistance under strain. The constant resistance results in consistent thermal heating via resistive heating. Thus allowing a substrate that comprises such network to serve as an effective heat provider.

Intellectual Property

U.S. Patent No. 11,102,883 B2, that issued on August 24, 2021, and U.S. Patent Application Serial No. 17/386,807, that was filed on July 28, 2021. Such patent and patent application being entitled ''*Substrates comprising a network comprising core shell liquid metal encapsulates comprising multi-functional ligands*''

V. The present invention relates to architected liquid metal networks and processes of making and using same. The predetermined template design technology of such architected liquid metal networks provides the desired spatial control of electrical, electromagnetic, and thermal properties as a function of strain. Thus, resulting in improved overall performance including process ability.

Intellectual Property

U.S. Patent Application Serial No. 16/671,750, that was filed on November 1, 2019, and entitled ''*Architected liquid metal networks and processes of making and using same*''.

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Adriane Paris,

Air Force Federal Register Liaison Officer.

[FR Doc. 2022–25122 Filed 11–17–22; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

[BPA File No. BP–24]

Fiscal Year (FY) 2024–2025 Proposed Power and Transmission Rate Adjustments Public Hearing and Opportunities for Public Review and Comment

AGENCY: Bonneville Power Administration (Bonneville or BPA), Department of Energy (DOE).

ACTION: Notice of FY 2024–2025 proposed power and transmission rate adjustments.

SUMMARY: Bonneville is initiating a rate proceeding under the Northwest Power Planning and Conservation Act (Northwest Power Act) to establish power, transmission, and ancillary and control area services rates for the period from October 1, 2023, through September 30, 2025. Bonneville has designated this proceeding Docket No. BP–24.

DATES:

Prehearing Conference: The BP–24 proceeding begins with a prehearing conference, which will be held via telephone at 10:00 a.m. on Friday, December 2, 2022.

Intervention: Anyone intending to become a party to the BP–24 proceeding must file a petition to intervene on Bonneville's secure website. Petitions to intervene may be filed beginning on the date of publication of this Notice and are due no later than 4:30 p.m. on Monday, December 5, 2022. Part III of this notice, ''Public Participation in BP–24,'' provides details on requesting access to the secure website and filing a petition to intervene.

ADDRESSES: Interested parties may obtain the call-in information by accessing Bonneville's BP–24 web page at *https://www.bpa.gov/goto/bp24* or by contacting the Hearing Clerk at *BP24clerk@gmail.com.*

Participant Comments: Written comments by non-party participants must be received by Friday, December 9, 2022, to be considered in the Administrator's Record of Decision (ROD). Part III of this notice, ''Public Participation in BP–24,'' provides details on submitting participant comments.

FOR FURTHER INFORMATION CONTACT: Ms. Elissa Haley, DKS–7, BPA Communications, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208; by phone toll-free at 1–800–622–4519; or by email to *enhaley@bpa.gov.*

The Hearing Clerk for this proceeding can be reached via email at *BP24clerk@gmail.com* or via telephone at (503) 479–8506.

Please direct questions regarding Bonneville's secure website to the Hearing Coordinator via email at *cwgriffen@bpa.gov* or, if the question is time-sensitive, via telephone at (503) 230–5107.

Responsible Officials: Mr. Daniel H. Fisher, Power Rates Manager, is the official responsible for the development of Bonneville's power rates, and Ms. Rebecca E. Fredrickson, Manager of Transmission Rates, Tariff, Regulatory and Compliance, is the official responsible for the development of Bonneville's transmission, ancillary, and control area services rates.

SUPPLEMENTARY INFORMATION:

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Part I—Introduction and Procedural Matters

A. Introduction

The Northwest Power Act provides that Bonneville must establish, and periodically review and revise, its power and transmission rates so that they recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, including amortization of the Federal investment in the Federal Columbia River Power System (FCRPS) over a reasonable number of years, and Bonneville's other costs and expenses. Section 7(i) of the Northwest Power Act requires that Bonneville's rates be established according to certain procedures, including publication in the **Federal Register**, of a notice of the proposed rates and one or more hearings conducted as expeditiously as practicable by a Hearing Officer to develop a full and complete record for a final decision by the Administrator. Bonneville is conducting the BP–24 proceeding to establish rates for FY 2024–2025.

Bonneville's Rules of Procedure will govern the BP–24 proceeding. The rules are posted on Bonneville's website at *https://www.bpa.gov/energy-and-services/rate-and-tariff-proceedings/rules-of-procedure-revision-process.*

B. 2022 Integrated Program Review

Bonneville's Integrated Program Review (IPR) process is designed to allow the public an opportunity to review and comment on Bonneville's expense and capital cost forecasts before the forecast costs are used to set rates. Bonneville's 2022 IPR process, which addressed the expense and capital program level cost forecasts for FY 2024–25, began in June 2022 and concluded with the issuance of the Final Close-Out Report in October 2022. At the discretion of the Administrator, Bonneville may hold additional processes to review these forecasts outside of the BP–24 rate proceeding.

C. Proposed Settlement of Rates for Power Sales and Transmission, Ancillary, and Control Area Services

Since August, Bonneville has been engaged in discussions with customers and other stakeholders to attempt to reach agreement on the proposed power and transmission rates, including ancillary and control area services rates, for the FY 2024–2025 rate period. These discussions have resulted in the BP–24 Rates Settlement, which includes the FY 2024–2025 rates and other terms that Bonneville is proposing to adopt in the BP–24 proceeding. A summary of Bonneville's proposed power and transmission rates is provided in Part IV of this notice. A link to the BP–24 Rates Settlement is provided in Part V.

The BP–24 Rates Settlement calls for Bonneville to file a motion with the BP–24 Hearing Officer to establish a deadline for parties in the BP–24 proceeding to either object to the proposed settlement or waive the right to contest the settlement. Bonneville intends to file its motion soon after the BP–24 prehearing conference. If no party in the BP–24 proceeding objects to the BP–24 Rates Settlement, Bonneville staff will continue moving forward with the proposal that the Administrator adopt the settlement. If a party objects to the BP–24 Rates Settlement, Bonneville will notify all parties and decide how to proceed with respect to rates proposed in the initial proposal.

D. Proposed Procedural Schedule

A proposed schedule for the BP–24 proceeding is provided below, which assumes the BP–24 Rates Settlement proceeds without objection. The official schedule will be established by the Hearing Officer and may be amended by the Hearing Officer as needed during the proceeding.

Prehearing Conference—December 2, 2022.
BPA Files Initial Proposal—December 2, 2022.
Deadline for Petitions to Intervene—December 5, 2022.
Deadline for Objections to Settlement Agreement—December 9, 2022.

Close of Participant Comments—
December 9, 2022.
Final ROD and Final Studies Issued—
February 9, 2023.

E. Ex Parte Communications

Section 1010.5 of Bonneville's Rules of Procedure prohibits *ex parte* communications. *Ex parte* communications include any oral or written communication (1) relevant to the merits of any issue in the proceeding; (2) that is not on the record; and (3) with respect to which reasonable prior notice has not been given. The *ex parte* rule applies to communications with all Bonneville and DOE employees and contractors, the Hearing Officer, and the Hearing Clerk during the proceeding. Except as provided, any communications with persons covered by the rule regarding the merits of any issue in the proceeding by other executive branch agencies, Congress, existing or potential Bonneville customers, nonprofit or public interest groups, or any other non-DOE parties are prohibited. The rule explicitly excludes and does not prohibit communications (1) relating to matters of procedure; (2) otherwise authorized by law or the Rules of Procedure; (3) from or to the Federal Energy Regulatory Commission (Commission); (4) that all litigants agree may be made on an *ex parte* basis; (5) in the ordinary course of business, about information required to be exchanged under contracts, or in information responding to a Freedom of Information Act request; (6) between the Hearing Officer and Hearing Clerk; (7) in meetings for which prior notice has been given; or (8) as otherwise specified in Section 1010.5(b) of Bonneville's Rules of Procedure. The *ex parte* rule remains in effect until the Administrator's Final ROD is issued.

Part II—Scope of BP–24 Rate Proceeding

A. Joint Rate Proceeding

The BP–24 proceeding is a joint proceeding for the adoption of both power and transmission rates for FY 2024–2025 (see Parts IV and V). This section provides guidance to the Hearing Officer regarding the scope of the rate proceeding and identifies specific issues that are outside the scope. In addition to the issues specifically listed below, any other issue that is not a ratemaking issue is outside the scope of this proceeding.

Bonneville may revise the scope of the proceeding to include new issues that arise as a result of circumstances or events occurring outside the proceeding that are substantially related to the rates under consideration in the proceeding. *See* Rules of Procedure, Section 1010.4(b)(8)(iii), (iv). If Bonneville revises the scope of the proceeding to include new issues, Bonneville will provide public notice on its website, present testimony or other information regarding such issues, and provide a reasonable opportunity to intervene and respond to Bonneville's testimony or other information. *Id.*

1. Expense and Capital Cost Forecasts

Bonneville's forecasts of its expense and capital costs are not determined in rate proceedings. Bonneville develops these forecasts for the purposes of setting rates in external processes, such as the IPR process described previously, with input from stakeholders. These forecasts are used in Bonneville's ratemaking, but do not establish Bonneville's budgets or spending levels for any program. Adjustments to, and selection of, projects for Bonneville's actual spending levels for its programmatic spending, including fish and wildlife spending, occur through the yearly budgetary review process, which includes submission of Bonneville's budget to Congress.

Bonneville also depreciates the capital spending on the Federal power and transmission systems over the service lives of the associated assets. Power's investments are depreciated over fixed periods. Transmission's depreciation is based on a depreciation study calculated consistent with industry standards. The service lives of power and transmission assets, as well as the depreciation study and resulting depreciation rates, are not determined in rate proceedings.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seek to raise issues with or challenge the appropriateness or reasonableness of: (1) the Administrator's forecasts of cost and spending levels, (2) the identification of projects used in Bonneville's cost forecasts,; or (3) any decisions on the depreciation rates that are used to calculate depreciation expense. If any re-examination of cost forecasts is necessary, such re-examination will occur outside of the rate proceeding.

The exclusion does not extend to those portions of the revenue requirement related to the following: (1) interest rate forecasts, (2) interest expense and credit, (3) Treasury repayment schedules, (4) calculation of depreciation and amortization expense, (5) forecasts of system replacements used in repayment studies, (6) purchased power expenses, (7) transmission cost incurred by Power Services, (8) generation cost incurred by Transmission Services, (9) minimum required net revenue, and (10) the costs of risk mitigation actions resulting from the expense and revenue uncertainties included in the risk analysis.

2. Federal and Non-Federal Debt Service and Debt Management

During the 2022 IPR process and in other forums, Bonneville provided the public with background information on Bonneville's internal Federal and non-Federal debt management policies and practices. While these policies and practices are not decided in the IPR process, these discussions were intended to inform interested parties about these matters so the parties would better understand Bonneville's debt structure. Bonneville's debt management policies and practices remain outside the scope of the rate proceeding.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address the appropriateness or reasonableness of Bonneville's debt management policies and practices. This exclusion does not encompass how debt management actions are reflected in ratemaking.

3. Financial and Accounting Policies and Practices

Bonneville's Financial Plan outlines objectives to sustain the agency's financial strength and resiliency. The Financial Plan focuses on four main areas: cost management; debt utilization; debt capacity; and liquidity. Bonneville has adopted certain financial policies to help further its financial objectives. Bonneville's Financial Reserves Policy establishes lower and upper thresholds for agency and business line financial reserves and parameters for actions to be taken when financial reserves are above or below the thresholds. Bonneville's Sustainable Capital Financing Policy guides BPA's use of debt and revenue financing to finance its capital investments. The terms of Bonneville's Financial Plan and Policies, along with Bonneville's internal financial and accounting policies and practices, are outside the scope of the BP–24 proceeding.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit the terms of

Bonneville's Financial Plan, Financial Reserves Policy, Sustainable Capital Financing Policy, internal financial and accounting policies and practices, and previous decisions regarding the adoption and implementation of the Financial Plan and Policies.

4. Tiered Rate Methodology (TRM)

The TRM restricts Bonneville and its customers with Contract High Water Mark (CHWM) contracts from proposing changes to the TRM's ratemaking guidelines unless certain procedures have been successfully concluded. No proposed changes have been subjected to the required procedures.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to propose revisions to the TRM made by Bonneville, customers with CHWM contracts, or their representatives. This exclusion does not extend to a party or customer that does not have a CHWM contract.

5. Rate Period High Water Mark (RHWM) Process

The RHWM Process preceded the start of the BP–24 proceeding. In that process, as directed by the TRM, Bonneville established FY 2024–2025 RHWMs for Public customers that signed contracts for firm requirements power service providing for tiered rates, referred to as CHWM contracts. Bonneville established the maximum planned amount of power a customer is eligible to purchase at Tier 1 rates during the rate period, the Above-RHWM Loads for each customer, the System Shaped Load for each customer, the Tier 1 System Firm Critical Output, RHWM Augmentation, the Rate Period Tier 1 System Capability (RT1SC), and the monthly/diurnal shape of RT1SC. The RHWM Process provided customers an opportunity to review, comment on, and challenge Bonneville's RHWM determinations.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit Bonneville's determination of a customer's FY 2024–2025 RHWM or other RHWM Process determinations.

6. 2008 Average System Cost Methodology (2008 ASCM) and Average System Cost Determinations

Section 5(c) of the Northwest Power Act established the Residential Exchange Program, which provides benefits to residential and farm consumers of Pacific Northwest utilities based, in part, on a utility's ''average system cost'' (ASC) of resources. The 2008 ASCM is not subject to challenge or review in a Section 7(i) proceeding. Determinations of the ASCs of participating utilities are made in separate processes conducted pursuant to the ASCM. Those processes began with ASC filings on June 1, 2022, and concluded in October 2022, with the publication of the Final ASC Reports.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit the appropriateness or reasonableness of the 2008 ASCM or of any of the ongoing ASC determinations.

7. 2012 Residential Exchange Program Settlement Agreement (2012 REP Settlement)

On July 26, 2011, the Administrator executed the 2012 REP Settlement, which resolved longstanding litigation over Bonneville's implementation of the Residential Exchange Program (REP) under Section 5(c) of the Northwest Power Act, 16 U.S.C. 839c(c). The Administrator's findings regarding the legal, factual, and policy challenges to the 2012 REP Settlement are explained in the REP–12 Record of Decision (REP–12 ROD). The Administrator's decisions regarding the 2012 REP Settlement and REP–12 ROD were upheld by the U.S. Court of Appeals for the Ninth Circuit in *Ass'n of Pub. Agency Customers* v. *Bonneville Power Admin.,* 733 F.3d 939 (9th Cir. 2013). Challenges to Bonneville's decision to adopt the 2012 REP Settlement and implement its terms in Bonneville's rate proceedings are not within the scope of this proceeding.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit in this rate proceeding Bonneville's determination to adopt the 2012 REP Settlement or its terms.

8. Service to the Direct Service Industries (DSIs)

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to revisit the appropriateness or reasonableness of Bonneville's decisions regarding service to the DSIs, including Bonneville's decision to offer contracts to the DSIs and the method, level of service, or other terms embodied in the existing DSI contracts.

9. Operation and Maintenance of the Power and Transmission Systems

Bonneville operates and maintains the Federal Columbia River Transmission System and, in coordination with other Federal entities, the FCRPS in accordance with good utility practice and with applicable reliability standards and operating requirements. Bonneville's power and transmission systems operation and maintenance practices and protocols, such as dispatcher standing orders, operating instructions, reliability of the system, compliance programs, and other operating requirements, are non-rate matters.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address issues regarding operation and maintenance practices and protocols.

10. Terms and Conditions of Transmission Service

Bonneville offers and provides transmission services, including interconnection service, and ancillary and control area services in accordance with the terms and conditions specified in its open access transmission tariff (Tariff), business practices, and applicable contracts. In addition to and concurrent with this rate proceeding, Bonneville is initiating the TC–24 proceeding to modify the Tariff terms and conditions. Bonneville's business practices provide implementation details for the Tariff. Bonneville's decisions regarding the business practices are determined in other forums and follow the procedures in Bonneville's Business Practice Process posted on its website. The Tariff terms and conditions, business practices, and the contracts and contract disputes between Bonneville and its customers are outside the scope of the BP–24 rate proceeding.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address issues regarding terms and conditions of transmission service, including interconnection service, and ancillary and control area services. This includes, but is not limited to, argument, testimony, or other evidence regarding Bonneville's decisions whether to offer particular transmission services, the terms and conditions for

participating in the EIM, the procedures and standards for modifications to Bonneville's Tariff or business practices, and whether to include certain terms and conditions in the Tariff or in business practices.

11. Oversupply Management Protocol

The proposed OS–24 Oversupply rate is a formula rate designed to recover Bonneville's actual oversupply costs incurred during the BP–24 rate period. Bonneville incurs oversupply costs pursuant to the Oversupply Management Protocol, Attachment P of Bonneville's Tariff.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address the terms of the Oversupply Management Protocol; whether the Oversupply Management Protocol complies with orders of the Commission; and whether Bonneville took all actions to avoid using the Oversupply Management Protocol, including the payment of negative prices to generators outside of Bonneville's balancing authority area. This exclusion does not extend to issues concerning the rates for recovering the costs of the Oversupply Management Protocol.

12. Market Initiatives and Regional Carbon Policies

Bonneville is engaged in a number of market initiatives that are outside of the scope of this proceeding. These include (1) the Western Energy Imbalance Market (EIM), which is an extension of the California Independent System Operator's (CAISO) real-time market; (2) the Western Resource Adequacy Program (WRAP); and (3) regional cap and trade policies.

Pursuant to Section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to raise or revisit Bonneville's decision to join the EIM, the WRAP, or review or address Bonneville's position on regional cap and trade policies. This exclusion does not extend to issues concerning rate incentives and the recovery or distribution of EIM-related, carbon-related, and WRAP-related costs or credits, which are within the scope of the BP–24 proceeding.

13. Potential Environmental Impacts, Biological Constraints, and Related Operations

Environmental impacts are addressed in a National Environmental Policy Act (NEPA) process Bonneville conducts concurrent with the rate proceeding. *See* Section II.B of this notice. In addition, biological constraints on hydropower operations are determined outside of the rate case through processes such as intra-agency consultations under the Endangered Species Act, 16 U.S.C. 1536(a)(2). Finally, implementation of the decision regarding operations, maintenance and configuration (management) of the Columbia River System evaluated in the Columbia River System Operations Environmental Impact Statement (CRSO EIS) and associated joint ROD with the U.S. Army Corps of Engineers and Bureau of Reclamation, and associated biological opinions, court orders, and other agreements, are also not issues to be addressed in this proceeding.

Pursuant to Section 1010.4(a)(8) of Bonneville's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address the potential environmental impacts of the rates being developed in this rate proceeding, potential biological effects of operations modeled in the proceeding, the appropriate hydroelectric constraints defined in these environmental compliance processes, or the operations, maintenance, and configuration, (management) assumptions, studies, decisions, or matters addressed in the CRSO EIS or CRSO EIS joint ROD and associated biological opinions, court orders, and other agreements.

B. The National Environmental Policy Act

Bonneville is in the process of assessing the potential environmental effects of its proposed power and transmission rate adjustments, consistent with NEPA. The NEPA process is conducted separately from the rate proceeding. As discussed above, all evidence and argument addressing potential environmental impacts of the rate adjustments being developed in the BP–24 rate proceeding are excluded from the rate proceeding record. Instead, comments on environmental effects should be directed to the NEPA process.

Based on its most current assessment of the proposed power and transmission rate adjustments, Bonneville believes this proposal may be the type of action typically excluded from further NEPA review pursuant to U.S. DOE NEPA regulations, which apply to Bonneville. More specifically, the proposal appears to solely involve changes to Bonneville's rates and other cost recovery and management mechanisms to ensure that there are sufficient revenues to meet Bonneville's financial obligations and other costs and expenses, while using existing generation sources operating within normal limits. As such, it appears this rate proposal falls within Categorical Exclusion B4.3, found at 10 CFR part 1021, subpart D, app. B4.3 (2015), which provides for the categorical exclusion from further NEPA review of ''[r]ate changes for electric power, power transmission, and other products or services provided by a Power Marketing Administration that are based on a change in revenue requirements if the operations of generation projects would remain within normal operating limits.''

Nonetheless, Bonneville is still assessing the proposal, and, depending upon the ongoing environmental review, Bonneville may instead issue another appropriate NEPA document. Comments regarding the potential environmental effects of the proposal may be submitted to Katey Grange, NEPA Compliance Officer, EC–4, Bonneville Power Administration, 905 NE 11th Avenue, Portland, Oregon 97232, and to *kcgrange@bpa.gov.* Any such comments received by the comment deadline for Participant Comments identified in Section III.A of this notice will be considered by Bonneville's NEPA compliance staff in the NEPA process that is being conducted for this proposal.

Part III—Public Participation in BP–24

A. Distinguishing Between ''Participants'' and ''Parties''

Bonneville distinguishes between ''participants in'' and ''parties to'' the BP–24 proceeding. Separate from the formal hearing process, Bonneville will receive written comments, views, opinions, and information from participants who may submit comments without being subject to the duties of, or having the privileges of, parties. Participants are not entitled to participate in the prehearing conference; may not cross-examine parties' witnesses, seek discovery, or serve or be served with documents; and are not subject to the same procedural requirements as parties. Bonneville customers whose rates are subject to this proceeding, or their affiliated customer groups, may not submit participant comments. Members or employees of organizations that have intervened in the proceeding may submit participant comments as private individuals (that is, not speaking for their organizations) but may not use the comment

procedures to address specific issues raised by their intervener organizations.

Written comments by participants will be included in the record and considered by the Administrator if they are received by Friday, December 9, 2022. Participants should submit comments through Bonneville's website at *www.bpa.gov/comment* or by hard copy to: BPA Public Involvement, DKE–7, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208. All comments should contain the designation ''BP–24'' in the subject line.

B. Interventions

Any entity or person intending to become a party in the BP–24 proceeding must file a petition to intervene through Bonneville's secure website (*https://ratecase.bpa.gov/).* A first-time user of Bonneville's secure website must create a user account to submit an intervention. Returning users may request access to the BP–24 proceeding through their existing accounts, and may submit interventions once their permissions have been updated. The secure website contains a link to the user guide, which provides step-by-step instructions for creating user accounts, generating filing numbers, submitting filings, and uploading interventions. Please contact the Hearing Coordinator via email at *cwgriffen@bpa.gov* or, if the question is time-sensitive, via telephone at (503) 230–5107, with any questions regarding the submission process.

All petitions to intervene must be submitted through the BP–24 proceeding secure website by the deadline established in the procedural schedule. Late interventions are strongly disfavored. Petitions to intervene must conform to the format and content requirements in Sections 1010.6 and 1010.11 of Bonneville's Rules of Procedure. Petitions must state the name and address of the entity or person requesting party status and the entity or person's interest in the hearing.

The Hearing Officer will rule on all petitions to intervene. Bonneville customers and affiliated customer groups will be granted intervention based on petitions filed in conformance with the Rules of Procedure. Other petitioners must explain their interests in sufficient detail to permit the Hearing Officer to determine whether the petitioners have a relevant interest in the hearing.

Bonneville or any party may oppose a petition to intervene. The deadline for opposing a timely petition to intervene is two business days after the deadline for filing the petition. Opposition to an untimely petition to intervene must be filed within two business days after service of the petition.

C. Developing the Record

The hearing record will include, among other things, the transcripts of the hearing, written evidence and argument entered into the record by Bonneville and the parties, written comments from participants, and other material accepted into the record by the Hearing Officer. The Hearing Officer will review and certify the record to the Administrator for final decision.

The Administrator will develop final rates based on the record and such other materials and information as may have been submitted to or developed by the Administrator. The Final ROD will be made available to all parties. Bonneville will file its rates with the Commission for confirmation and approval after issuance of the Final ROD.

Part IV—Summary of Rate Proposals

Bonneville is proposing power and transmission rates for FY 2024–25 that are consistent with the terms of the BP–24 Rates Settlement.

A. Summary of the Power Rate Proposal

Bonneville is proposing four primary rates for Federal power sales and services, along with general rate schedule provisions to implement such rates.

1. Priority Firm Power Rate (PF–24)

The PF rate schedule applies to sales of firm power to public body, cooperative, and Federal agency customers to meet their requirements pursuant to Section 5(b) of the Northwest Power Act. The PF Public rate applies to the sale of Firm Requirements Power under CHWM contracts with customers taking Load Following, Block, or Slice/Block service. Consistent with the TRM, Tier 1 rates include three charges: (1) customer charges, (2) a demand charge, and (3) a load shaping charge. In addition, two Tier 2 Short-Term rates are proposed, the Short-Term and Load Growth rates. These rates would be applicable to customers that have elected to purchase power from Bonneville for service to their Above-RHWM Load.

The proposed average Tier 1 non-Slice product rate impact, which represents the majority of Bonneville's power sales, is flat relative to BP–22. The overall average PF Tier 1 rate impact that includes the Slice and non-Slice products will be a slight decrease relative to BP–22. Customer-specific results will vary around these average impacts, with some customers experiencing higher rate impacts and some lower rate impacts, based on the specific situation of a particular customer.

The Base PF Exchange rate and its associated surcharges apply to sales pursuant to Residential Purchase and Sale Agreements and Residential Exchange Program Settlement Implementation Agreements with regional utilities that participate in the REP established under Section 5(c) of the Northwest Power Act, 16 U.S.C. 839c(c). The Base PF Exchange rate establishes the threshold for participation in the REP; only utilities with ASCs above the appropriate Base PF Exchange rate may receive REP benefits. If a utility meets the threshold, a utility-specific PF Exchange rate will be established in this proceeding for each eligible utility. The utility-specific PF Exchange rate is used in calculating the REP benefits each REP participant will receive during FY 2024–2025.

The proposed PF–24 rate schedule also includes resource support services rates for customers with non-Federal resources, and a melded PF rate for Public customers that have elected power sales contracts other than CHWM contracts for firm requirements service.

2. New Resource Firm Power Rate (NR–24)

The NR–24 rate applies to firm power sales to investor-owned utilities (IOUs) to meet their net requirements pursuant to Section 5(b) of the Northwest Power Act. The NR–24 rate is also applied to sales of firm power to Public customers when this power is used to serve new large single loads. In addition, the NR rate schedule includes rates for services to support Public customers serving new large single loads with non-Federal resources. In the BP–24 Initial Proposal, Bonneville is forecasting no power sales at the NR rate.

3. Industrial Firm Power Rate (IP–24)

The IP rate is applicable to firm power sales to DSI customers authorized by Section 5(d)(1)(A) of the Northwest Power Act, 16 U.S.C. 839c(d)(1)(A). In the BP–24 Initial Proposal, Bonneville is forecasting sales to one DSI customer at the IP rate.

4. Firm Power and Surplus Products and Services Rate (FPS–24)

The FPS rate schedule is applicable to sales of various surplus power products and surplus transmission capacity for use inside and outside the Pacific Northwest. The rates for these products are negotiated between Bonneville and the purchasers. The FPS–24 rate schedule also includes rates for customers with non-Federal resources;

the Unanticipated Load Service rate; rates for other capacity, energy, and scheduling products and services; rates for reserve services for use outside the Bonneville balancing authority area; and real power losses rates for customers that elect financial settlement of real power losses. Bonneville is proposing a new FPS rate, the Firm Water Transition Power rate that would be applicable to specific Slice customers to help transition them to Bonneville's recently adopted 30-water year and 10th percentile metrics for forecasting firm output.

5. Power General Rate Schedule Provisions (GRSPs)

The Power GRSPs include general rate schedule terms and conditions applicable to Bonneville's power rates. In addition, the Power GRSPs contain special rate adjustments, charges, credits, and pass-through mechanisms for specific events and customer circumstances. Among other matters covered by the Power GRSPs are provisions related to calculating rates, resource support services, charges associated with transfer service, risk adjustments, Slice True-up, the Residential Exchange Program, conservation, payment options, and other charges. Bonneville is proposing two new GRSPs: the Washington Cap-and-Invest Program Charge that would be applicable if Bonneville becomes a First Jurisdictional Deliverer in this program; and a Resource Adequacy Service credit and charge that would be applicable if Bonneville begins participation in a binding season in the Western Resource Adequacy Program under certain defined conditions. Bonneville is also proposing a change in the market index it uses for various services and rates as well as proposing the addition of a rate cap on the Unauthorized Increase Charge.

B. Summary of the Transmission Rate Proposal

Bonneville is proposing to extend the current (BP–22) transmission rate levels for the FY 2024–25 rate period, pursuant to the BP–24 Rates Settlement. Bonneville is proposing separate transmission rates for its Network segment, intertie segments, ancillary and control area services, and for various specific purposes.

1. Network Rates

The Network Integration Transmission Rate (NT–24) applies to customers taking network integration service, which allows customers to flexibly serve retail load.

The Point-to-Point Rate (PTP–24) is a contract demand rate that applies to customers taking Point-to-Point service on Bonneville's network. Point-to-Point service provides customers with service from identified points of receipt to identified points of delivery. There are separate rates for long-term firm service, and various increments of firm and non-firm short-term service.

The Formula Power Transmission Rate (FPT–24.1) is based on the cost of using specific types of facilities, including a distance component for the use of transmission lines, and is charged on a contract demand basis.

2. Intertie Rates

The Southern Intertie Rate (IS–24) is a contract demand rate that applies to customers taking Point-to-Point service on the Southern Intertie.

The Montana Intertie Rate (IM–24) applies to customers taking Point-to-Point service on the Eastern Intertie and that are not parties to the Montana Intertie Agreement.

The Townsend-Garrison Transmission Rate (TGT–24) applies to parties to the Montana Intertie Agreement taking firm service over Bonneville's section of the Montana Intertie.

The Eastern Intertie Rate (IE–24) applies to parties to the Montana Intertie Agreement taking non-firm service on the portion of the Eastern Intertie capacity that exceeds Bonneville's firm transmission rights.

3. Other Transmission Rates and General Rate Schedule Provisions

The Use-of-Facilities Rate (UFT–24) establishes a formula rate for the use of a specific facility based on the annual cost of that facility.

The Advance Funding Rate (AF–24) allows Bonneville to collect the capital and related costs of specific facilities through an advance-funding mechanism.

The Regional Compliance Enforcement and Regional Coordinator rate (RC–24) recovers costs assessed to Bonneville for regional reliability compliance monitoring, enforcement, and reliability coordination services.

The Oversupply Rate (OS–24) recovers the costs Bonneville incurs to displace generation under the Oversupply Management Protocol, Attachment P to Bonneville's Tariff.

Other proposed transmission rates and charges include: a Utility Delivery Charge for the use of low-voltage delivery substations; a Reservation Fee for customers that postpone the service commencement date of transmission service; incremental cost rates for transmission service requests that require new facilities; a penalty charge for failure to comply with dispatch, curtailment, redispatch, or load shedding orders; an Unauthorized Increase Charge for use of the transmission system in excess of contracted-for demand; and rate adjustment mechanisms consistent with Bonneville's Financial Policies.

Bonneville's proposes two new charges associated with real power loss returns. First, Bonneville is proposing a charge to settle loss imbalances associated with in-kind loss returns. In addition, the Invalid Loss Return penalty charge is proposed to replace the Financial for Inaccuracy penalty charge in the current rate schedules and incent accurate and timely return of in-kind loss return obligations.

4. Ancillary Service and Control Area Service Rates

The BP–24 Transmission Rates Proposal includes rates for Bonneville's Ancillary and Control Area Services, along with certain updates to those rates and new rates. Bonneville proposes two new rates and certain changes to existing rates to support its participation in the EIM.

The EIM Contingency Rate is a new rate Bonneville is proposing to apply under temporary EIM contingency events that require corrective action. This rate would allow the EIM market operator to settle using an alternative pricing index when EIM pricing is unavailable.

Bonneville is proposing a new rate to recover credits and charges for the Flexible Ramping Product associated with EIM participation. Bonneville did not previously recover these credits and charges in rates.

Bonneville proposes to remove or revise certain provisions of the rate schedules that were adopted in the BP–22 rate proceeding to account for the mid-rate period transition to the Western EIM.

D. Risk Mitigation Tools

Bonneville is proposing three rate adjustment mechanisms for BP–24 power and transmission rates, primarily to buffer against poor financial performance over the rate period and protect the agency's solvency and strong credit rating. These mechanisms implement Bonneville's Financial Reserves Policy (FRP) and provide for adjustments to a business line's rates or other action in the event the business line's financial reserves for risk (Financial Reserves) fall below or exceed certain thresholds.

The Cost Recovery Adjustment Clause (CRAC) will adjust rates upward to

generate additional revenue within the rate period if business line Financial Reserves fall below a defined lower threshold.

The Financial Reserves Policy Surcharge (FRP Surcharge) will also adjust rates upward to generate additional revenue within the rate period if business line Financial Reserves fall below a defined lower threshold.

Finally, the Reserves Distribution Clause (RDC) will trigger if Financial Reserves exceed upper thresholds for the business line and the agency as a whole. If the RDC triggers, Bonneville will consider the amount of Financial Reserves above the threshold for rate relief or investment in high-value, business line-specific purposes such as debt retirement.

Bonneville is proposing certain revisions in the three risk adjustment clauses. First, for FY 2024, the three Power risk adjustment clauses will not be applicable to the portion of a customer's service at PF Tier 1 rates that has been converted from a Slice product to a non-Slice product beginning October 1, 2023. However, the three risk adjustment clauses will apply to such customer's entire service at PF Tier 1 rates for FY 2025. Second, any FY 2024 or 2025 Power RDC will automatically provide a dividend distribution in an amount equal to the lesser of the RDC amount and the amount of Planned Net Revenues for Risk included in the BP–24 power rates. And third, the caps on the Power and Transmission RDCs are removed for the BP–24 rate period, FY 2024–2025.

Part V—Proposed BP–24 Power Rate Schedules and BP–24 Transmission Rates Schedules

Bonneville's proposed BP–24 Power Rate Schedules and BP–24 Transmission Rate Schedules, which includes Transmission, Ancillary, and Control Area Services Rate Schedules, are a part of this notice and are available for viewing and downloading on Bonneville's website at *https://www.bpa.gov/goto/BP24.* The BP–24 Rates Settlement agreement is also posted at this website.

Signing Authority

This document of the Department of Energy was signed on November 8, 2022, by John L. Hairston, Administrator and Chief Executive Officer of the Bonneville Power Administration, pursuant to delegated authority from the Secretary of Energy. This document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 15, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–25196 Filed 11–17–22; 8:45 am]

BILLING CODE 6450–01–P

Southwest Power Pool, Inc	Docket No. ER23–72–000.
Southwest Power Pool, Inc	Docket No. EL22–70–000.
Public Service Company of New Mexico	Docket No. ER22–2158–001.
Public Service Company of New Mexico	Docket No. EL22–40–000.
Idaho Power Company	Docket No. EL22–37–000.
PacifiCorp	Docket Nos. EL22–38–000, EL22–38–001.
Public Service Company of Colorado	Docket No. EL22–39–000.
Puget Sound Energy, Inc	Docket No. EL22–41–000.
Puget Sound Energy, Inc	Docket No. ER23–22–000.
PPL Electric Utilities Corporation	Docket No. ER22–2719–000.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD21–15–000]

Joint Federal-State Task Force on Electric Transmission; Supplemental Notice of Meeting

As first announced in the Commission's September 8, 2022 Notice [1] in the above-captioned docket, the next public meeting of the Joint Federal-State Task Force on Electric Transmission (Task Force) will be held on November 15, 2022, at the New Orleans Marriott in New Orleans, LA, from approximately 8:00 a.m. to 10:30 a.m. Central time. Commissioners may attend and participate in this meeting. Attached to this Notice is an agenda for the meeting.

The meeting will be open to the public for listening and observing and on the record. There is no fee for attendance and registration is not required. The public may attend in person or via Webcast.[2] This conference will be transcribed. Transcripts will be available for a fee from Ace Reporting, 202–347–3700.

Discussions at the meeting may involve issues raised in proceedings that are currently pending before the Commission. These proceedings include, but are not limited to:

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

More information about the Task Force, including frequently asked questions, is available here: *https://www.ferc.gov/TFSOET.* For more information about this meeting, please contact: Gretchen Kershaw, 202–502–8213, *gretchen.kershaw@ferc.gov;* or Jennifer Murphy, 202–898–1350, *jmurphy@naruc.org.* For information related to logistics, please contact Benjamin Williams, 202–502–8506, *benjamin.williams@ferc.gov;* or Rob Thormeyer, 202–502–8694, *robert.thormeyer@ferc.gov.*

[1] *Joint Fed.-State Task Force on Elec. Transmission,* Notice, Docket No. AD21–15–000 (issued Sept. 8, 2022).

[2] A link to the Webcast will be available on the day of the event at *https://www.ferc.gov/TFSOET.*

Dated: November 14, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

Joint Federal-State Task Force on Electric Transmission

Docket No. AD21–15–000

November 15, 2022

Agenda

8:00 a.m.–10:30 a.m.—Addressing Regulatory Gaps/Challenges in Oversight of Transmission Development

[FR Doc. 2022–25160 Filed 11–17–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC23–26–000.

Applicants: EdSan 1B Group 1 Edwards, LLC, EdSan 1B Group 1 Sanborn, LLC, EdSan 1B Group 2, LLC, EdSan 1B Group 3, LLC, Daylight I, LLC, Edwards Solar Line I, LLC, Sanborn Solar Line I, LLC, Axium ES Holdings LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of EdSan 1B Group 1 Edwards, LLC, et al.

Filed Date: 11/10/22.

Accession Number: 20221110–5246.

Comment Date: 5 p.m. ET 12/27/22.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–23–000.

Applicants: AES Kuihelani Solar, LLC.

Description: AES Kuihelani Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/14/22.

Accession Number: 20221114–5069.

Comment Date: 5 p.m. ET 12/5/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2374–015; ER22–2649–000; ER17–2059–009; EL22–57–000.

Applicants: Puget Sound Energy, Inc., Puget Sound Energy, Inc., Puget Sound Energy, Inc., Puget Sound Energy, Inc.

Description: Refund Report of Puget Sound Energy, Inc. et al.

Filed Date: 11/10/22.

Accession Number: 20221110–5266.

Comment Date: 5 p.m. ET 12/1/22.

Docket Numbers: ER23–273–001.

Applicants: Wisconsin Public Service Corporation.

Description: Tariff Amendment: Amendment to Revisions to the AS Tariff for Reactive Supply Service to be effective 1/1/2023.

Filed Date: 11/14/22.

Accession Number: 20221114–5248.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–415–000.

Applicants: Idaho Power Company.

Description: Compliance filing: Interconnection Study Metric Report to be effective N/A.

Filed Date: 11/14/22.

Accession Number: 20221114–5004.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–416–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6703; Queue Nos. AB2–077/AB2–078/AB2–079 to be effective 10/12/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5006.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–417–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2022–11–11 Nereo Amnd LGIA—643–0.0.0 to be effective 11/12/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5007.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–418–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc., requests a one-time prospective waiver of Section 5.13.1, of its Market Administration and Control Area Services Tariff.

Filed Date: 11/10/22.

Accession Number: 20221110–5248.

Comment Date: 5 p.m. ET 11/15/22.

Docket Numbers: ER23–419–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2022–11–14_SA 3328 Termination of Badger Hollow Solar Farm-ATC E&P (J870 J871) to be effective 11/15/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5055.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–420–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Montana Intertie Proj Trans Agmt Ex F Concurrence to be effective 10/1/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5068.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–421–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2022–11–14_SA 3471 Entergy Mississippi-Tunica Windpower 1st Rev GIA (J866) to be effective 10/19/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5090.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–422–000.

Applicants: American Electric Power Service Corporation, AEP Indiana Michigan Transmission Company, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii): AEP submits CIAC, SA No. 6679 CIAC with IMTCO and NIPSCO to be effective 10/17/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5113.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–423–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OA re: termination of Hill Energy Resources & Services, LLC to be effective 1/17/2023.

Filed Date: 11/14/22.

Accession Number: 20221114–5150.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–424–000.

Applicants: Midcontinent Independent System Operator, Inc., ITC Midwest LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2022–11–14_SA 3929 ITC Midwest-Salt Creek E&P (J1365) to be effective 11/8/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5173.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–425–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 6062; Queue No. AG1–253 to be effective 4/6/2021.

Filed Date: 11/14/22.

Accession Number: 20221114–5256.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–426–000.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2022–11–14 Compliance Filing—NAESB Standards to be effective 12/31/9998.

Filed Date: 11/14/22.

Accession Number: 20221114–5286.

Comment Date: 5 p.m. ET 12/5/22.

Docket Numbers: ER23–427–000.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2022–11–14 Waiver Filing—NAESB Standards to be effective N/A.

Filed Date: 11/14/22.

Accession Number: 20221114–5288.

Comment Date: 5 p.m. ET 12/5/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 14, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–25159 Filed 11–17–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: PR23–6–001.

Applicants: Questar Gas Company.

Description: § 284.123 Rate Filing: Amendment to 1 to be effective 12/1/2022.

Filed Date: 11/10/22.

Accession Number: 20221110–5146.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP20–957–001.

Applicants: Golden Pass LNG Terminal LLC.

Description: Petition to Amend Waiver of the Buy-Sell Prohibition of Golden Pass LNG Terminal LLC under RP20–957.

Filed Date: 11/14/22.

Accession Number: 20221114–5115.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP21–1093–001.

Applicants: Enable Gas Transmission, LLC.

Description: Compliance filing: Activity Report for First Year of Firm PALS Service to be effective N/A.

Filed Date: 11/14/22.

Accession Number: 20221114–5106.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP22–320–001.

Applicants: ANR Pipeline Company.

Description: Report Filing: Supplement to GCXP Notice of Commencement to be effective N/A.

Filed Date: 11/14/22.

Accession Number: 20221114–5189.

Comment Date: 5 p.m. ET 11/28/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

Filings Instituting Proceedings

Docket Numbers: RP23–182–000.

Applicants: Caledonia Energy Partners, L.L.C.

Description: § 4(d) Rate Filing: Caledonia Energy Partners, LLC Housekeeping Filing to be effective 12/10/2022.

Filed Date: 11/10/22.

Accession Number: 20221110–5196.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: RP23–183–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Bug Co to Atlantic 810133 eff 11–11–2022 to be effective 11/11/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5000.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP23–184–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: REX 2022–11–11 Negotiated Rate Agreement Amendment to be effective 11/12/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5001.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP23–185–000.

Applicants: Northwest Pipeline LLC.

Description: § 4(d) Rate Filing: 2022 Housekeeping Filing to be effective 12/12/2022.

Filed Date: 11/14/22.

Accession Number: 20221114–5003.

Comment Date: 5 p.m. ET 11/28/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 14, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–25158 Filed 11–17–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2021–0083; FRL–9409–07–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients October 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before December 19, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2021–0083, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–1400, email address:

BPPDFRNotices@epa.gov. The mailing address is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*https://www.epa.gov/pesticide-registration/participation-process-registration-actions*).

Notice of Receipt—New Active Ingredients

File Symbol: 69553–RE. *Docket ID number:* EPA–HQ–OPP–2022–0853. *Applicant:* Andermatt Group AG, Stahlermatten 6, CH–6146 Grossdietwil, Switzerland c/o Andermatt USA Corporation, 107 Gilbreth Parkway, Mullica Hill, NJ 08062. *Product name:* Madex XLV. *Active ingredient:* Insecticide—*Cydia pomonella* granulovirus isolate GV–0017 at 0.06%. *Proposed use:* For use against the codling moth on fruit or nut trees in commercial and residential areas. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 8, 2022.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2022–25133 Filed 11–17–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0163; FRL–9408–10–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Uses October 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before December 19, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2022–0163, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–1400, email address: *BPPDFRNotices@epa.gov;* or Dan Rosenblatt, Registration Division (RD) (7505T), main telephone number: (202) 566–2875, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

Notice of Receipt—New Uses

1. *File Symbols:* 62719–497, 62719–621. *Docket ID Number:* EPA–HQ–OPP–2022–0386. *Applicant:* Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active Ingredient:* Spinosad. *Product Type:* Insecticide. *Proposed Uses:* Stalk and stem vegetable subgroup 22A, greenhouse uses on cucumber, lettuce head and leafy, pepper and tomato, and a crop group conversion of existing tolerances for Spice Subgroup 19B except black pepper to spice group 26. *Contact:* RD.

2. *File Symbols:* 62719–539, 62719–541, 62719–545. *Docket ID Number:* EPA–HQ–OPP–2022–0384. *Applicant:* Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active Ingredient:* Spinetoram. *Product Type:* Insecticide. *Proposed Uses:* Stalk and stem vegetable subgroup 22A, greenhouse uses on cucumber, lettuce head and leafy, pepper and tomato, and a crop group conversion of existing tolerances for spice subgroup 19B except black pepper to spice group 26. *Contact:* RD.

3. *EPA Registration Number:* 71840–26. *Docket ID number:* EPA–HQ–OPP–2022–0852. *Applicant:* BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. *Active ingredients: Bacillus subtilis* strain BU1814 and *Bacillus amyloliquefaciens* strain MBI 600. *Product type:* Fungicide. *Proposed use:* In-furrow. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 8, 2022.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2022–25190 Filed 11–17–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–044]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS) Filed November 4, 2022 10 a.m. EST Through November 14, 2022 10 a.m. EST Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20220164, Draft, FHWA, LA, I–10 Calcasieu River Bridge Improvements, Comment Period Ends: 01/03/2023, Contact: Daniel Suarez 225–757–7615.

EIS No. 20220165, Draft, USFWS, OR, Elliott State Research Forest Habitat Conservation Plan, Comment Period Ends: 01/03/2023, Contact: Shauna Everett 503–231–6949.

EIS No. 20220166, Final, EPA, IBWC, CA, United States-Mexico-Canada Agreement Mitigation of Contaminated Transboundary Flows Project, Review Period Ends: 12/19/2022, Contact: Steven Smith 415–972–3752.

EIS No. 20220167, Draft, USFS, CA, North Yuba Landscape Resilience Project, Comment Period Ends: 01/03/2023, Contact: John I Brokaw 530–265–4531.

EIS No. 20220168, Final, NMFS, PRO, Programmatic Environmental Impact Statement for the Marine Mammal Health and Stranding Response Program, Review Period Ends: 12/19/2022, Contact: Stephen Manley 301–427–8476.

EIS No. 20220169, Final, BLM, USFS, ID, Husky 1 North Dry Ridge Phosphate Mine, Review Period Ends: 12/19/2022, Contact: Wes Gilmer 208–478–6369.

EIS No. 20220170, Draft Supplement, FHWA, WI, I–94 East—West (16th Street—70th Street) Milwaukee County, WI, Comment Period Ends: 01/17/2023, Contact: Bethaney Bacher-Gresock 608–662–2119.

EIS No. 20220171, Draft, BOEM, NY, Empire Offshore Wind, Comment Period Ends: 01/17/2023, Contact: Brandi Sangunett 703–787–1015.

Dated: November 14, 2022.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–25194 Filed 11–17–22; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice EIB–2022–0020]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP089351XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with the Export-Import Bank Act of 1945, as amended, the Export-Import Bank of the United States (''EXIM'') has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million. Comments received within the comment period specified below will be presented to the EXIM Board of Directors prior to final action on this Transaction.

Comments received within the comment period specified below will be presented to the EXIM Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before December 13, 2022 to be assured of consideration before final consideration of the transaction by the Board of Directors of EXIM.

ADDRESSES: Comments may be submitted through *Regulations.gov* at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2022–0020 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2022–0020 on any attached document.

SUPPLEMENTARY INFORMATION:

Reference: AP089351XX.

Purpose and Use:

Brief description of the purpose of the transaction: The U.K. obligor is seeking EXIM financing to cover the procurement of two U.S. rocket launches and U.S. brokered launch and initial in-orbit insurance services to support the deployment of two communication satellites.

Brief non-proprietary description of the anticipated use of the items being exported: The U.K. obligor will use the U.S. rocket launches and U.S. brokered insurance services to deploy two

communications satellites that will provide satellite connectivity for fixed and mobile services.

To the extent that EXIM is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Suppliers: Space Exploration Technologies Corp, United Launch Services LLC and Aon International Space Brokers, a division of Aon Risk Services Inc. of Washington, DC.

Obligor: Viasat Technologies Ltd.

Guarantor(s): Viasat Inc.

Description of Items Being Exported: Launch Services and Insurance Services.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2022–25151 Filed 11–17–22; 8:45 am]

BILLING CODE P

EXPORT-IMPORT BANK

[Public Notice EIB–2022–0019]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP089457XX

AGENCY: Export-Import Bank.

ACTION: Notice.

SUMMARY: This Notice is to inform the public the Export-Import Bank of the United States (''EXIM'') has received an application for final commitments for aggregated long-term loans or financial guarantees in excess of $100 million. Comments received within the comment period specified below will be presented to the EXIM Board of Directors prior to final action on these Transactions.

DATES: Comments must be received on or before December 13, 2022 to be assured of consideration before final consideration of the transactions by the Board of Directors of EXIM.

ADDRESSES: Comments may be submitted through *Regulations.gov* at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2022–0019 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2022–0019 on any attached document.

SUPPLEMENTARY INFORMATION:

Reference: AP089457XX.

Purpose and Use:

Brief description of the purpose of the transaction: To support the export of U.S.-manufactured commercial aircraft to Ethiopia.

Brief non-proprietary description of the anticipated use of the items being exported: To be used for passenger and cargo air transport between Ethiopia and countries within Africa, the Middle East and Europe.

To the extent that EXIM is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: The Boeing Company.

Obligor: Ethiopian Airlines Group.

Guarantor(s): N/A.

Description of Items Being Exported: Boeing commercial jet aircraft.

Information on Decision: Information on the final decision for these transactions will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Authority: Section 3(c)(10) of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635a(c)(10)).

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2022–25153 Filed 11–17–22; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Annual Report for Fiscal Year 2022 and Three-Year Plan

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued its *Annual Report for Fiscal Year 2022 and Three-Year Plan.* Respondents are encouraged to comment on the content of the annual report and FASAB's project priorities for the next three years. Written comments are requested by January 18, 2023, and should be sent to *fasab@fasab.gov* or Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

ADDRESSES: The *Annual Report for Fiscal Year 2022 and Three-Year Plan* is available on the FASAB website at *https://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: 31 U.S.C. 3511(d), Federal Advisory Committee Act, as amended (5 U.S.C. App.).

Dated: November 15, 2022.

Monica R. Valentine,

Executive Director.

[FR Doc. 2022–25189 Filed 11–17–22; 8:45 am]

BILLING CODE 1610–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0095; FR ID 114444]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this

opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments shall be submitted on or before January 17, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0095.

Title: Multi-Channel Video Programming Distributors Annual Employment Report, FCC Form 395–A.

Form Number: FCC Form 395–A.

Type of Review: Extension of currently approved collection.

Respondents: Business or other for-profit entities; Not for profit institutions

Number of Respondents and Responses: 2,500 respondents; 2,500 responses.

Estimated Time per Response: One hour.

Frequency of Response: Recordkeeping requirement and annual reporting requirement.

Total Annual Burden: 2,500 hours.

Total Annual Cost: No cost.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) and 634 of the Communications Act of 1934, as amended.

Needs and Uses: FCC Form 395–A, ''The Multi-Channel Video Programming Distributor Annual Employment Report,'' is a data collection device used to assess industry employment trends and provide reports to Congress. The report identifies employees by gender and race/ethnicity in sixteen job categories. FCC Form 395–A contains a grid which collects data on full and part-time employees and requests a list of employees by job title, indicating the job category and full or part-time status of the position. Every cable entity with 6 or more full-time employees and all Satellite Master Antenna Television Systems (SMATV) serving 50 or more subscribers and having 6 or more full-time employees must complete Form 395–A in its entirety and file it by September 30 each year. However, cable entities with 5 or fewer full-time employees are not required to file but if they do, they need to complete and file only Sections I, II and VIII of the FCC Form 395–A, and thereafter need not file again unless their employment increases.

On June 4, 2004, the FCC released the Third Report and Order and Fourth Notice of Proposed Rulemaking (3rd R&O), In the *Matter of Review of the Commission's Broadcast and Cable Equal Employment Opportunity Rules and Policies, MM Docket No. 98–204, FCC 04–103,* in which it considers issues relating to the Annual Employment Report forms, including FCC Form 395–A, ''The Multi-Channel Video Programming Distributor Annual Employment Report.'' In the 3rd R&O, the Commission is adopting revised rules for MVPDs to file FCC Form 395–A, which cable and other MVPDs will use to file annual employment reports. The intent of this 3rd R&O is to update rules for MVPDs to file Form 395–A consistent with new rules adopted in the 2nd R&O. The intent of the Fourth Notice of Proposed Rulemaking is to provide time for cable and other MVPDs and the public to address the issue of whether the Commission should keep these forms confidential after they are filed.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–25197 Filed 11–17–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, December 1, 2022 at 10 a.m.

PLACE: Hybrid meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

Note: For those attending the meeting in person, current COVID–19 safety protocols for visitors, which are based on the CDC COVID–19 community level in Washington, DC, will be updated on the commission's contact page by the Monday before the meeting. See the contact page at *www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the COVID–19 community level and corresponding health and safety procedures. to access the meeting virtually, go to the commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

REG 2011–02 Draft Final Rule and Explanation and Justification on internet Communications Disclaimers

REG 2021–01 Draft Notice of Proposed Rulemaking on Candidate Salaries

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Submitted: November 15, 2022.

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2022–25240 Filed 11–16–22; 11:15 am]

BILLING CODE 6715–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MRB–2022–05; Docket No. GAPFAC 2022–0001; Sequence No. 1]

GSA Acquisition Policy Federal Advisory Committee; Notification of Upcoming Web-Based Public Subcommittee Meetings

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: Notice of these web-based subcommittee meetings is being provided in accordance with GSA Policy. This notice provides the schedule for a series of web-based meetings for three subcommittees of the GSA Acquisition Policy Federal Advisory Committee (GAP FAC): the Acquisition Workforce Subcommittee, the Industry Partnerships Subcommittee, and the Policy and Practice Subcommittee. It is GSA policy that subcommittee meetings are open for the public to observe. Information on attending and providing written public comment is under the MEETING REGISTRATION section.

DATES: The Acquisition Workforce Subcommittee will hold recurring web-based meetings every other Tuesday from December 6, 2022 through September 26, 2023, from 3:00 p.m. to 5:00 p.m., Eastern Standard Time (EST). The Industry Partnerships Subcommittee will hold recurring web-based meetings every other Wednesday from December 7, 2022, through September 27, 2023, from 3:00 p.m. to 5:00 p.m., EST. The Policy and Practice Subcommittee will hold recurring web-based meetings every other Thursday from December 8, 2022, through September 28, 2023, from 3:00 p.m. to 5:00 p.m., EST.

ADDRESSES: The meetings will be accessible via webcast. Registrants will receive the webcast information before the meeting.

FOR FURTHER INFORMATION CONTACT: Boris Arratia, Designated Federal Officer, Office of Government-wide Policy, 703–795–0816, or email: *boris.arratia@gsa.gov;* or Stephanie Hardison, Office of Government-wide Policy, 202–258–6823, or email: *stephanie.hardison@gsa.gov.* Additional *information about* the subcommittees and the Committee, including meeting materials and agendas, will be available on-line at *https://gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee.*

SUPPLEMENTARY INFORMATION: The Administrator of GSA established the GAP FAC as a discretionary advisory committee under agency authority in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app 2). As America's buyer, GSA is uniquely positioned to enable a modern, accessible, and streamlined acquisition ecosystem and a robust marketplace connecting buyers to the suppliers and businesses that meet their mission needs. The GAP FAC will assist GSA in this endeavor through expert advice on a broad range of innovative solutions to acquisition policy, workforce, and industry partnership challenges.

The GAP FAC will serve as an advisory body to GSA's Administrator on how GSA can use its acquisition tools and authorities to target the highest priority Federal acquisition challenges. The GAP FAC will advise GSA's Administrator on emerging acquisition issues, challenges, and opportunities to support its role as America's buyer. The initial focus for the GAP FAC will be on driving regulatory, policy, and process changes required to embed climate and sustainability considerations in Federal acquisition. This includes examining and recommending steps GSA can take to support its workforce and industry partners in ensuring climate and sustainability issues are fully considered in the acquisition process. To accomplish its work, the GAP FAC established three subcommittees: Policy and Practices, Industry Partnerships, and Acquisition Workforce.

The Policy and Practice Subcommittee will focus on procurement policy that supports robust climate and sustainability action. This group will focus on regulatory, policy, and process changes required to embed climate and sustainability considerations in Federal acquisitions.

The Industry Partnerships Subcommittee will investigate ways to expand a climate focus on Federal acquisition while reinforcing inclusion, domestic sourcing, small business opportunity, and innovation from an Industry standpoint. This includes identifying and addressing gaps in sustainable attributes standards for the goods and services that the Federal government buys.

The Acquisition Workforce Subcommittee will explore ways to advance a culture of sustainability and climate action within the acquisition workforce. This includes equipping and enabling the acquisition workforce to effectively use sustainability as a critical element in the evaluation and source selection process.

Purpose of the Meetings

The purpose of these web-based meetings is for the subcommittees to develop recommendations for submission to the full Committee. The Committee will, in turn, deliberate on the subcommittees recommendations and decide whether to proceed with formal advice to GSA based upon them.

Meeting Agenda

- Opening Remarks
- Subject Matter Experts Presentations
- Subcommittee Member Discussions
- Closing Remarks and Adjourn

Meeting Registration

The subcommittee meetings are open to the public and will be accessible by webcast. All public attendees will need to register to obtain the meeting webcast information. Registration information is located on the GAP FAC website: *https://www.gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee.* All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive webcast access information via email.

Public Comments

Written public comments are being accepted via *http://www.regulations.gov,* the Federal eRulemaking portal throughout the life of the three Subcommittees. To submit a written public comment, go to *http://www.regulations.gov* and search for GAPFAC–2022–0001. Select the link ''Comment Now'' that corresponds with this notice. Follow the instructions provided on the screen. Please include your name, company name (if applicable), and ''GAPFAC–2022–0001, Notification of Upcoming Web-Based Public Meetings'' on your attached document (if applicable).

Special Accomodations

For information on services for individuals with disabilities, or to request accommodation of a disability, please contact the Designated Federal Officer at least 10 business days prior to the meeting to give GSA as much time as possible to process the request. Live ASL interpreter services will be available.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Government-wide Policy.

[FR Doc. 2022–25228 Filed 11–17–22; 8:45 am]

BILLING CODE 6820–RV–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0306; Docket No. 2022–0001; Sequence No. 14]

Submission for OMB Review; General Services Administration Acquisition Regulation; Transactional Data Reporting

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division is submitting a request to the Office of Management and Budget (OMB) to review and approve an extension of a previously approved information collection requirement regarding OMB Control No. 3090–0306, Transactional Data Reporting.

DATES: Submit comments on or before: December 19, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments''; or by using the search function.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas O'Linn, Procurement Analyst, General Services Acquisition Policy Division, GSA, 202–445–0390 or email *gsarpolicy@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection is for GSA Federal Supply Schedules (FSS) and non-FSS offerors and contractors subject to transactional data report (TDR) requirements. Transactional data encompasses the historical details of the products or services delivered by a contractor during the performance of task or delivery orders issued against a contract subject to TDR requirements. TDR requirements are found within Alternate I of General Services Administration Acquisition Regulation (GSAR) clause 552.238–80, Industrial Funding Fee and Sales Reporting, and 552.216–75, Transactional Data Reporting. GSAR clauses 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts (Deviation II); Alternate I of 552.238–81, Price Reductions; 552.238–83 Examination of Records by GSA; and 552.238–85, Contractor's Billing Responsibilities, are additional GSAR clause directly associated with FSS contracts subject to these requirements. This information collection does not apply to GSA FSS offerors and contractors subject to pricing disclosures and sales reporting requirements. The burden associated with pricing disclosures and sales reporting requirements is covered under information collection OMB control number 3090–0235, Federal Supply Schedule Pricing Disclosures and Sales Reporting.

B. Annual Reporting Burden

The total estimated annual public cost burden for this information collection is estimated to be $18,104,484.46. The total estimated annual public burden hours resulting from this information collection is 281,344 hours. These numbers are calculated by adding up the total estimated annual burden cost/hour for each of the following GSAR clauses covered by this information collection: 552.216–75, Transactional Data Reporting; Alternate I of 552.238–80, Industrial Funding Fee and Sales Reporting; Alternate I of 552.238–81, Price Reductions; 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts (Deviation II); 552.238–83, Examination of Records by GSA; and 552.238–85, Contractor's Billing Responsibilities.

Burden Cost/Hour Calculation.

Total estimated burden hour/cost for the basic version of 552.216–75, Transactional Data Reporting, and Alternate I of GSAR clause 552.238–80, Industrial Funding Fee and Sales Reporting.

The two primary activities associated with 552.216–75, Transactional Data Reporting, and Alternate I of GSAR clause 552.238–80, Industrial Funding Fee and Sales Reporting, are initial setup and monthly reporting. The below provides the basis for calculating these two activities.

Initial Setup

○ Estimated hourly rate & job position equivalency. The estimated hourly cost associated with this task is based on the task being accomplished by senior level personnel equivalent to a GS–14, Step 5 employee. A GS–14, Step 5 employee hourly rate for 2022 is $82.51 (''Rest of U.S.'' locality using OPM Salary Table 2022–GS, Effective January 2022).

○ Estimated hours by system for initial set-up. A contractor complying with TDR requirements will absorb a one-time setup burden for purposes of establishing a reporting system (*i.e.,* automated reporting system vs. manual reporting system). The estimated setup time varies between automated and manual reporting systems. GSA estimates the average one-time initial setup burden is 8 hours for a manual system and 240 hours for an automated system.

Monthly Reporting

○ Estimated hourly rate & job position equivalency. The estimated hourly cost associated with this task is based on the task being accomplished by mid-level personnel equivalent to a GS–12, Step 5 employee. A GS–12, Step 5 employee hourly rate for 2022 is $58.72 (*i.e.,* using ''Rest of U.S.'' locality within the OPM Salary Table for 2022–GS, Effective January 2022).

○ Categorization of contractors by sales revenue. GSA estimates the likelihood of contractors with lower to no reportable sales will spend relatively little time on reporting. In contrast, contractors with more reportable sales will face a higher reporting burden. To account for this difference, GSA is using the below sale revenue categories:

Category 1: No sales activity/revenue (*i.e.,* $0.00)

Category 2: Sales between $0.01 and $25,000.00

Category 3: Sales between $25,000.01 and $250,000.00

Category 4: Sales between $250,000.01 and $1 million

Category 5: Sales over $1 million

The below table show the estimated number of contractors (*i.e.,* both FSS and Non-FSS contractors) by sales revenue category:

ESTIMATED NUMBER OF FSS AND NON-FSS CONTRACTORS BY SALES REVENUE CATEGORY

	FSS	Non-FSS	FSS & non-FSS
Category 1	100	622	722
Category 2	500	2	502
Category 3	1,000	32	1,032

ESTIMATED NUMBER OF FSS AND NON-FSS CONTRACTORS BY SALES REVENUE CATEGORY—Continued

	FSS	Non-FSS	FSS & non-FSS
Category 4	500	73	573
Category 5	672	418	1,090
Total	2,822	1,147	3,969

○ Automated system vs. manual reporting system. GSA estimates the likelihood of a contractor creating an automated reporting system increases with a contractor's sales revenue. In contrast, contractors with little to no sales revenue are unlikely to expend the effort needed to establish an automated reporting system. To account for this difference, GSA is using the below table. The below table shows by sales revenue category the estimated percentage of the likelihood of a contractor using a manual reporting system vs automated reporting system:

PERCENTAGE OF CONTRACTORS BY TYPE OF REPORTING SYSTEM

Sales category	Manual system (%)	Automated system (%)
Category 1	100	0
Category 2	100	0
Category 3	90	10
Category 4	50	50
Category 5	10	90

The following table show the estimated number of contractors for both FSS contracts and Non-FSS contracts by type of reporting system:

ESTIMATED NUMBER OF CONTRACTORS FOR BOTH FSS CONTRACTS AND NON-FSS CONTRACTS BY TYPE OF REPORTING SYSTEM

	Manual system (FSS)	Automated system (FSS)	Manual system (non-FSS)	Automated system (non-FSS)
Category 1	100	0	622	0
Category 2	500	0	2	0
Category 3	900	100	29	3
Category 4	275	275	36	37
Category 5	67	605	42	376
Totals	1,842	980	731	416

○ Estimated monthly reporting time (hours)—by reporting system and sales revenue category. GSA estimates that the monthly reporting time varies by type of reporting system (*i.e.,* manual or automated) and by respective sales revenue category. The below table shows GSA's estimated monthly reporting times per sales revenue category and system type:

MONTHLY HOURS BY TYPE OF REPORTING SYSTEM AND CATEGORY

	Manual systems	Automated systems
Category 1	0.25	2.00
Category 2	2.00	2.00
Category 3	4.00	2.00
Category 4	16.00	2.00
Category 5	48.00	2.00

Total estimated burden hour/cost for GSAR clause 552.216–75, Transactional Data Reporting.

Initial Setup.

Total estimated annual burden hours: 28,464

Total estimated annual cost burden: $2,348,650.03

Monthly Reporting.

Total estimated annual burden hours: 44,394

Total estimated annual cost burden: $2,606,982.16

Total estimated burden hour/cost for Alternate I of GSAR clause 552.238–80, Industrial Funding Fee and Sales Reporting.

Initial Setup.

Total estimated annual burden hours: 34,328

Total estimated annual cost burden: $2,832,506.26

Monthly Reporting.

Total estimated annual burden hours: 170,412

Total estimated annual cost burden: $10,007,231.69

Total estimated annual burden hour/cost for 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts (Deviation II).

Estimated # of responses per year: 461

Estimated burden hours per response: × 4.25

Total estimated annual burden hours: 1,959.25

Estimated cost per hour: × $82.51

Total estimate annual cost burden: $161,663.60

Total estimated annual burden hour/cost for Alternate I of GSAR clause 552.238–81, Price Reductions.

Estimated # of responses per year: 25

Estimated burden hours per response: × 4.25

Total estimated annual burden hours: 106

Estimated cost per hour**: × $82.51

Total estimate annual cost burden: $8,775.00

Total estimated annual burden hour/cost for GSAR clause 552.238–83, Examination of Records by GSA.

Estimated # of respondents per year: 8

Estimated burden hours per respondent: × 455

Total estimated annual burden hours: 3,640

Estimated cost per hour**: × $82.51

Total estimated annual cost burden: $300,347.32

Total estimated annual burden hour/cost for GSAR clause 552.238–85, Contractor's Billing Responsibilities, is 0 burden hours/$0.00 burden cost. The reason for zero burden being associated with this clause is because the record keeping requirement contained in this clause does not add any additional burden to what is already captured by Alternate I of GSAR clause 552.238–80, Industrial Funding Fee and Sales Reporting, which is covered by this information collection.

Total Estimated Annual Burden Hour/Cost

The total estimated annual burden hour/cost imposed by this information collection is as follows:

Total estimated annual burden hours

FSS contracts: 210,446

Non-FSS contracts: *72,858*

Total estimated annual burden hour: 281,344

Total estimated annual cost burden

FSS contracts: $13,310,515.87

Non-FSS contracts: *$4,955,632.19*

Total estimated annual cost burden: $18,104,484.46

C. Public Comments

A 60-day notice published in the **Federal Register** at 87 FR 51418 on August 22, 2022. In response, GSA received a letter from the Coalition for Government Procurement (the Coalition). The following is a summary of the letter:

1. Comment: The Coalition supports the TDR program and generally agrees with GSA's assessment of the burden associated with the renewal of this information collection.

Response: GSA appreciates the Coalition's support of the TDR program and its assessment of the burden for this renewal.

2. Comment: The Coalition believes GSA underestimates the average burden of automated reporting in both absolute time required and the complexity of the process. Specifically, the Coalition believes the estimated burden for automated reporting should be 10 hours.

Response: GSA believes the estimated hours for automated reporting is valid given TDR imposes a progressive burden—one that increases with a contractor's sales volume. Namely, reporting time increases with a contractor's applicable sales volume, so contractors with lower to no reportable sales will spend little time on monthly reporting, while those contractors with more reportable sales may have a higher reporting burden, such as the suggested 10 hours.

3. Comment: The Coalition recommends GSA expand the use of TDR as an option across the MAS Program and provide further guidance and training on the use of TDR data.

Response: GSA anticipates expanding the use of TDR as an option across the MAS program as well as providing any additional guidance and training as part of any such expansion.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov*. Please cite ''Information Collection 3090–0306, Transactional Data Reporting'', in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2022–25229 Filed 11–17–22; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) reapprove the proposed information collection project: ''*Medical Expenditure Panel Survey—Insurance Component.*''

This proposed information collection was previously published in the **Federal Register** on September 6th, 2022 and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public during this period. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by December 19, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Expenditure Panel Survey—Insurance Component

In 2021 employer-sponsored health insurance was the source of coverage for 90.5 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical

Expenditure Panel Survey—Insurance Component (MEPS–IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. These statistics are produced at the National, State, and sub-State (metropolitan area) level for private industry. Statistics are also produced for State and Local governments.

This research has the following goals:

(1) to provide data for Federal policymakers evaluating the effects of National and State health care reforms.

(2) to provide descriptive data on the current employer-sponsored health insurance system and data for modeling the differential impacts of proposed health policy initiatives.

(3) to supply critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product.

This study is being conducted by AHRQ through the Bureau of the Census, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b–2.

Method of Collection

To achieve the goals of this project the following data collections for both private sector and state and local government employers will be implemented:

(1) Prescreener Questionnaire—The purpose of the Prescreener Questionnaire, which is collected via telephone, varies depending on the insurance status of the establishment contacted (establishment is defined as a single, physical location in the private sector and a governmental unit in state and local governments). For establishments that do not offer health insurance to their employees, the prescreener is used to collect basic information such as number of employees. Collection is completed for these establishments through this telephone call. For establishments that do offer health insurance, contact name and address information is collected that is used for the mailout of the establishment and plan questionnaires. Obtaining this contact information helps ensure that the questionnaires are directed to the person in the establishment best equipped to complete them.

(2) Establishment Questionnaire—The purpose of the mailed Establishment Questionnaire is to obtain general information from employers that provide health insurance to their employees. Information such as total active enrollment in health insurance, other employee benefits, demographic characteristics of employees, and retiree health insurance is collected through the establishment questionnaire.

(3) Plan Questionnaire—The purpose of the mailed Plan Questionnaire is to collect plan-specific information on each plan (up to four plans) offered by establishments that provide health insurance to their employees. This questionnaire obtains information on total premiums, employer and employee contributions to the premium, and plan enrollment for each type of coverage offered—single, employee-plus-one, and family—within a plan. It also asks for information on deductibles, copays, and other plan characteristics.

The primary objective of the MEPS–IC is to collect information on employer-sponsored health insurance. Such information is needed in order to provide the tools for Federal, State, and academic researchers to evaluate current and proposed health policies and to support the production of important statistical measures for other Federal agencies.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the MEPS–IC. The Prescreener questionnaire will be completed by 25,200 respondents and takes 5 minutes to complete. The Establishment questionnaire will be completed by 21,738 respondents and takes 20 minutes to complete. The Plan questionnaire will be completed by 19,246 respondents and will require an average of 2.3 responses per respondent. Each Plan questionnaire takes 11 minutes to complete. The total annualized burden hours are estimated to be 17,461 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this data collection. The annualized cost burden is estimated to be $619,691.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR THE 2023–2025 MEPS–IC

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Prescreener Questionnaire	25,200	1	5/60	2,100
Establishment Questionnaire	21,738	1	*20/60	7,246
Plan Questionnaire	19,246	2.3	11/60	8,115
Total	66,184	na	na	17,461

*The burden estimate printed on the establishment questionnaire is 45 minutes which includes the burden estimate for completing the establishment questionnaire and two plan questionnaires (on average, each establishment completes 2.3 plan questionnaires). The establishment and plan questionnaires are sent to the respondent as a package and are completed by the respondent at the same time.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2023–2025 MEPS–IC

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Prescreener Questionnaire	25,200	2,100	35.49	$74,529
Establishment Questionnaire	21,738	7,246	35.49	257,161
Plan Questionnaire	19,246	8,115	35.49	288,001

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2023–2025 MEPS–IC—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Total	66,184	17,461	na	619,691

* Based upon the mean hourly wage for Compensation, Benefits, and Job Analysis Specialists occupation code 13–1141, at *https://www.bls.gov/oes/current/oes131141.htm* (U.S. Department of Labor, Bureau of Labor Statistics.)

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 14, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–25176 Filed 11–17–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10227]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 17, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10227 PACE State Plan Amendment Preprint

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* PACE State Plan Amendment Preprint; *Use:* If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as ''Enclosures 3, 4, 5, 6, and 7.'' CMS will review the information provided in order to determine if the state has properly elected to cover PACE services as a state plan option. In the event that the state changes something in the state plan, only the affected page must be updated. *Form Number:* CMS–10227 (OMB control number: 0938–1027); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number*

of Respondents: 7; *Total Annual Responses:* 2; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Angela Cimino at 410–786–2638.)

Dated: November 15, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–25162 Filed 11–17–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for Reviewer Recruitment Forms

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) proposes to extend approval of the existing overarching generic clearance for Reviewer Recruitment Forms (Office of Management and Budget (OMB) #0970–0477). No changes are proposed to the terms of the overarching generic.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comments on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *opreinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The overarching generic clearance for Reviewer Recruitment Forms provides ACF with the opportunity to collect from potential reviewers, such as those who review grant proposals, conference proposals, research/evaluation plans, study designs, report drafts, and/or other ACF materials.

ACF developed this generic because each program office and within ACF has slightly different needs for information about reviewer applicants based on the specific activities for which reviewers are needed, yet the individual forms submitted under the generic will serve an identical function. The overarching purpose is to select qualified reviewers for ACF review processes and activities based on professional qualifications. Information will be collection through questions on forms and documents provided by candidates. Example documents include writing samples and curriculum vitae and/or resume. ACF uses the information collected to recruit well-qualified reviewers with relevant background experience and knowledge.

The abbreviated clearance process of the generic clearance allows program offices to gather a suitable pool of candidates within the varied time periods available for reviewer recruitment.

These forms submitted under this generic will be voluntary, low-burden and uncontroversial.

Respondents: Individuals who may apply to review materials for ACF.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)
Reviewer Recruitment Form	3,000	1	.5	1,500

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–25202 Filed 11–17–22; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 17, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 3, 2022 (87 FR 47425). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Ammonium lactate (multiple reference listed drugs).
Budesonide.
Calcitonin salmon.
Clindamycin phosphate.
Deferiprone.
Drospirenone; Estetrol.
Eteplirsen.
Fidaxomicin.
Fosdenopterin hydrobromide.
Hydrocortisone.
Hydroxyurea.
Inotersen sodium.
Ketotifen fumarate.
Magnesium sulfate; Potassium chloride; Sodium sulfate.
Melphalan flufenamide hydrochloride.
Miconazole nitrate; White petrolatum; Zinc oxide.
Mometasone furoate.
Nicardipine hydrochloride.
Omeprazole magnesium.
Patisiran sodium.
Ponesimod.
Ranolazine.
Tepotinib hydrochloride.
Tivozanib hydrochloride.
Triamcinolone acetonide.
Trilaciclib dihydrochloride.
Varenicline tartrate.
Voclosporin.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances

for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Acyclovir.
Baricitinib.
Calcium carbonate; Famotidine; Magnesium hydroxide.
Daunorubicin citrate.
Deferiprone.
Ethinyl estradiol; Norethindrone acetate.
Ferric oxyhydroxide (multiple reference listed drugs).
Goserelin acetate (multiple reference listed drugs).
Icosapent ethyl.
Lapatinib ditosylate.
Lidocaine.
Oxycodone.
Progesterone.
Ranolazine.
Rifaximin.
Sodium phosphate, dibasic, anhydrous; Sodium phosphate, monobasic, monohydrate.
Sumatriptan succinate (multiple product-specific guidances).

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25210 Filed 11–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Member Conflict.

Date: December 2, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 451–0000, *jolanta.topczewska@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Capstone Centers for Multidisciplinary Research in Child Abuse and Neglect.

Date: December 8–9, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health & Human Development, National Institute Health, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892, (301) 827–4902, *kimberly.houston@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Program Project Grants for HIV Research.

Date: December 13–14, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20817, (301) 451–4989, *crobbins@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: November 14, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25165 Filed 11–17–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: December 7, 2022.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Imoh S. Okon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–347–8881, *imoh.okon@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Acute Neural Injury and Epilepsy.

Date: December 7, 2022.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5201, Bethesda, MD 20892, 301–760–8207, *schauweckerpe@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 14, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25164 Filed 11–17–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–22–017 Somatic Cell Genome Editing Program Translational Coordination and Dissemination Center.

Date: December 14, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca Catherine Burgess, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–8034, *rebecca.burgess@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics on Tumor Biology.

Date: December 14, 2022.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jingwu Xie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8625, *jingwu.xie@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

Date: December 15–16, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, (240) 498–7546, *diramig@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Autoimmunity.

Date: December 15, 2022.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Xinrui Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–2084, *xinrui.li@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 14, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25167 Filed 11–17–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0830]

National Boating Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard is accepting applications to fill two vacancies on the National Boating Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national recreational boating safety.

DATES: Completed applications must reach the U.S. Coast Guard on or before December 19, 2022.

ADDRESSES: Applications must be emailed to Mr. Jeff Decker at *NBSAC@uscg.mil* with subject line ''Application for NBSAC''.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Decker, Alternate Designated Federal Officer of the National Boating Safety Advisory Committee; telephone 202–372–1507 or email at *NBSAC@uscg.mil*.

SUPPLEMENTARY INFORMATION: The National Boating Safety Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law No 115–282, 132 Stat. 4192 (codified, at 46 U.S.C. 15105). The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. appendix), and 46 U.S.C. 15109. The National Boating Safety Advisory Committee provides advice, consults with, and make recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national recreational boating safety.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel Regulations.

As required by 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. Members serve at the pleasure of the Secretary of Homeland Security and may be removed prior to the end of their term for just cause. In this solicitation for Committee members, we will consider applications for two (2) positions:

- State official responsible for State boating safety programs.

Each member of the Committee serves as a representative and must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

In order for the Department, to fully leverage broad-ranging experience and education, the National Boating Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your application to *NBSAC@uscg.mil* as provided in the **ADDRESS** section of this notice. Applications must include: (1) a cover letter expressing interest in an appointment to the National Boating Safety Advisory Committee; (2) a resume detailing the applicant's relevant experience and (3) a brief biography of the applicant. The U.S. Coast Guard will not consider incomplete or late applications.

Dated: November 15, 2022.

Jason D. Neubauer,

Captain, U.S. Coast Guard, Acting Director of Inspections and Compliance.

[FR Doc. 2022–25154 Filed 11–17–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2022–0044]

Commercial Customs Operations Advisory Committee

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, December 7, 2022, in College Park, Maryland. The meeting will be open for the public to attend in person or via webinar. Due to COVID–19 restrictions, the in-person capacity is limited to 100 persons for public attendees.

DATES: The COAC will meet on Wednesday, December 7, 2022, from 1 p.m. to 5 p.m. EST. Please note that the meeting may close early if the committee has completed its business. Registration to attend and comments must be submitted no later than December 2, 2022.

ADDRESSES: The meeting will be held at the National Archives and Records Administration College Park, 8601 Adelphi Road, College Park, MD 20740, on the basement level in Lecture Rooms C, D, and E. All in-person participants are required to show valid government-issued identification to enter the building. For virtual participants, the webinar link and conference number will be provided to all registrants by 5:00 p.m. EST on December 6, 2022. For information or to request special assistance for the meeting, contact Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344–1440, as soon as possible.

Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for Docket Number USCBP–2022–0044. To submit a comment, click the ''Comment'' button located on the top-right hand side of the docket page.
- *Email: tradeevents@cbp.dhs.gov.* Include Docket Number USCBP–2022–0044 in the subject line of the message.

Comments must be submitted in writing no later than December 2, 2022, and must be identified by Docket No. USCBP–2022–0044. All submissions received must also include the words ''Department of Homeland Security.'' All comments received will be posted without change to *https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings* and *www.regulations.gov.* Therefore, please refrain from including any personal information you do not wish to be posted. You may wish to view the Privacy and Security Notice which is available via a link on the homepage of *www.regulations.gov.*

See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing.

FOR FURTHER INFORMATION CONTACT: Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229, (202) 344–1440; or Ms. Felicia M. Pullam, Designated Federal Officer, at (202) 344–1440 or via email at *tradeevents@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the authority of the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Pre-Registration: Meeting participants may attend either in person or via webinar. All participants must register using one of the methods indicated below:

For members of the public who plan to participate in person, please register online at *https://teregistration.cbp.gov/index.asp?w=296* by 5 p.m. EST on December 2, 2022. For members of the public who are pre-registered to attend the meeting in person and later need to cancel, please do so by 5 p.m. EST on December 2, 2022, utilizing the following link: *https://teregistration.cbp.gov/cancel.asp?w=296.*

For members of the public who plan to participate via webinar, please register online at *https://teregistration.cbp.gov/index.asp?w=295* by 5 p.m. EST on December 2, 2022. For members of the public who are pre-registered to attend the meeting via webinar and later need to cancel, please do so by 5 p.m. EST on December 2, 2022, utilizing the following link: *https://teregistration.cbp.gov/cancel.asp?w=295.*

The COAC is committed to ensuring that all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Mrs. Latoria Martin at (202)–344–1440 as soon as possible.

Please feel free to share this information with other interested members of your organization or association.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

There will be multiple public comment periods held during the meeting on December 7, 2022. Speakers

are requested to limit their comments to two minutes or less to facilitate greater participation. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page: *http://www.cbp.gov/trade/stakeholder-engagement/coac.*

Agenda

The COAC will hear from the current subcommittees on the topics listed below:

1. The Next Generation Facilitation Subcommittee will provide updates on its task forces and working groups, including an update on the progress of the 21st Century Customs Framework (21CCF) and E-Commerce Task Forces. The 21CCF Task Force will provide an update on the work addressed this past quarter, which includes discussions with Partner Government Agencies (PGAs) and some of the discussion drafts of trade-related legislative proposals stemming from the 21CCF Task Force and Focus Group. The Automated Commercial Environment (ACE) 2.0 Working Group will provide an update regarding adding new members to the working group to help focus on the identified gaps and potential solutions for ACE 2.0 Modernization. Finally, the One United States Government (1USG) Working Group will provide updates on some of the discussions held this past quarter pertaining to involvement of PGAs in a trusted trader program, with benefits to the trade stakeholders, as well as single window automation with the PGAs.

2. The Rapid Response Subcommittee will provide updates for the Broker Modernization Working Group, Domestic Manufacturing and Production (DMAP) Working Group, and the United States-Mexico-Canada Agreement (USMCA) Working Group. The Broker Modernization Working Group currently meets monthly with the expectation that recommendations will be developed and submitted for consideration at an upcoming COAC public meeting. The DMAP Working Group meets bi-weekly to obtain input from industry stakeholders on trade enforcement areas affecting domestic manufacturers and producers. The USMCA Working Group has reconvened and meets bi-weekly. The focus of this working group is on Chapter 7 of the trade agreement, specifically the trilateral Committee on Trade Facilitation established pursuant to Article 7.24, which is composed of government representatives of each party to the USMCA.

3. The Secure Trade Lanes Subcommittee will provide updates on its four active working groups: the Cross-Border Recognition Working Group, the Export Modernization Working Group, the In-Bond Working Group, and the Trade Partnership and Engagement Working Group. Recommendations for the committee's consideration are anticipated from the Export Modernization Working Group regarding export-related benefits for Customs Trade Partnership Against Terrorism (CTPAT) partners. The In-Bond Working Group plans to present recommendations for the committee's consideration related to the trade community's proposed regulatory revisions/updates to 19 CFR part 18. The Trade Partnership and Engagement Working Group continues to provide an opportunity for input on CTPAT Trade Compliance program development and implementation from trade members with broad subject matter expertise. The Cross-Border Recognition Working Group continues to work on developing recommendations for the committee's consideration regarding potential changes to the current joint inspection program (Unified Cargo Processing) and has continued its discussions on CBP's CTPAT program and Mexico's Authorized Economic Operator program to ensure alignment and compliance with the mutual recognition arrangement signed in 2014.

4. The Intelligent Enforcement Subcommittee will provide updates on the work completed and topics discussed in its working groups. The Antidumping/Countervailing Duty (AD/CVD) Working Group will provide updates regarding its work and discussions on importer compliance with AD/CVD requirements. The Intellectual Property Rights Working Group (IPRWG) will provide recommendations for the committee's consideration relating to the automation of the CBP detention and seizure process and suggested enhancements to the CBP IPR web page. The Bond Working Group will report on the ongoing discussions and status updates for eBond requirements. The Forced Labor Working Group will submit recommendations for the committee's consideration regarding the Uyghur Forced Labor Prevention Act (UFLPA). Meeting materials will be available on November 28, 2022, at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.*

Dated: November 14, 2022.

Felicia M. Pullam,

Executive Director, Office of Trade Relations.

[FR Doc. 2022–25091 Filed 11–17–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Cybersecurity and Infrastructure Security Agency

[Docket No. CISA–2022–0008]

Notice of Cybersecurity and Infrastructure Security Agency Cybersecurity Advisory Committee Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of Federal Advisory Committee Act (FACA) meeting; request for comments.

SUMMARY: CISA is publishing this notice to announce the CISA Cybersecurity Advisory Committee Quarterly Meeting will meet in person on Tuesday, December 6, 2022. This meeting will be partially closed to the public. Members of the public may join the public portion of the meeting by teleconference.

DATES:

Meeting Registration: Registration to attend the meeting is required and must be received no later than 5:00 p.m. Eastern Standard Time (EST) on December 4, 2022.

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5:00 p.m. EST on December 4, 2022.

Written Comments: Written comments must be received no later than 5:00 p.m. EST on December 4, 2022.

Meeting Date: The CISA Cybersecurity Advisory Committee will meet in-person at Apple Park in Cupertino, California on December 6, 2022, from 9:30 a.m. to 3:00 p.m. Pacific Standard Time (PST). The meeting may close early if the committee has completed its business.

ADDRESSES: The CISA Cybersecurity Advisory Committee's meeting will be open to the public, per 41 CFR 102–3.150 and will be held in person at One Apple Park Way, Cupertino, CA 95014. Members of the public may participate via teleconference only. For access to the conference call bridge, information on services for individuals with disabilities, or to request special assistance, please email *CISA_CybersecurityAdvisoryCommittee@cisa.dhs.gov.* by 5:00 p.m. EST December 4, 2022. The CISA Cybersecurity Advisory Committee is committed to ensuring all participants have equal access regardless of

disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Ms. Megan Tsuyi at (202) 594–7374 as soon as possible.

Comments: Members of the public are invited to provide comment on issues that will be considered by the committee as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials that may be discussed during the meeting will be made available for review at *https://www.cisa.gov/cisa-cybersecurity-advisory-committee-meeting-resources* by December 1, 2022. Comments should be submitted by 5:00 p.m. EST on December 4, 2022 and must be identified by Docket Number CISA–2022–0008. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Please follow the instructions for submitting written comments.
- *Email: CISA_CybersecurityAdvisoryCommittee@cisa.dhs.gov.* Include the Docket Number CISA–2022–0008 in the subject line of the email.

Instructions: All submissions received must include the words ''Cybersecurity and Infrastructure Security Agency'' and the Docket Number for this action. Comments received will be posted without alteration to *www.regulations.gov,* including any personal information provided. You may wish to review the Privacy & Security notice available via a link on the homepage of *www.regulations.gov.*

Docket: For access to the docket and comments received by the CISA Cybersecurity Advisory Committee, please go to *www.regulations.gov* and enter docket number CISA–2022–0008.

A public comment period is scheduled to be held during the meeting from 2:50 p.m. to 3:00 p.m. PST. Speakers who wish to participate in the public comment period must email *CISA_CybersecurityAdvisoryCommittee@cisa.dhs.gov* to register. Speakers should limit their comments to 3 minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, depending on the number of speakers who register to participate.

FOR FURTHER INFORMATION CONTACT: Megan Tsuyi, 202–594–7374, *CISA_CybersecurityAdvisoryCommittee@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The CISA Cybersecurity Advisory Committee was established under the National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283. Notice of this meeting is given under FACA, 5 U.S.C. Appendix (Pub. L. 92–463). The CISA Cybersecurity Advisory Committee advises the CISA Director on matters related to the development, refinement, and implementation of policies, programs, planning, and training pertaining to the cybersecurity mission of the Agency.

Agenda: The CISA Cybersecurity Advisory Committee will hold an in-person meeting on Tuesday, December 6, 2022, from 9:30 a.m. to 3:00 p.m. PST to discuss current CISA Cybersecurity Advisory Committee activities. The open session will include: (1) a period for public comment (2) a discussion on the status of previous CISA Cybersecurity Advisory Committee recommendations (3) a member roundtable on the CISA Cybersecurity Advisory Committee strategic focus for 2023, and (4) discussion on the CISA Cybersecurity Advisory Committee annual report.

The committee will also meet in a closed session from 9:30 a.m. to 12:30 p.m. PST to participate in an operational discussion that will address areas of critical cybersecurity vulnerabilities and priorities for CISA. Government officials will share sensitive information with CSAC members on initiatives and future security requirements for assessing cyber risks to critical infrastructure.

Basis for Closure: In accordance with section 10(d) of FACA and 5 U.S.C. 552b(c)(9)(B), *The Government in the Sunshine Act,* it has been determined that certain agenda items require closure, as the premature disclosure of the information that will be discussed would be likely to significantly frustrate implementation of proposed agency actions.

This agenda item addresses areas of CISA's operations that include critical cybersecurity vulnerabilities and priorities for CISA. Government officials will share sensitive information with CSAC members on initiatives and future security requirements for assessing cyber risks to critical infrastructure.

As the premature disclosure of the information that will be discussed would be likely to significantly frustrate implementation of proposed agency action, this portion of the meeting is required to be closed pursuant to section 10(d) of FACA and 5 U.S.C. 552b(c)(9)(B).

Megan M. Tsuyi,

Designated Federal Officer, CISA Cybersecurity Advisory Committee, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2022–25110 Filed 11–17–22; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2022–0032

Privacy Act of 1974; System of Records

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to modify a current DHS system of records titled, ''DHS/Federal Emergency Management Agency (FEMA)-006 Citizen Corps Program System of Records'' and retitle it, ''DHS/FEMA–006 Individual and Community Preparedness Division System of Records.'' This system of records allows DHS/FEMA to collect from and maintain records on individuals who contact the agency about their interest in preparedness and specific voluntary programs, register and participate in FEMA's Individual and Community Preparedness Division (ICPD) programs, correspond with community stakeholder organizations, and receive survey responses. DHS/FEMA is updating this System of Records Notice to (1) revise the system name, (2) modify the system location, (3) update the purpose of the system, (4) update the authority for maintenance of the system, (5) revise the category of individuals covered by the system, (6) update the category of records in the system, (7) update record source categories; (8) update record access procedures; and (9) revise and add routine uses. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. This modified system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before December 19, 2022. This modified system will be effective upon publication. New or modified routine uses will be effective December 19, 2022.

ADDRESSES: You may submit comments, identified by docket number DHS–2022–0032 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Lynn Parker Dupree, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number DHS–2022–0032 All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Tammi Hines, (202) 212–5100, *FEMA-Privacy@fema.dhs.gov,* Senior Director for Information Management, Federal Emergency Management Agency, Department of Homeland Security, Washington, DC 20472. For privacy questions, please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

This modified System of Records Notice is being published because the Federal Emergency Management Agency (FEMA) collects, maintains, uses, retrieves, and disseminates the personally identifiable information (PII) of individuals who contact the agency about their interest in preparedness and specific voluntary programs, register and participate in FEMA's Individual and Community Preparedness Division (ICPD) programs, correspond with community stakeholder organizations, and receive survey responses to facilitate development of emergency preparedness measures and strengthen collaborations with stakeholders to better prepare individuals and communities to respond to disasters.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 93–288, as amended, at Section 611, 42 U.S.C. 5196(e)(1), authorizes the FEMA Administrator to ''study and develop emergency preparedness measures designed to afford adequate protection of life and property, including—research and studies as to the best methods of treating the effects of hazards.''

According to 6 U.S.C. 313(b)(1), ''the primary mission of the Agency is to reduce the loss of life and property and protect the nation from all hazards, including natural disasters, acts of terrorism, and other man-made disasters, by leading and supporting the Nation in a risk-based, comprehensive emergency management system of preparedness, protection, response, recovery, and mitigation.''

According to 6 U.S.C. 314(a)(9)(B), the Administrator is required to take leadership in preparedness, by planning, training, and building the emergency management profession to prepare effectively for, mitigate against, respond to, and recover from any hazard.

FEMA's Individual and Community Preparedness Division supports the FEMA mission by connecting individuals, organizations, and communities with research and tools to build and sustain capabilities to prepare for any disaster or emergency. The Individual and Community Preparedness Division conducts research to develop emergency preparedness measures and conducts surveys to better understand effective preparedness actions and ways to motivate the public to take those actions. Through the Individual and Community Preparedness Division, FEMA administers the Citizen Responder Program, which includes Citizen Corps and Community Emergency Response Teams (CERT); the Youth Preparedness Council; the National Household Survey on Disaster Preparedness; the Post-Disaster Survivor Survey Preparedness Research; and the Preparedness Activity Registration and Feedback collection.

Citizen Responder aims to strengthen the collaboration with communities and to enhance their preparation and response to threats of terrorism, crime, public health issues, and disasters of all kinds. As part of this responsibility to help and support emergency response providers, FEMA supports efforts to train and assist in organizing citizen responder programs. Citizen Responder allows the Individual and Community Preparedness Division to analyze program activities, structures, and proper sponsorship. Data collected indicates, at a state, local, tribal, and territorial (SLTT) level, how local grassroots programs help to prepare communities and individuals. This information is required to link members of the public who are interested in getting prepared with organizations in their community that can help.

The Youth Preparedness Council (YPC) brings together youth leaders nationwide who are highly interested and engaged in advocating youth disaster preparedness and making a difference in their communities. Youth applicants, between the ages of 13 and 17, apply to the Youth Preparedness Council in their 8th, 9th, 10th, or 11th grade. Youth Preparedness Council members represent the youth perspective on emergency preparedness and share this information with their communities. FEMA collects information from Youth Preparedness Council applicants in various forms (paper, electronic, video, or web), as well contact information for parents of applicants under the age of 18, and individuals providing recommendations of applicants.

The National Household Survey on Disaster Preparedness identifies progress and gaps in individual and community preparedness and helps FEMA better understand the motivators and barriers to preparedness and specific hazards. The survey measures the public's knowledge, attitudes, and behaviors relative to preparing for a wide range of hazards and is used by FEMA to tailor messaging and public information efforts, community outreach, and strategic planning initiatives.

The Post-Disaster Survivor Preparedness Survey was created after the 2017 hurricane season where Hurricanes Harvey, Irma, and Maria significantly impacted historically underserved communities and illustrated the critical importance of tailoring preparedness and warning information for specific local features, and the need for protective action guidance based on these likely local impacts. This survey helps identify how members of specific communities impacted by disasters prepare, as well as the barriers that prevent underserved individuals and families from being more prepared.

The Preparedness Activity Registration and Feedback collection provides general feedback on the (1) effectiveness of national FEMA preparedness programs and initiatives; (2) website user experience; (3) activity details and other information regarding the type, size, and location of preparedness activities hosted by members of the public and community organizers; (4) point of contact information for registration within the site, follow-on communication, if needed, and future engagement requests that will allow for the public to enroll in the Individual and Community Preparedness Division newsletter or other public communications; and (6) publication ordering via submitting

requests to the FEMA publication warehouse to have materials shipped directly to members of the public.

FEMA is updating this System of Records Notice to reflect the following changes. First, the system name is revised to incorporate additional Individual and Community Preparedness Division programs and activities. When the system of records was established, Citizen Corps was the primary program in the Individual and Community Preparedness Division. Since that time, Citizen Corps has become one of many Individual and Community Preparedness Division programs and the purpose of this update is to incorporate all current Individual and Community Preparedness Division collections. The system name has been updated to accurately align with additional Individual and Community Preparedness Division programs.

Second, the system location is updated to accurately reflect the location of the records within the Federal Risk and Authorization Management Program (FedRAMP) approved Salesforce Government Cloud environment, a Software-as-a-Service (SaaS) cloud system located in Salesforce Data Center, Ashburn, VA.

Third, the purpose of the system is updated to document the various preparedness activities, programs, and surveys administered by FEMA, in addition to the Citizen Corp and CERT programs.

Fourth, the authority for maintenance of the system is updated to include FEMA's statutory authority to administer preparedness activities, programs, and surveys.

Fifth, the category of individuals has been revised to include individuals engaging in preparedness programs, in addition to Citizen Corp and CERT programs, and survey respondents for preparedness assessment surveys.

Sixth, the category of records has been updated to include date of birth, race/ethnicity, gender/sex, academic records, letters of recommendation, school grade level and extracurricular activities (for Youth Preparedness Council only; disciplinary records are not requested or required). Other CERT program information has been removed.

Seventh, the record source categories are modified to align with the system's purpose and to include additional sources of records.

Eighth, record access procedures are updated to include notification procedures that reflect FEMA's internal reorganization.

Finally, routine uses are updated to comply with OMB Memorandum M–17–12 requiring disclosure of information necessary to respond to a breach either of the agency's personally identifiable information or, as appropriate, to assist another agency in its response to a breach. The incident-related routine uses will help identify what information was potentially compromised, the population of individuals potentially affected, the purpose for which the information had originally been collected, the permitted uses and disclosures of the information, and other information that may be useful when developing the agency's incident response. Former Routine Use H has been removed from the System of Records Notice. Previous Routine Uses I and J have been combined, re-lettered, and modified to reflect the current name of the program, Citizen Responder and CERT. Routine Use J has been added to account for the use of FEMA data to conduct testing of new technologies, with the exception of Youth Preparedness Council data.

DHS/FEMA may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies, consistent with the routine uses set forth in this System of Records Notice.

This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The fair information practice principles found in the Privacy Act underpin the statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides covered persons with a statutory right to make requests for access and amendment to covered records, as defined by the Judicial Redress Act, along with judicial review for denials of such requests. In addition, the Judicial Redress Act prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/FEMA–006 Individual and Community Preparedness System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Homeland Security (DHS)/Federal Emergency Management Agency (FEMA)-006 Individual and Community Preparedness System of Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at the FEMA Headquarters in Washington, DC, and field offices. Records also are maintained in the Salesforce Government Cloud environment located in Salesforce Data Center, Ashburn, VA.

SYSTEM MANAGER(S):

Individual and Community Preparedness Division (ICPD) Preparedness Behavior Change Branch Chief, 500 C St SW, Washington, DC 20472.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 93–288, as amended, Sec. 611, at 42 U.S.C 5196(e); 6 U.S.C. 314(a)(9)(B); 6 U.S.C. 313(b)(1), (b)(2)(H); Exec. Order (E.O.) No. 13254, ''Establishing the USA Freedom Corps'', Jan. 29, 2002, as amended by E.O. 13286.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to enable FEMA to facilitate contact between individuals, communities, and organizations about their interest in preparedness and specific voluntary programs; enable individuals, communities, and organizations to register and participate in FEMA's Individual and Community Preparedness Division programs; and enable FEMA to correspond with community stakeholder organizations, administer surveys, and receive survey responses. As a whole, these records enable FEMA and the Individual and Community Preparedness Division to connect with individuals, organizations, and communities with research, training, and tools to build and sustain capabilities to prepare for any disaster, hazard, or emergency.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals designated as the points of contact for a citizen responder team (Community Emergency Response Team (CERT) or Citizen Corps partner organization), members of the public who contact the agency about their interest in preparedness programs,

which may include youth between grades 8 and 11, their parents or guardians, or individuals recommending the youth for preparedness programs. This system will also include members of the public who respond to FEMA-administered preparedness assessment surveys.

CATEGORIES OF RECORDS IN THE SYSTEM:

- Individual's Name;
- Organization or Sponsoring Organization;
- Telephone Number;
- Fax Number;
- Mailing Address;
- Email Address;
- Unique User ID (for IT system access);
- Password (for IT system access);
- User Type;
- Date of Birth;
- Race/Ethnicity;
- Gender/Sex;
- Academic Records;
- Letter of Recommendation, including Relationship to Applicant;
- School Grade Level;
- Extracurricular Activities;
- Volunteer Program Area and Type of Interest;
- Emergency Preparedness Training Information (*e.g.,* courses taken and dates of courses);
- Community Preparedness Surveys and Instruments (aggregate self-reported attitudes, opinions and experiences of disasters and preparedness)

RECORD SOURCE CATEGORIES:

FEMA collects information directly from the individuals who contact, correspond with, register for, and participate in FEMA's Individual and Community Preparedness programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including the U.S. Attorneys Offices, or other federal agencies conducting litigation or proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity, only when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. secs. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another federal agency or federal entity, when DHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

H. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

I. To organizations participating, partnering, or affiliated with the Citizen Responder Program if an individual has volunteered to assist or requested information about this specific type of organization.

J. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations, with the approval of the Chief Privacy Officer, when DHS is aware of a need to use relevant aggregate, deidentified data, that relate to the purpose(s) stated in this System of Records Notice, for purposes of testing new technology. Data collected through the Youth Preparedness Council will not be used to test new technology.

K. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/FEMA stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital/electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

DHS/FEMA may retrieve records using a system-generated case number associated with a unique application, or by Name, Mailing Address, Email Address, Phone Number, and User ID and password. DHS/FEMA may also retrieve records by non-personal information in aggregate, such as CERTs or survey respondents by county or state location, preparedness events by number of training events held per period-of-time, average positive feedback rating on preparedness surveys, and types of preparedness events and activities conducted by individuals.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Youth Preparedness Council applications are maintained in accordance with National Archives and

Records Administration N1–311–86–1, Item 1K1c (Administrative records common to most offices in FEMA). In accordance with N1–311–86–1, Item 1K1c, for enrolled applicants, Youth Preparedness Council application records will be destroyed at the end of the calendar year of the applicant's last year in the program. For applicants that are not enrolled, Youth Preparedness Council application records will be destroyed at the end of calendar year submitted.

For all other Individual and Community Preparedness Division records (*e.g.,* results from surveys) that are not Youth Preparedness Council applications, the records are only retained until they are incorporated into the master file in accordance with NARA General Records Schedule 5.2, Item 20. (Intermediary Records). Individual and Community Preparedness Division staff use the collected data for studies and development of trend analysis. Records are continuously used and monitored and are retained until they are no longer deemed useful for analysis after which the records will be destroyed after another 3 years in accordance with NARA General Records Schedule 5.3, Item 010 (continuity planning and related emergency planning files).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/FEMA safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/FEMA has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and the FEMA Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contact Information.'' If an individual believes more than one component maintains Privacy Act records concerning them, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, Washington, DC 20528–0655 or electronically at *https://www.dhs.gov/dhs-foia-privacy-act-request-submission-form*. Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about you may be available under the Freedom of Information Act.

When an individual is seeking records about themself from this system of records or any other Departmental system of records, the individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify their identity, meaning that the individual must provide their full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. An individual may obtain more information about this process at *http://www.dhs.gov/*foia. In addition, the individual should, whenever possible:

- Explain why they believe the Department would have information being requested;
- Identify which component(s) of the Department they believe may have the information;
- Specify when the individual believes the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records;

If the request is seeking records pertaining to another living individual, the request must include an authorization from the individual whose record is being requested, authorizing the release to the requester.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered Judicial Redress Act records, individuals may make a request for amendment or correction of a record of the Department about the individual by writing directly to the Department component that maintains the record, unless the record is not subject to amendment or correction. The request should identify each particular record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful. If the individual believes that the same record is in more than one system of records, the request should state that and be addressed to each component that maintains a system of records containing the record.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

78 FR 43890 (July 22, 2013); 73 FR 77785 (December 19, 2008).

* * * * *

Lynn P. Dupree,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2022–25124 Filed 11–17–22; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–50]

60-Day Notice of Proposed Information Collection: Multifamily Housing Procedures for Projects Affected by Presidentially-Declared Disasters, OMB Approval No.: 2502–0582

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) to extend the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed extension of collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available

information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Disaster Management.

OMB Approval Number: 2502–0582.

OMB Expiration Date: June 30, 2023.

Type of Request: Extension of currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: Disaster relief is intended to provide an orderly and continuing means of assistance by the Federal Government to non-profit institutions in carrying out their responsibilities to alleviate the suffering and damage which result from such disasters. The purpose of this information collection is to ensure that owners follow HUD procedures, as laid out in HUD Housing Handbook 4350.1, chapter 38, regarding recovery efforts after a Presidentially declared disaster.'' This information collection is used to ensure these procedures minimize disruption to HUD's normal business requirements by owners and set guidelines for owner/tenant responsibilities under these circumstances. Affected owners are provided instruction and assistance to respond with disaster management. Disaster Relief is limited to the period following a disaster event.

Respondents: Non-profit institutions.

Estimated Number of Respondents: 5,367.

Estimated Number of Responses: 5,367.

Frequency of Response: 1.

Average Hours per Response: 0.25.

Total Estimated Burden: 1,342.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond—including through the use of appropriate automated collection techniques or other forms of information technology, such as permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–25142 Filed 11–17–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–51]

60-Day Notice of Proposed Information Collection: Capital Needs Assessment (CNAs), OMB Control No.: 2502–0505

AGENCY: Office of the Assistant Secretary for Housing–Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Capital Needs Assessment (CNAs).

OMB Approval Number: 2502–0505.

OMB Expiration Date: 08/31/2023.

Type of Request: Extension of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: A Capital Needs Assessment is a detailed review of a property's expected capital expenditures over future years. It is needed to appropriately value a project/property, to determine financial

sustainability, and to plan for funding of an escrow account to be used for capital repair and replacement needs during the estimate period. It is used by external parties, and HUD for valuation, underwriting, and asset management purposes.

Respondents: Assessor firms, lender originator, lender servicer, Participating Administrative Entity (PAE), Public Housing Agency (PHA) for RAD Projects, and the Project Rental Assistance Contract (PRAC) owner.

Estimated Number of Respondents: 2,041.

Estimated Number of Responses: 2,041.

Frequency of Response: Once periodically.

Average Hours per Response: 36 hours.

Total Estimated Burden: 73,476 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–25155 Filed 11–17–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–37]

60-Day Notice of Proposed Information Collection: Multifamily Project Monthly Accounting Reports, OMB Control No.: 2502–0108

AGENCY: Office of the Assistant Secretary for Housing–Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at Colette.*Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Multifamily Project Monthly Accounting Reports.

OMB Approval Number: 2502–0108.

OMB Expiration Date: September 30, 2020.

Type of Request: Reinstatement, without change, of previously approved collection for which approval has expired.

Form Number: HUD–93479, HUD–93480, and HUD–93481.

Description of the need for the information and proposed use: This information is necessary for HUD to monitor compliance with contractual agreements and to analyze cash flow trends as well as occupancy and rent collection levels.

Respondents: Business and other for profit and non-profit entities.

Estimated Number of Respondents: 8,192.

Estimated Number of Responses: 1,638.

Frequency of Response: 12.

Average Hours per Response: 0.08 each.

Total Estimated Burden: 4,719 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–25144 Filed 11–17–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–38]

60-Day Notice of Proposed Information Collection: Mortgage Insurance for Cooperative and Condominium Housing, OMB Control No.: 2502–0141

AGENCY: Office of the Assistant Secretary for Housing–Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 17, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Mortgage Insurance for Cooperative and Condominium Housing.

OMB Approval Number: 2502–0141.

OMB Expiration Date: November 30, 2020.

Type of Request: Reinstatement, without change, of previously approved collection for which approval has expired.

Form Number: HUD–93201.

Description of the need for the information and proposed use: The information collected on the ''Application for Mortgage Insurance for Cooperative Housing'' form is used to analyze data, cost data, drawings, and specifications to determine cooperative or condominium project eligibility for FHA mortgage insurance.

Respondents: 12.

Estimated Number of Respondents: 12.

Estimated Number of Responses: 12.

Frequency of Response: On Occasion.

Average Hours per Response: 2.

Total Estimated Burden: 24.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–25145 Filed 11–17–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R1–ES–2022–0029; ES11140100000–234–FF01E0000]

Draft Environmental Impact Statement for the Elliott State Research Forest Habitat Conservation Plan in Coos and Douglas Counties, OR

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; notice of public meeting; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (together, the Services), have received two separate incidental take permit (ITP) applications from the Oregon Department of State Lands (ODSL; applicant), associated with ODSL's Elliott State Research Forest habitat conservation plan (HCP). The applications, including the HCP, have been submitted pursuant to the Endangered Species Act. ODSL is seeking authorization from the Services for the incidental take of three species (two under FWS jurisdiction, and one under NMFS jurisdiction), expected to result from research and management activities on the Elliott State Forest in Coos and Douglas Counties, Oregon. In accordance with the National Environmental Policy Act (NEPA), this notice also announces the availability of a draft environmental impact statement (DEIS). FWS is the lead Federal agency under NEPA, and NMFS is a cooperating agency. We invite public comments on the HCP and DEIS from the public and Federal, Tribal, State, and local governments.

DATES:

Submitting Comments: We will accept online or hardcopy comments. Hardcopy comments must be received or postmarked on or before January 3, 2023. (See **ADDRESSES.**) Comments submitted online at *https://www.regulations.gov/* must be received

by 11:59 p.m. Eastern Time on January 3, 2023.

Virtual Public Meeting: FWS will hold a virtual public meeting on December 13, 2022, from 2 to 3:30 p.m. Pacific Time. For more information, see Public Comments and Virtual Public Meeting under **SUPPLEMENTARY INFORMATION**.

ADDRESSES:

Submitting Comments: You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R1–ES–2022–0029.
- *U.S. Mail:* Public Comments Processing; Attn: Docket No. FWS–R1–ES–2022–0029; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will post all comments on *https://www.regulations.gov.* This generally means that we will post online any personal information that you provide. We request that you submit comments by only the methods above. For additional information about submitting comments, see Public Comments and Virtual Public Meeting under **SUPPLEMENTARY INFORMATION.**

Public Meeting: A link and access instructions to the virtual meeting will be posted to *https://www.fws.gov/project/elliott-state-research-forest-habitat-conservation-plan/* at least 1 week prior to the public meeting date.

Reviewing U.S. Environmental Protection Agency (EPA) Comments on the Draft HCP and DEIS: See EPA's Role in the EIS Process under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Shauna Everett, by telephone at 503–231–6949, or by email at *shauna_everett@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (FWS), have prepared a draft environmental impact statement (DEIS) pursuant to the requirements of the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*) to evaluate applications for incidental take permits (ITPs) received on October 10, 2022, from the Oregon Department of State Lands (ODSL; applicant). ODSL submitted two applications, one for two species under FWS jurisdiction, and the second application for one species under National Marine Fisheries Service (NMFS) jurisdiction. NMFS is a cooperating agency under NEPA. In support of the ITP applications, the ODSL prepared the draft Elliott State Research Forest Habitat Conservation Plan (ESRF HCP), which, among other components, specifies the impacts that will likely result from the take of covered species, describes the steps the applicant will take to avoid, minimize, and mitigate such impacts, and explains the funding available to implement such steps.

Background

Section 9 of the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) prohibits ''take'' of fish and wildlife species listed as endangered under section 4 (16 U.S.C. 1538 and 16 U.S.C. 1533, respectively). The ESA implementing regulations extend, under certain circumstances, the prohibition of take to threatened species (50 CFR 17.31). Under section 3 of the ESA, the term ''take'' means to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct'' (16 U.S.C. 1532(19)). The term ''harm'' is defined by FWS regulations as ''an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering'' (50 CFR 17.3; see 50 CFR 222.102 for NMFS regulations).

Under section 10(a) of the ESA, the Services may issue permits to authorize incidental take of listed fish and wildlife species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Section 10(a)(1)(B) of the ESA contains provisions for issuing ITPs to non-Federal entities for the take of endangered and threatened species, provided the following criteria are met:

1. The taking will be incidental;
2. The applicant will, to the maximum extent practicable, minimize and mitigate the impact of such taking;
3. The applicant will ensure that adequate funding for the plan will be provided;
4. The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and
5. The applicant will carry out any other measures that FWS (or NMFS) may require as being necessary or appropriate for the purposes of the HCP.

Applicant's Proposal

In accordance with the requirements of the ESA, ODSL is requesting authorization of incidental take of the threatened northern spotted owl (*Strix occidentalis caurina*), threatened marbled murrelet (*Brachyramphus marmoratus*), and threatened Oregon Coast coho salmon (*Oncorhynchus kisutch*) (together, the covered species), each of which is known to occur in the Elliott State Forest. Incidental take permits for the northern spotted owl and marbled murrelet fall under the jurisdiction of FWS; incidental take permits for the Oregon Coast coho salmon fall under the jurisdiction of NMFS.

ODSL is seeking incidental take coverage for a variety of research and management activities on the Elliott State Forest, located in Coos and Douglas Counties in southwestern Oregon. The proposed covered activities include forest research treatments, timber removal, forest and species research projects, supporting management activities, supporting infrastructure management, and activities identified in the conservation strategy and monitoring program that may result in effects on covered species. These activities are described further in the draft HCP and in the DEIS. The proposed permit term is 80 years.

The draft HCP and DEIS include analyses of projected impacts to covered species. ODSL anticipates that take of northern spotted owl or murrelets is likely to occur as a result of habitat loss and modification. For this reason, and because it is not practical to detect take of individual northern spotted owls or marbled murrelets, ODSL has established modeled habitat units as a surrogate for use in take estimates. Similarly, to estimate take for Oregon Coast coho salmon, ODSL established surrogate habitat units based on the proportion of each independent population within the permit area and the acres of projected harvest levels within the watersheds that overlap with each evolutionarily significant unit. More details regarding ODSL's methodology for estimating and quantifying take and related conservation outcomes over time can be found in the draft HCP.

Measures to minimize and mitigate impacts on covered species are described in the draft HCP for each species as conservation measures and conditions on covered activities, guided by goals and objectives in the conservation strategy of the HCP. ODSL

would monitor implementation of these measures for compliance and effectiveness. Minimization and mitigation measures are subject to adaptive management to ensure their effectiveness, and to ensure achievement of the ESRF HCP's biological goals and objectives.

The ESRF HCP includes funding information and assurances, monitoring requirements, adaptive management, and provisions for changed and unforeseen circumstances to help ensure conservation outcomes for the covered species over the permit term. Annual reports to the Services would confirm the amount, type, and location of impacts and mitigation, as well as the status of monitoring, adaptive management, changed circumstances, and funding.

National Environmental Policy Act Compliance

Draft Environmental Impact Statement

The FWS, with input from NMFS as a cooperating agency, prepared a draft environmental impact statement (DEIS) to evaluate the impacts of the proposed ITP action on the human environment, consistent with the purpose and goals of NEPA (42 U.S.C. 4321 *et seq.*). This DEIS was prepared pursuant to the Council on Environmental Quality's implementing NEPA regulations at 40 CFR parts 1500–1508, which became effective on May 20, 2022 (April 20, 2022, 87 FR 23453). The DEIS analyzes the proposed action and a reasonable range of alternatives to the proposed action. The environmental consequences of each alternative, including the direct, indirect, and cumulative effects, were analyzed to determine if significant impacts to the human environment would occur. Four alternatives are analyzed in detail in the DEIS.

Alternative 1—No-Action Alternative: The Services would not issue incidental take authorizations to ODSL, and ODSL would not implement the HCP. ODSL's mandate to manage lands under its jurisdiction with the objective of obtaining the greatest benefit for the people of the State, consistent with the conservation of the resource under sound techniques of land management, would remain in place, and ODSL would continue to be subject to the ESA as well as other Federal, State, and local requirements for any forest management activities in the Elliott State Forest. The No Action alternative assumes that ODSL would manage the Elliott State Forest for timber harvest using a take avoidance approach to ESA compliance.

Alternative 2—Proposed Action: The Services would, in accordance with applicable law, issue the requested ITPs to ODSL for the incidental take of covered species from covered activities in the permit area and implementation of the conservation strategy for a term of 80 years. ODSL would implement the ESRF HCP and its conservation strategy, including conditions on covered activities, mitigation measures to offset the impacts of the taking on covered species, and monitoring and reporting requirements. ODSL would provide funding for HCP implementation.

Alternative 3—Increased Conservation: The Services would, in accordance with applicable law, issue ITPs to ODSL with the same permit area, permit term, covered species, and monitoring and adaptive management program as the proposed action. The HCP's covered activities and conservation strategy would be modified to allocate additional covered species' habitat and forest stands of a certain age (≤80 years) to reserves; expand protected riparian areas around certain categories of streams, prohibit harvest activities such as restoration thinning on steep slopes and in stands of a certain age (>65 years), and implement additional conditions for permanent new road miles and vacated roads.

Alternative 4—Increased Harvest: The Services would issue ITPs to ODSL with the same permit area, covered activities, covered species, permit term, and monitoring and adaptive management program as the proposed action. The HCP's research design would be modified to eliminate reserve areas located outside of occupied and modeled potential marbled murrelet habitat. In these areas, intensive and extensive prescriptions would be applied to stands under 65 years of age as of 2020 and over 65 years of age as of 2020, respectively. Protected riparian areas would be reduced around certain categories of streams and on the Lower Millicoma River. Under this alternative, the requirement for no net increase in permanent road miles in certain conservation areas would not apply.

EPA's Role in the EIS Process

The EPA is charged under section 309 of the Clean Air Act with reviewing all Federal agencies' EISs and commenting on the adequacy and acceptability of the environmental impacts of proposed actions. Under the CEQ NEPA regulations, EPA is also responsible for administering the EIS filing process. EPA is publishing a notice in the **Federal Register** announcing this DEIS. The publication date of EPA's notice of availability is the official beginning of the public comment period. EPA serves as the repository (EIS database) for EISs prepared by Federal agencies. You may search for EPA comments on EISs, along with EISs themselves, at *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search*.

Public Comments and Virtual Public Meeting

Submitting Comments

You may submit your comments and materials on the draft HCP and the DEIS by one of the methods in **ADDRESSES**. We specifically request information on the following:

1. Biological information, analysis, and relevant data concerning the covered species, other wildlife, and ecosystems.

2. Potential effects that the proposed permit actions could have on the covered species, and other endangered or threatened species, and their habitats, including the interaction of the effects of the project with climate change and other stressors.

3. Adequacy of the proposed actions to minimize and mitigate the impact of the taking on covered species, including but not limited to conservation measures, conditions on covered activities, and adaptive management procedures.

4. Potential effects that the proposed permit action could have on other aspects of the human environment, including effects on plants and animals, water resources, and aesthetic, historic, cultural, economic, social, environmental justice, climate change, or health effects.

5. The alternatives analysis conducted by FWS, including the alternatives analyzed, the range of alternatives analyzed, and the alternatives considered but not analyzed in detail.

6. The presence of historic properties—including archaeological sites, buildings and structures, historic events, sacred and traditional areas, and other historic preservation concerns—in the proposed permit area, which are required to be considered in project planning by the National Historic Preservation Act.

7. Cumulative effects, which are effects on the environment that result from the incremental effects of the action when added to the effects of other past, present, and reasonably foreseeable actions, as well as any connected actions that are closely related and should be discussed in the same DEIS.

8. The alternatives, information, and analyses submitted during the public

scoping period and the summary thereof.

9. Other information relevant to the ESRF HCP and its impacts on the human environment.

Virtual Public Meeting

To provide for the wide attendance of interested parties and help protect the public from potential spread of the COVID–19 virus, a virtual public meeting will be conducted. See **DATES** and **ADDRESSES** for the date and time of the virtual public meeting. During the virtual public meeting, ODSL and the Services will present information pertinent to the ESRF HCP and give the public the opportunity to ask questions about the draft HCP and DEIS. Oral comments will not be accepted during the meeting; written comments may be submitted by the methods listed in **ADDRESSES**.

Reasonable Accommodations

Persons needing reasonable accommodations in order to participate in the public meeting should contact the Service's Oregon Fish and Wildlife Office as soon as possible, using one of the methods listed in **ADDRESSES**. In order to allow sufficient time to process requests, please make contact at least 15 days before the public meeting. Information regarding this proposed action is available in alternative formats upon request.

Public Availability of Comments

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. Before including your address, phone number, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—might be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Comments and materials we receive, as well as references for supporting documentation we used in preparing the DEIS, will be available for public inspection online in Docket No. FWS–R1–ES–2022–0029 at *https://www.regulations.gov/* (see **FOR FURTHER INFORMATION CONTACT**).

Next Steps and Decision To Be Made

After public review and comment, the Services will evaluate the respective permit applications, associated documents, and any comments received, to determine whether the permit applications meet the requirements of section 10(a)(1)(B) of the ESA. The decisions will also be informed by the data, analyses, and findings in the EIS and public comments received on the Draft EIS and HCP. The Services will each document their determinations independently in an ESA section 10 findings document, ESA section 7 biological opinion, and a NEPA record of decision developed at the conclusion of the ESA and NEPA compliance processes. FWS expects to submit a Final EIS for publication in the **Federal Register** by June 2023. At least 30 days after the FEIS is published, we expect that the Services will complete records of decision on the requested ITPs in accordance with applicable timeframes established in 40 CFR 1506.11, and that the Services will issue decisions on the requested ITPs. The current estimate for the issuance of records of decision is August 2023.

Authority

We provide this notice in accordance with the requirements of section 10(c) of the ESA (16 U.S.C. 1539(c)) and NEPA and its implementing regulations (40 CFR 1503.1 and 1506.6).

Nanette Seto,

Acting Deputy Regional Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–24980 Filed 11–17–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R6–ES–2014–0048; FXES11140600000–234–FF06E22000]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the R-Project Transmission Line Revised Habitat Conservation Plan, Nebraska

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; virtual public scoping meeting; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS), provide this notice to open a public scoping period and announce virtual public scoping meetings, in accordance with requirements of the National Environmental Policy Act and its implementing regulations. The scoping period is associated with the preparation of a supplemental environmental impact statement (SEIS) to the February 2019 *Final Environmental Impact Statement on Issuance of an Incidental Take Permit and Implementation of a Habitat Conservation Plan for the R-Project Transmission Line.* Nebraska Public Power District (NPPD, applicant) is preparing a revised habitat conservation plan (HCP) in support of its anticipated resubmission of an application for an incidental take permit (ITP) under the Endangered Species Act (ESA) for activities it will undertake in constructing, operating, and maintaining a new transmission line (known as the R-Project) in central Nebraska. The SEIS will evaluate the impacts on the human environment related to the proposed issuance of the ITP and implementation of the HCP, including addressing the issues identified by the U.S. District Court for the District of Colorado in its remand of the ITP that FWS issued June 12, 2019.

DATES:

Submitting Comments: We will accept online or hardcopy comments. Hardcopy comments must be received or postmarked on or before December 19, 2022. (See **ADDRESSES**.) Comments submitted online at *https://www.regulations.gov/* must be received by 11:59 p.m. Eastern Time on December 19, 2022.

Public Meetings: The FWS will hold 2 virtual public scoping meetings during the scoping period at the following times:

- December 8, 2022, at 10:00 a.m. CST.
- December 8, 2022, at 6:30 p.m. CST.

Registration and information on the virtual public meetings are available at *https://www.fws.gov/project/r-project-transmission-line*. Additionally, a recording of a public scoping meeting will be available for viewing by the public online, at *https://www.fws.gov/project/r-project-transmission-line* and at the following locations:

- North Platte Public Library, 120 W 4th St., North Platte, NE 69101;
- Thomas County Library, 501 Main St., Thedford, NE 69166;
- Taylor Public Library, 106 William St., Taylor, NE 68879.

ADDRESSES:

Submitting Comments: You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov*. Follow the instructions for submitting comments on FWS–R6–ES–2014–0048.

• *U.S. mail:* Public Comments Processing; Attn: Docket No. FWS–R6–ES–2014–0048; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For additional information about submitting comments, see Public Scoping Process under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jeff Runge, by telephone at 308–382–6468, or by email at *jeff_runge@fws.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The U.S. Fish and Wildlife Service (FWS) issued an incidental take permit (ITP) to Nebraska Public Power District (NPPD) on June 12, 2019, authorizing incidental take of the American buying beetle (*Nicrophorus americanus*) that would result from the R-Project, a 345,000-volt, 226-mile-long transmission line. The **Federal Register** notice of availability for ITP, Habitat Conservation Plan (HCP), and Final Environmental Impact Statement published on February 8, 2019 (84 FR 2900). The proposed project starts at NPPD's Gerald Gentleman Substation near Sutherland, Nebraska; goes north to a 345 kV substation located in Thomas County near Thedford; and then extends eastward to another 345 kV substation sited in Holt County, which is to interconnect with Western Area Power Administration's existing Fort Thompson to Grand Island 345 kV line that is located on the eastern border of Holt County.

The purpose of the R-Project is three-fold: (1) relieve electrical congestion within the existing transmission system; (2) enhance system reliability; and (3) provide opportunities for development of renewable resources. On June 17, 2020, the U.S. District Court for the District of Colorado issued a decision on a lawsuit challenging the FWS's decision to issue the ITP under the Endangered Species Act (ESA), National Environmental Policy Act (NEPA), and the National Historic Preservation Act. In its ruling, the court vacated and remanded the ITP to the FWS for further proceedings consistent with the court's order. The FWS is preparing a Supplemental Environmental Impact Statement (SEIS) to address the anticipated resubmission of NPPD's ITP application, the issues identified by the court, and to address new information and changes in circumstances, as relevant, to the R-Project Revised HCP.

In accordance with section 10(a)(2)(A) of the ESA, NPPD intends to submit the Revised HCP to the FWS in support of a resubmitted application for an ITP for the threatened American burying beetle. The requested ITP would authorize incidental take of the American burying beetle likely to result from construction and anticipated emergency repairs of the R-Project. The Revised HCP is required to include measures to minimize and mitigate the impacts of the taking on American burying beetle to the maximum extent practicable.

We intend to prepare a draft SEIS and, later, a final SEIS, to evaluate the effects on the human environment of issuing an ITP under the anticipated resubmitted application, and NPPD's implementation of the R-Project Revised HCP. The SEIS is necessary to meet our requirements under NEPA; 42 U.S.C 4321 *et seq.*) and its implementing regulations. The FWS's purpose and need for the proposed action is to (1) process the applicant's resubmitted request for an ITP and (2) either grant, grant with conditions, or deny the ITP request in compliance with the FWS's authority under applicable law, including, without limitation, section 10(a)(1)(B) of the ESA and applicable ESA implementing regulations.

Preliminary Proposed Action and Alternatives

Consistent with 40 CFR 1501.9(d)(2), the preliminary description of the proposed action is issuance of an ITP authorizing incidental take of a covered species in association with covered activities and Revised HCP implementation.

The draft SEIS will include a reasonable range of alternatives, which may include but are not limited to scope of the covered activities, variations in the level of permitted take, the length of the permit term, type of conservation minimization and mitigation measures, and implementation and effectiveness monitoring. Additionally, a No Action Alternative will be included, in which the FWS would not issue an ITP and would assume that NPPD would not construct the R-Project.

Background

Section 9 of the ESA prohibits ''take'' of fish and wildlife species listed as endangered under section 4 (16 U.S.C. 1538 and 16 U.S.C. 1533, respectively). The ESA implementing regulations extend, under certain circumstances, the prohibition of take to threatened species (50 CFR 17.31). Under section 3 of the ESA, the term ''take'' means to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct'' (16 U.S.C. 1532(19)). The term ''harm'' is defined by regulations as ''an act which actually kills or injures wildlife'' (50 CFR 17.3). ''Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering'' (50 CFR 222.102).

Under section 10(a) of the ESA, FWS may issue permits to authorize incidental take of listed fish and wildlife species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Section 10(a)(1)(B) of the ESA contains provisions for issuing ITPs to non-Federal entities for the take of endangered and threatened species, provided the following criteria are met:

1. The taking will be incidental;
2. The applicant will, to the maximum extent practicable, minimize and mitigate the impact of such taking;
3. The applicant will ensure that adequate funding for the plan will be provided;
4. The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and
5. The applicant will carry out any other measures the FWS may require as being necessary or appropriate for the purposes of the HCP.

R-Project Revised Habitat Conservation Plan

NPPD intends to implement the R-Project Revised HCP to cover construction and anticipated emergency repairs of the R-Project. The R-Project Revised HCP includes measures to minimize and mitigate impacts of the taking on American burying beetle. NPPD is expected to request a 50-year ITP from the FWS.

Covered Activities

The proposed covered activities will likely include:

• *Access:* Creation of temporary access routes and permanent access roads.

• *Right-of-way preparation:* Removal of trees and tall brush from the 200-foot-wide right-of-way.

• *Temporary work areas:* Grading and filling to create temporary work areas including assembly areas, construction yard, staging areas, and structure work areas.

- *Tower installation:* Construction associated with power line foundation installation and structure erection.
- *Power line installation:* Stringing, pulling, and tensioning necessary for power line placement on towers.
- *Relocation of existing infrastructure:* Relocation of existing overhead distribution power lines and livestock and center-pivot irrigation wells to outside the right-of-way.
- *Emergency repairs:* Repairs to isolated damages, such as single insulators or weak points on conductors, as well as large-scale repairs following damage from severe weather events.
- *HCP Implementation Activities:* Activities identified in the conservation strategy and monitoring program that may result in short-term effects on covered species.

Covered Species

The American burying beetle is the species anticipated to be proposed for coverage under the R-Project Revised HCP and ITP. The American burying beetle is known to occur within the proposed corridor for the R-Project. The R-Project Revised HCP will include an analysis of impacts to American burying beetle and methodology for estimating and quantifying take from covered activities and minimization and mitigation measures. The R-Project Revised HCP is anticipated to include analysis of evaluated species, which are species that may occur in the project area but for which NPPD is not requesting take authorization. The HCP describes measures to avoid take of these species. Species anticipated as evaluated species may include the following:

Bald eagle (*Haliaeetus leucocephalus*)
Blanding's turtle (*Emydoidea blandingii*)
Blowout penstemon (*Penstemon haydenii*)
Golden eagle (*Aquila chrysaetos*)
Northern long-eared bat (*Myotis septentrionalis*)
Tricolored bat (*Perimyotis subflavus*)
Piping plover (*Charadrius melodus*)
Rufa red knot (*Calidris canutus rufa*)
Topeka shiner (*Notropis topeka* [=*tristis*])
Western prairie-fringed orchid (*Platanthera praeclara*)
Whooping crane (*Grus americana*)

Measures to minimize and mitigate impacts on the American burying beetle will be described in the Revised HCP as conservation measures and conditions on covered activities, guided by goals and objectives in the conservation strategy of the Revised HCP. These measures would be systematically implemented and monitored for success. Impacts would be offset by the protection of high-quality habitat for the American burying beetle. Minimization and mitigation measures are subject to adaptive management to ensure their effectiveness and to ensure achievement of the R-Project HCP's biological goals and objectives.

The R-Project Revised HCP will include funding information and assurances, monitoring requirements, adaptive management, and changed circumstance provisions to help ensure conservation outcomes for American burying beetle. Annual reports would confirm the amount, type, and location of impacts and mitigation, as well as the status of monitoring, adaptive management, changed circumstances, and funding.

Summary of Expected Impacts

The draft SEIS will identify and describe the effects of the proposed Federal action on the human environment that are reasonably foreseeable, including direct, indirect, and cumulative effects. This includes effects that occur at the same time and place as the proposed action or alternatives and effects that are later in time or farther removed in distance from the proposed action or alternatives. Expected impacts may include, but are not limited to, positive and negative impacts to the American burying beetle, biological resources, visual resources/aesthetics, and cultural and historic resources. The effects of these expected impacts will be analyzed in the SEIS (see 40 CFR 1508.1(g) and 40 CFR 1502.16).

Schedule for the Decision Making Process

The FWS will conduct an environmental review to analyze the effects of the proposed permit action, along with other alternatives considered and the associated impacts of each alternative for the development of the draft SEIS. Following completion of the environmental review, the FWS will publish a notice of availability and request for public comments on the draft SEIS and the draft Revised HCP resubmitted with the ITP application. The FWS expects to make the draft SEIS and draft HCP available to the public in summer 2023. After public review and comment, the FWS will evaluate the permit application and associated documents, and any comments received, to determine whether the requirements of section 10(a)(2) of the ESA and implementing permit regulations are met. The FWS expects to make the final SEIS and final Revised HCP available to the public in spring 2024. At least 30 days after the final SEIS is available, the FWS's record of decision will be completed in accordance with applicable timeframes established in 40 CFR 1506.11. If appropriate, the FWS would issue the ITP after the issuance of the record of decision. If issued, the permit may include such terms and conditions deemed necessary or appropriate to carry out the purposes of the ITP and the Revised HCP.

Public Scoping Process

Virtual Public Meeting

This notice of intent initiates the scoping process, which aids in the development of the EIS.

See **DATES** and **ADDRESSES** for the date and time of the virtual public scoping meetings. The virtual public scoping meetings will provide FWS with an opportunity to present to the public information pertinent to the R-Project Revised HCP, and for the public to ask questions on the scope of issues and alternatives that FWS should consider when preparing the SEIS. We will accept only written comments. Written comments may be submitted by the methods listed in **ADDRESSES**.

Reasonable Accommodations

Persons needing reasonable accommodations to attend and participate in the virtual public scoping meetings should contact the FWS's Nebraska Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**) as soon as possible. To allow sufficient time to process requests, please make contact no later than 1 week before the desired public meeting. Information and documents are available in alternative formats upon request.

Request for Information

We request comments on the proposed action, concerning the scope of the analysis and identification of relevant information, studies, and analyses from the public; affected Federal, State, Tribal, and local governments, agencies, and offices; the scientific community; industry; or any other interested party. We will consider these comments in developing the draft SEIS. Specifically, we seek:

1. Biological information, analysis, and relevant data concerning the covered species, evaluated species, and other wildlife;

2. Potential effects that the proposed permit action could have on the covered species, and/or other endangered or

threatened species, and their associated ecological communities or habitats;

3. Potential effects that the proposed permit action could have on other aspects of the human environment;

4. Other possible reasonable alternatives that FWS should consider, including additional or alternative avoidance, minimization, and mitigation measures;

5. The presence of historic properties—including archaeological sites, buildings, and structures; historic events; sacred and traditional areas; and other historic preservation concerns—in the proposed plan and permit area, which are required to be considered in project planning by the National Historic Preservation Act;

6. Information on other current or planned activities in, or in the vicinity of, the R-Project and their possible impacts on the covered species, including any connected actions that are closely related and should be discussed in the same draft SEIS; and

7. Other information relevant to the R-Project Revised HCP and its impacts on the human environment.

Public Availability of Comments

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. Before including your address, phone number, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—might be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Comments and materials we receive, as well as supporting documentation we use in preparing the DEIS, will be available for public inspection online in Docket No. FWS–R6–ES–2014–0048, at *https://www.regulations.gov/*.

Next Steps

Once the draft SEIS is prepared, there will be further opportunity for comment on the proposed permit action through an additional public comment period.

Lead and Cooperating Agencies

The FWS is the lead agency for the NEPA process. Cooperating agencies include the Advisory Council on Historic Preservation, History Nebraska, the Nebraska Game and Parks Commission, the National Park Service, the U.S. Army Corps of Engineers, and the U.S. Environmental Protection Agency. The FWS welcomes inquiries from other Federal, State, or Tribal, or local agencies potentially interested in being a cooperating agency for the NEPA process.

Decisionmakers and Nature of Decision To Be Made

The decisionmaker is the FWS Regional Director of the Mountain-Prairie Region. If, after publication of the record of decision, the agencies determine that all requirements are met for ITP issuance, the decisionmaker will issue a decision on the requested ITP.

Authority

We provide this notice in accordance with the requirements of section 10(c) of the ESA (16 U.S.C. 1539(c)) and NEPA regulations on the publication of a notice of intent to issue an EIS (40 CFR 1501.9(d)).

Drue DeBerry,

Acting Assistant Regional Director, Ecological Services, Mountain-Prairie Region.

[FR Doc. 2022–25217 Filed 11–17–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–FAC–2022–N059; FXFR13360900000–FF09F14000–201]

Aquatic Nuisance Species Task Force Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Fish and Wildlife Service gives notice of a public meeting of the Aquatic Nuisance Species (ANS) Task Force, in accordance with the Federal Advisory Committee Act. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

DATES: The ANS Task Force will meet Wednesday and Thursday, January 11–12, 2023, from 8 a.m. to 5 p.m. each day (Eastern Time).

Registration: Registration is required. The deadline for registration is January 6, 2023.

Accessibility: The deadline for accessibility accommodation requests is January 6, 2023. Please see *Accessibility Information,* below.

ADDRESSES: The ANS Task Force meeting will take place at the U.S. Fish and Wildlife Service Headquarters, 5275 Leesburg Pike, Falls Church, VA 22041. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) or visit the ANS Task Force website at *https://www.fws.gov/program/aquatic-nuisance-species-task-force.*

FOR FURTHER INFORMATION CONTACT: Susan Pasko, Executive Secretary, ANS Task Force, by telephone at (703) 358–2466, or by email at *Susan_Pasko@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Aquatic Nuisance Species (ANS) Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended (16 U.S.C. 4721–4728), and is composed of Federal and ex-officio members. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

This meeting is open to the public. The meeting agenda will include: reports from ANS Task Force members and subcommittees; discussion on priority outputs to advance the goals identified in the ANS Task Force Strategic Plan for 2020–2025; presentations on new species occurrences in the United States; aquatic invasive species risk mitigation measures, advancement of the early detection rapid response framework, and progress on updating or implementing species management plans; recommendations by the ANS Task Force regional panels; and public comment. The final agenda and other related meeting information will be posted on the ANS Task Force website, *https://www.fws.gov/program/aquatic-nuisance-species-task-force.*

Public Input

If you wish to provide oral public comment or provide a written comment for the ANS Task Force to consider, contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than Friday, January 6, 2023.

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the ANS Task Force Executive Secretary, in writing (see **FOR FURTHER INFORMATION CONTACT**), for placement on the public speaker list for this meeting. Requests to address the ANS Task Force during the meeting will be accommodated in the order the requests are received. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the Executive Secretary up to 30 days following the meeting.

Accessibility Information

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. Please contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than Friday, January 6, 2023, to give the U.S. Fish and Wildlife Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 2.

David A. Miko,

Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 2022–25107 Filed 11–17–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX23ZS00COM0000; OMB Control Number 1028–NEW]

Agency Information Collection Activities; AstroLink Community Survey on the Archive, Access, and Use of Planetary Information

AGENCY: Geological Survey.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing approval of a collection currently in use without approval.

DATES: Interested persons are invited to submit comments on or before January 17, 2023.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Marc Hunter by email at *mahunter@usgs.gov* or by telephone at 928–556–7220. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval. We may not conduct or sponsor, nor are you required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency might minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: This survey will gather opinions, experiences, and preferences regarding the state of planetary science information, both for data producers and consumers. The results of this survey will be used to provide summary statistics that reflect all aspects of the planetary science community, to include the interested public, and provide actionable information to stakeholders.

Title of Collection: AstroLink Community Survey on the Archive, Access and Use of Planetary Information

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Respondents: 100.

Total Estimated Number of Annual Responses: 100.

Estimated Completion Time per Response: 10 minutes.

Total Estimated Number of Annual Burden Hours: 17.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: 0.

An agency may not conduct or sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501 *et seq.*).

Justin Hagerty,

USGS Astrogeology Science Center Director, Southwest Region.

[FR Doc. 2022–25085 Filed 11–17–22; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX23EF000COM00; OMB Control Number 1028–0092]

Agency information collection Activities; Submission to the Office of Management and Budget for Review and Approval; Topographic and Hydrography Data Grants

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before December 19, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0092 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Susan Buto by email at *sbuto@usgs.gov,* or by telephone at 775–546–3059. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on December 22, 2021 (86 FR 72613). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency might minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: The USGS gathers topographic data through the 3D Elevation Program (3DEP) and, contingent on funding, the 3D Hydrography Program (3DHP). The primary goal of 3DEP is to systematically collect three-dimensional (3D) elevation data in the form of high-quality light detection and ranging (lidar) data for the conterminous United States, Hawaii, and the U.S. territories and to collect interferometric synthetic aperture radar (IfSAR) data for Alaska. The primary goal of the 3DHP is to leverage 3DEP data to create a high-precision, z-enabled representation of the surface waters of the United States and its territories. The implementation model for 3DEP is based on multi-agency partnership funding for topographic data acquisition, with the USGS leading management of the program to facilitate planning and acquisition and use of government contracts and partnership agreements for the broader community. The USGS issues an annual Broad Agency Announcement (BAA), which is a competitive solicitation issued to facilitate agreements with partners to collect lidar and derived elevation data for 3DEP. The BAA has been included in the annual Catalog of Federal Domestic Assistance under USGS 15.8 17. Federal agencies, state and local governments, tribes, academic institutions, and the private sector are eligible to submit proposals. The USGS collects information from applicants about their proposed topographic data collection and cost-sharing offers and then uses that information to determine grant awards. Implementation of 3DHP will follow the 3DEP model over time as funding permits. This ICR expands the scope of the collection to include proposals for both the 3DEP and 3DHP BAA activities.

Title of Collection: Topographic and Hydrography Data Grants.

OMB Control Number: 1028–0092.

Form Number: None

Type of Review: Extension of a currently approved collection with revision.

Respondents/Affected Public: Federal agencies, State and local governments, tribes, academic institutions, and the private sector.

Total Estimated Number of Annual Respondents: 80.

Total Estimated Number of Annual Responses: 80.

Estimated Completion Time per Response: 41 hours.

Total Estimated Number of Annual Burden Hours: 3,280.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501 *et seq.*).

Michael Tischler,

Director, USGS National Geospatial Program.

[FR Doc. 2022–25094 Filed 11–17–22; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAD01000.223L1109AF.L12200000.FH0000.LXSSB0280000; MO#4500164048]

Notice of Temporary Annual Closure on Public Lands for the King of the Hammers Race, San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of temporary closure.

SUMMARY: As authorized under the provisions of the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) is giving notice that certain public lands located near Johnson Valley, California, within the Johnson Valley Off-Highway Vehicle Recreation Area, will be temporarily closed to all public use to enhance public safety during Hammerking Productions' annual King of the Hammers desert race authorized under a 5-year Special Recreation Permit (SRP).

DATES: This action is in effect for a 10-day period in January and February each year from 2023 through 2027 for the King of the Hammers race. The race takes place annually from approximately the end of January through mid-February. The next King of the Hammers closure will take place February 2–12, 2023. The week prior to the race will be dedicated to set up and the building of the short course. The BLM will post the dates for King of the Hammers, the dates of the temporary closures, and a map of the closure area at the main entry points into the Johnson Valley Off-Highway Vehicle Recreation Area, the California Desert District Office, the Barstow Field Office, and on the BLM website at the addresses provided below every year at least 30 days prior to the events.

ADDRESSES: California Desert District, 1201 Bird Springs Drive, Palm Springs CA, 92262; Barstow Field Office, 2601 Barstow Road, Barstow CA, 92311; BLM website: *www.blm.gov/california.*

FOR FURTHER INFORMATION CONTACT: Dana Stephenson, Outdoor Recreation Planner, 300 South Richmond Rd, Ridgecrest, CA 93555, telephone: (760) 384–5429, email: *dstephenson@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This closure applies to all public use, including pedestrian use and vehicles. Over the 5-year SRP (beginning in 2023 and ending in 2027), the annual 10-day closure will comply with the management plan for the area, ensuring that a minimum of three staging areas within the Johnson Valley Off-Highway Vehicle Recreation Area remain open to the public every weekend (Saturday and Sunday) throughout the closure period.

Exclusive Use: During the 10-day closure period, the closure area will be for the exclusive use of King of the Hammers participants, registered spectators for the King of the Hammers, and other authorized users with an authorized SRP valid for activities within the closure area.

Exceptions: Closure restrictions do not apply to medical and rescue personnel in the performance of their official duties; official United States military and Federal, State, and local law enforcement; Federal, State, and local officers and employees in the performance of their official duties; King of the Hammers event officials and race participants; vendors with a valid BLM SRP; and registered event spectators.

Enforcement: Any person who violates the temporary closure order may be tried before a United States Magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of California law.

(Authority: 43 CFR 8360.0–7 and 8364.1).

Michelle Lynch,

BLM California Desert District Manager.

[FR Doc. 2022–25169 Filed 11–17–22; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM930000.L14400000.BJ0000.BX0000]

Notice of Filing of Plat of Survey; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plat of survey of the following described lands is scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management (BLM), New Mexico Office, Santa Fe, New Mexico. The survey announced in this notice is necessary for the management of lands administered by the agency indicated.

ADDRESSES: This plat will be available for inspection in the New Mexico Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico, 85004–4427. Protests of a survey should be sent to the New Mexico Director at the above address.

FOR FURTHER INFORMATION CONTACT: Michael J. Purtee, Chief Cadastral Surveyor; (505) 761–8903; *mpurtee@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico

The plat, representing the conditional corrective resurvey of a portion of certain tracts in section 8, within the Pojoaque Grant, Township 19 North, Range 9 East, accepted November 9, 2022, for Group 1120, New Mexico.

This plat was prepared to correct the plat requested by the Bureau of Indian Affairs, Southwestern Region, accepted November 2, 2011, for Group 1120, New Mexico.

A person or party who wishes to protest against this survey must file a written notice of protest within 30 calendar days from the date of this publication with the New Mexico Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest

is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Michael J. Purtee,

Chief Cadastral Surveyor of New Mexico.

[FR Doc. 2022–25120 Filed 11–17–22; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF AGRICULTURE

Forest Service

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[223.LLIDI00000.L1330000.EO0000.241A]

Notice of Availability of the Final Environmental Impact Statement for the Proposed Husky 1 North Dry Ridge Phosphate Mine, Caribou County, ID

AGENCY: Forest Service, Agriculture (USDA); Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) and the U.S. Department of Agriculture, Forest Service (USFS) Caribou-Targhee National Forest (CTNF), announce the availability of the Final Environmental Impact Statement (EIS) for the proposed Husky 1 North Dry Ridge Phosphate Mine (Project).

DATES: The Final EIS and the USFS Draft Record of Decision (ROD) are now available for public review. A 45-day objection period for the USFS Draft ROD will start when the USFS publishes a legal notice in the newspaper of record. The BLM will not issue a decision on the proposal for a minimum of 30 days after the date that the Environmental Protection Agency (EPA) publishes its Notice of Availability (NOA) in the **Federal Register**. The USFS will issue a Final ROD following resolution of any objections.

ADDRESSES: The Final EIS and documents pertinent to this proposal are available for review on the BLM ePlanning project website at *https://go.usa.gov/x7HSJ;* the Caribou-Targhee National Forest Current and Recent Projects at *http://www.fs.usda.gov/projects/ctnf/landmanagement/projects;* or at the BLM Pocatello Field Office at 4350 Cliffs Drive, Pocatello, ID 83204.

FOR FURTHER INFORMATION CONTACT: Wes Gilmer, BLM Pocatello Field Office, 4350 Cliffs Drive, Pocatello, ID 83204; phone (208) 478–6369; email: *wgilmer@blm.gov;* fax (208) 478–6376. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Gilmer. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Itafos Conda LLC (Itafos) submitted a proposed mine and reclamation plan (MRP) for the Husky 1 North Dry Ridge Phosphate Mine to conduct operations and recover phosphate ore from existing leases (IDI–8289, IDI–05549, I–04, and IDI–0678). The MRP proposes surface mining, support and reclamation activities on approximately 1,146 acres of mostly National Forest System (NFS) land. A modification (enlargement by 559 acres) of Federal phosphate lease IDI–05549 to recover adjacent ore reserves that would otherwise be bypassed and rendered unmineable in the future is also requested.

The BLM, the Federal lease administrator, is the lead agency, and the USFS, the Federal land management agency, is the co-lead agency. The United States Army Corps of Engineers, Idaho Department of Environmental Quality, Idaho Department of Lands and Idaho Governor's Office of Energy and Mineral Resources are cooperating agencies.

The NOA for the Draft EIS was published on October 22, 2021 (86 FR 58686), initiating a 45-day public comment period that ended on December 6, 2021. Agencies, organizations and individual stakeholders provided comments on the Draft EIS via mail, email and through the project website.

Comments on the Draft EIS received from the public were considered and incorporated as appropriate into the Final EIS. Public comments resulted in the addition of clarifying text and two new alternatives but did not significantly change the proposed action or predicted impacts of the proposal.

The Final EIS addresses issues identified during scoping and public review of the Draft EIS by analyzing impacts to the human and natural environment including water resources, air quality, health and safety, socioeconomics and wildlife. It also addresses reclamation, financial assurance, mitigation and monitoring. The Final EIS considers a range of alternatives and evaluates several in detail: the proposed action, an alternative cover, an alternative stream routing, two alternative access routes, an alternative sequence of mining and the No Action alternative. The agencies' preferred alternative combines four alternatives that modify the proposed action to be more protective of natural resources, including: alternative cover that reduces impacts to surface water and ground water by reducing infiltration of meteoric water into waste rock; alternative stream routing to limit long-term impacts to Stewart Creek by returning it permanently to its natural channel after mining; alternative access Option 2 that permanently relocates NFS Road 134 to maintain public and tribal access to the site and through NFS lands; and the alternative mine sequence in which mining would begin in the North Dry Ridge area prior to developing the Husky 1 area.

The BLM and USFS will make separate but coordinated decisions related to the Project. The BLM will either approve, approve with modifications, or deny the MRP; and decide whether to modify lease IDI–05549. The BLM will base its decisions on the Final EIS; public, Tribal, and agency input; and any recommendations that the USFS may have regarding surface management of leased NFS lands. The USFS will make recommendations to the BLM concerning surface management and best management practices on leased lands within the CTNF and issue decisions on approval of proposed special use authorizations (SUAs) for off-lease mining support activities and the alternative access. The USFS SUAs are necessary for any off-lease disturbances or structures associated with the Project located within the CTNF. The reroute of the Simplot slurry line, which crosses the proposed mine operations, will require an amendment of the Caribou National Forest Revised Land and Resource Management Plan (2003 Revised Forest Plan (RFP)).

The portion of the Project related to proposed USFS SUAs for off-lease activities, the selection of the alternative access and the amendment of the 2003 RFP are subject to the objection process pursuant to 36 CFR 218 subparts A and B. Instructions for filing objections will be provided in the legal notice

published in the newspaper of record for the USFS Draft ROD. Objections will be accepted only from those who have previously submitted specific written comments regarding the proposed project, either during scoping or other designated opportunities for public comment, in accordance with 36 CFR 218.5. Issues raised in objections must be based on previously submitted, timely and specific written comments regarding the proposed project, unless based on new information arising after designated opportunities.

(Authority: 36 CFR 218; 40 CFR 1506.6, 40 CFR 1506.10; 43 CFR 46; and 43 CFR 3590.)

Mary D'Aversa,

Idaho Falls District Manager, Bureau of Land Management.

Melvin Bolling,

Forest Supervisor, Caribou-Targhee National Forest.

[FR Doc. 2022–25048 Filed 11–17–22; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L51010000.ER0000.LVRWB19B6670. LLCAD01000.19X (MO #4500161985)]

Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Ivanpah-Control Project, Inyo, Kern, and San Bernardino Counties, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) California Desert District Office, Palm Springs, California, intends to prepare an Environmental Impact Statement (EIS) to consider the effects of the Ivanpah-Control Project (Project) and by this notice is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the EIS. The BLM requests comments concerning the scope of the analysis and identification of relevant information and studies by January 3, 2023. To afford the BLM the opportunity to consider comments in the Draft EIS, please ensure your comments are received prior to the close of the 45-day scoping period or 15 days after the last public meeting, whichever is later. The BLM will hold public scoping meetings; the dates, locations, and times will be announced at least 15 days in advance through public notices, media releases, mailings, and the BLM website at: *https://bit.ly/3knv8cm.*

ADDRESSES: You may submit comments related to the Ivanpah-Control Project by any of the following methods:

- *Website: https://bit.ly/3knv8cm.*
- *Email: BLM_CA_CD_TLRR_IvanpahControl@blm.gov.*
- *Fax:* 760–833–7199.
- *Mail:* Ivanpah-Control Environmental Impact Statement, Bureau of Land Management California Desert District Office, 1201 Bird Center Drive, Palm Springs CA 92262.

Documents pertinent to this proposal may be examined online at *https://bit.ly/3knv8cm* and at the BLM California Desert District Office.

FOR FURTHER INFORMATION CONTACT: Joan Patrovsky, Project Manager, Ivanpah-Control Project, telephone: (760) 252–6032; address: Bureau of Land Management California Desert District Office, 1201 Bird Center Drive, Palm Springs CA 9226; email: *jpatrovs@blm.gov.* Contact Ms. Patrovsky to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Patrovsky. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

The purpose of this Federal action is to respond to a right-of-way application from Southern California Edison for demolition, construction, operations, and maintenance of the Ivanpah-Control 115 kilovolt transmission line on BLM-administered lands, consistent with applicable laws, regulations, and policies. The Secretary of the Interior is authorized to grant rights-of-way on public lands for systems for generation, transmission, and distribution of electric energy (43 U.S.C. Section 1761(a)(4)); the need for the BLM's action is established by this delegated authority under Title V of FLPMA.

The applicant is Southern California Edison and the purpose for the Project is to ensure compliance with the California Public Utilities Commission's General Order 95 and National Electric Reliability Corporation reliability standards. The proposed action is to implement engineering solutions to remediate approximately 2,950 discrepancies along the Ivanpah-Control alignment, continue to provide safe and reliable electrical service, meet Project needs while minimizing environmental impacts, and design and construct the physical components of the Project in conformance with industry and/or Southern California Edison's approved engineering, design, and construction standards for substation and subtransmission system projects.

Preliminary Proposed Action and Alternatives

Southern California Edison proposes to remediate physical clearance discrepancies on existing 115 kilovolt subtransmission lines, referred to collectively as the Ivanpah-Control transmission line, located in southern California. The Project is composed of five segments (1, 2, 3N, 3S, and 4) spanning Inyo County, northeast Kern County, and northern San Bernardino County. The northern/western terminus is the Control Substation, approximately 5 miles west of the city of Bishop in Inyo County; the eastern terminus is at Ivanpah Substation, located in California approximately 6 miles southwest of Primm, Nevada. To address the discrepancies, Southern California Edison proposes to conduct the following activities:

- Segment 1: Control Substation (Bishop) to Inyokern Substation (126-mile segment): The subtransmission lines would be rebuilt in a new alignment adjacent to the existing alignment (but outside the existing right-of-way) and the existing subtransmission structures would be removed. This would involve removing approximately 1,161 existing structures and replacing with 905 new structures.
- Segment 2: Inyokern Substation to Kramer Junction (48-mile segment): The subtransmission line would be rebuilt in a new alignment adjacent to the existing alignment (but within the existing right-of-way) and the existing subtransmission structures would be removed. This would involve removing approximately 390 transmission structures and installing 342 new structures.
- Segment 3N: Kramer Junction–Coolwater Substation (44-mile segment): The subtransmission line would be reconductored. Some existing subtransmission structures would be replaced with steel and wood H-frames and wood pole multipole structures; most replacement structures would be installed proximate to existing structures that would be removed. This would involve removing approximately

43 existing structures and installing approximately 45 structures.

- Segment 3S: Kramer Junction–Tortilla Substation–Coolwater Substation (44-mile segment): The subtransmission line would be reconductored. Some existing subtransmission structures would be replaced with tubular steel pole and wood multipole structures, and steel and wood H-frames; replacement structures would be installed proximate to existing structures which would be removed. This would involve removing approximately 42 existing structures and installing approximately 42 structures.
- Segment 4: Coolwater Substation to Ivanpah Substation (98-mile segment): The existing subtransmission circuit would be derated, which would remediate some existing discrepancies with no physical modification to the facilities. To remediate the remaining discrepancies, some existing subtransmission structures would be replaced with steel and wood H-frames; these replacement structures would mostly be installed proximate to existing structures which would be removed. This would involve removing approximately 60 structures, installing approximately 62 structures, and modifying approximately 83 structures.

A range of reasonable alternatives will be developed and analyzed in the EIS after considering information received during the scoping period. Preliminary action alternatives include a full rebuild in segments 3N, 3S, and 4 and the use of different pole designs in portions of segments 1 and 2. The range of reasonable alternatives will include a no action alternative, under which the BLM would deny the application and the Ivanpah-Control line would remain as existing with ongoing maintenance activities as needed. The BLM welcomes comments on all preliminary alternatives as well as suggestions for additional alternatives. As alternatives should resolve a problem with the Proposed Action, please indicate the purpose of any suggested alternative.

Summary of Expected Impacts

Preliminary issues, either beneficial or adverse and of varying intensity, for the Project have been identified by BLM personnel and in consultation with Federal, State, and local agencies, Tribes, and other Cooperating Agencies. These preliminary issues include potential impacts to:

- Special status wildlife and vegetation species;
- Visual resources;
- Cultural resources; and
- Areas of Critical Environmental Concern

The public scoping process will guide determination of relevant issues that will influence the scope of the environmental analysis, including alternatives and mitigation measures. The EIS will identify and describe the effects of the Proposed Action and alternatives on the human environment. The BLM also requests the identification of potential impacts that should be analyzed. Impacts should be a result of the action; therefore, please identify the activity along with the potential impact.

Anticipated Permits and Authorizations

In addition to the requested right-of-way grant, other Federal, State, and local authorizations will be required for the Project. These include authorizations under the Bald and Golden Eagle Protection Act, the Endangered Species Act, Clean Water Act, 14 CFR part 77, and other laws and regulations determined to be applicable to the Project.

Schedule for the Decision-Making Process

The BLM will provide additional opportunities for public participation consistent with the NEPA process, including a 45-day comment period on the Draft EIS. The Draft EIS is anticipated to be available for public review in Fall 2023 and the Final EIS is anticipated to be released in Summer 2024 with a Record of Decision in Summer/Fall 2024.

Public Scoping Process

This notice of intent initiates the scoping period. The BLM will be holding at least two virtual public scoping meetings. The specific date(s) and location(s) of these scoping meetings will be announced at least 15 days in advance through public notices, media releases, mailings, and the BLM website above.

Lead and Cooperating Agencies

The BLM is the lead Federal agency for this EIS and the related National Historic Preservation Act Section 106 process. The following have agreed to participate in the environmental analysis of the Project as Cooperating Agencies: Inyo County, Los Angeles Department of Water and Power, United States Fish and Wildlife Service, National Park Service, United States Army Corps of Engineers, United States Environmental Protection Agency, Fort Irwin National Training Center, Marine Corps Logistics Base Barstow, Edwards Air Force Base, and Naval Air Weapons Station China Lake. Twenty-eight entities declined or did not respond to the BLM's offer to participate in the Project as a Cooperating Agency. Federal, State, and local agencies, Tribes, and stakeholders interested in the scoping process may request or be requested by the BLM, if eligible, to participate in the development of the EIS as a Cooperating Agency.

Responsible Official

The BLM California State Director is the responsible official who will make the decisions below.

Nature of Decision to Be Made

The BLM will use the analysis in the EIS to inform the following: whether to grant, grant with conditions, or deny the application for a right-of-way. Pursuant to 43 CFR 2805.10, if the BLM issues a grant, the BLM decision maker may include terms, conditions, and stipulations determined to be in the public interest.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed action and all analyzed reasonable alternatives and, in accordance with 40 CFR 1502.14(e), include appropriate mitigation measures not already included in the proposed action or alternatives. Mitigation may include avoidance, minimization, rectification, reduction or elimination over time, and compensation, and may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA process to help support compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including public involvement requirements of Section 106. The information about historic and cultural resources and threatened and endangered species within the area potentially affected by the proposed plan will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM MS 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and stakeholders that may be

interested in or affected by the proposed Ivanpah-Control Project that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency. The BLM has sent invitations to potentially affected Tribal Nations and initiated government-to-government consultation meetings and intends to continue coordination throughout the NEPA process.

The Project is in conformance with the California Desert Conservation Area Plan as amended and would not require any plan amendments. The Ivanpah-Control transmission lines are within west-wide energy corridors (established under Section 368 of the Energy Policy Act of 2005), including corridor numbers 23–25, which BLM anticipates reviewing in an upcoming revision. The Project is not in conflict with nor would it require the revision of any existing or proposed west-wide energy corridors.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9).

Karen Mouritsen,

Bureau of Land Management California State Director.

[FR Doc. 2022–25168 Filed 11–17–22; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034878; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Warren Anatomical Museum, Harvard University, Boston, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Archaeology and Ethnology and Warren Anatomical Museum, Harvard University have completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and have determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Peabody Museum of Archaeology and Ethnology, Harvard University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Peabody Museum of Archaeology and Ethnology, Harvard University at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Warren Anatomical Museum, Harvard University, Boston, MA. The human remains were removed from Barnstable County, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Peabody Museum of Archaeology and Ethnology and Warren Anatomical Museum professional staff in consultation with representatives of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.); Narragansett Indian Tribe; Wampanoag Tribe of Gay Head (Aquinnah); and the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group (hereafter referred to as ''The Consulted Tribes and Group'').

History and Description of the Remains

In 1831, human remains representing, at minimum, two individuals were removed from an ''Indian burial ground'' in Yarmouth, Barnstable County, MA, by an unknown person. In December of 1883, J. Collins Warren donated these human remains to the Warren Anatomical Museum as part of the J. Mason Warren Collection. These individuals were buried approximately two feet below the ground surface in a mound of gravel and sand near the water's edge. The human remains were described as having been interred in a flexed position. The human remains are the nearly complete cranium of an adult male and the nearly complete mandible of an adult that is probably male. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Peabody Museum of Archaeology and Ethnology and the Warren Anatomical Museum, Harvard University

Officials of the Peabody Museum of Archaeology and Ethnology and the Warren Anatomical Museum, Harvard University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on osteological analysis, archeological context, and museum records.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah) (hereafter referred to as ''The Tribes'').
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of

the request to Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Peabody Museum of Archaeology and Ethnology on behalf of the Warren Anatomical Museum, Harvard University is responsible for notifying The Consulted Tribes and Group that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25126 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034881; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Milwaukee Public Museum, Milwaukee, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Milwaukee Public Museum intends to repatriate a cultural item that meets the definitions of both a sacred object and an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was obtained in WI.

DATES: Repatriation of the cultural item in this notice may occur on or after December 19, 2022.

ADDRESSES: Dawn Scher Thomae, Milwaukee Public Museum, 800 W. Wells Street, Milwaukee, WI 53233, telephone (414) 278–6157, email *thomae@mpm.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Milwaukee Public Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Milwaukee Public Museum.

Description

The cultural item, a drum, originated in northern Wisconsin. The drum was donated to the Milwaukee Public Museum in 1941 by Ms. Odelia Mumm Abel of Tomahawk, WI. She obtained the drum from her father, Mr. H.L. Mumm, who operated several trading posts at various locations in northern Wisconsin between 1914 and 1952. The object is documented as a Chief's drum.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical information, historical information, kinship, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Milwaukee Public Museum has determined that:

- The cultural item described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- The cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Forest County Potawatomi Community, Wisconsin.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **ADDRESSES.** Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after December 19, 2022. If competing requests for repatriation are received, the Milwaukee Public Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Milwaukee Public Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25127 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034883; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent to Repatriate Cultural Items: Bryn Mawr College, Bryn Mawr, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Bryn Mawr College intends to repatriate certain cultural items that meet the definition of sacred objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Humboldt County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after December 19, 2022.

ADDRESSES: Marianne Weldon, Bryn Mawr College, 101 N Merion Avenue, Bryn Mawr, PA 19010, telephone (610) 526–5022, email *mweldon@brynmawr.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Bryn Mawr College. The National Park Service is not responsible for the determinations in this notice. Additional information

on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by Bryn Mawr College.

Description

Six cultural items were removed from Humboldt Bay, Humboldt County, CA, in the spring of 1963, by Frederica de Laguna, who later donated them to Bryn Mawr College. The six sacred objects are one clam shell fragment (64.5.2), four lots of fire-cracked rocks (64.5.4.a—64.5.4.d), and one piece of flaked chert (64.5.3).

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical information and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, Bryn Mawr College has determined that:

- The six cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Wiyot Tribe, California (*previously* listed as Table Bluff Reservation—Wiyot Tribe).

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 19, 2022. If competing requests for repatriation are received, Bryn Mawr College must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. Bryn Mawr College is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25172 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034882; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Central Museum of History, Central Methodist University, Fayette, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Central Museum of History, Central Methodist University has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Central Museum of History. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Central Museum of History at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Robert P. Wiegers, Central Museum of History, 411 CMU Square, Fayette, MO 65248, telephone (660) 248–6341, email *rwiegers@centralmethodist.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Central Museum of History, Central Methodist University, Fayette, MO. The human remains were removed from Howard County, MO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Central Museum of History professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Miami Tribe of Oklahoma; Seneca-Cayuga Nation (*previously* listed as Seneca-Cayuga Tribe of Oklahoma); and The Osage Nation (*previously* listed as Osage Tribe) (hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, two individuals were removed from a mound in Howard County, MO. The human remains include one cranium without mandible, a left mandible, right maxilla fragment, left femur, femur fragments, associated teeth, and bone fragments. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Central Museum of History, Central Methodist University

Officials of the Central Museum of History, Central Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on a handwritten note attached to the human remains.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.

• The Treaty of 1808, also known as the treaty of Fort Clark, indicates that the land from which the Native American human remains were removed is the aboriginal land of The Osage Nation (*previously* listed as Osage Tribe).

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Osage Nation (*previously* listed as Osage Tribe).

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Robert P. Wiegers, Central Museum of History, 411 CMU Square, Fayette, MO 65248, telephone (660) 248–6341, email *rwiegers@centralmethodist.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Osage Nation (*previously* listed as Osage Tribe) may proceed.

The Central Museum of History, Central Methodist University is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25128 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034873; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Louisiana State University, Museum of Natural Science, Baton Rouge, LA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Louisiana State University, Museum of Natural Science (LSUMNS), has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to LSUMNS. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to LSUMNS at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Saunders, Louisiana State University, Museum of Natural Science, 119 Foster Hall, LSU, Baton Rouge, LA 70803, telephone (225) 578–6562 or (225) 588–0909, email *rsaunde@lsu.edu*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Louisiana State University, Museum of Natural Science, Baton Rouge, LA. The human remains and associated funerary objects were removed from multiple sites and parishes in the State of Louisiana.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by LSUMNS professional staff in consultation with representatives of the Chitimacha Tribe of Louisiana and members of the STARR Alliance.

History and Description of the Remains

In 1973, human remains representing, at minimum, two individuals, were removed from the Diversion Canal site (16AN16), in Ascension Parish, LA. The two burials were excavated by Richard Weinstein when he was examining the site as part of the research for his M.A. thesis (Weinstein 1974). At the time, the burials were eroding into the canal. Weinstein laid out excavation units encompassing the human remains and excavated them. The human remains were taken to LSUMNS, where Weinstein's major professor, Robert Neuman, was Curator of Anthropology. Burial 1 contained the human remains of an adult female. Burial 2 also contained the human remains of an adult, probably female. No known individuals were identified. No associated funerary objects are present.

In 1952, human remains representing, at minimum, 10 individuals were removed from the Big Goddel Bayou site (16AS1), in Assumption Parish, LA. Based on LSUMNS site cards and State site forms, these human remains derive from two separate surface collections made on August 2, 1952 by, respectively, Ed Orton (working for the McIntire Delta survey) and individuals from Louisiana State University (LSU). Nine of the individuals are adults and one is a subadult; all are of unknown sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, nine individuals, were removed from the Marksville State Historic Site Museum, in Avoyelles Parish, LA. Two of the individuals are certainly from the Marksville site; provenience of the other individuals is unclear. In 1987, the Marksville State Historic Site Museum transferred some of these human remains to LSUMNS, and sometime between 1993 and 2000, it transferred the remainder to the Louisiana Division of Archaeology (LDOA). In 2000, LDOA transferred to LSUMNS the human remains it had obtained from the Marksville State Historic Site Museum. The human remains—primarily crania—belong to nine adults. No known individuals were identified. No associated funerary objects are present.

Between 1938 and 1940, and again between 1988 and 1989, human remains representing, at minimum, 112 individuals were removed from the Greenhouse Site (16AV2), in Avoyelles Parish, LA. Of this number, 107 individuals were removed during excavations conducted by the Works Progress Administration (WPA), under the direction of Robert Neitzel and Edward Doran. The human remains of an additional five individuals were removed from the site by Dennis Jones, during his work on the *Archaeological Atlas and Report of Prehistoric Mounds* (The Atlas). No known individuals were identified. No associated funerary objects are present.

In 1939, human remains representing, at minimum, one individual were removed from the Moncla Mound site (16AV9), in Avoyelles Parish, LA, by William Mulloy during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1939, human remains representing, at minimum, one individual were removed from the Johnson Place Cemetery site (16AV14) (also known as Emile Saucier Place), in Avoyelles Parish, LA, during a surface collection made by Robert S. Neitzel. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

Between May and June of 1979, human remains representing, at minimum, 13 individuals, were removed from the Lake St. Agnes site (16AV26) (also known as Lac St. Agnes, and related to LMS 28–I–1), in Avoyelles Parish, LA, by Alan Toth during excavations overseen by Robert Neuman. Toth's field count reported 18 individuals, but this number was amended to 13 as a result of thesis research by Ken Tremblay in 2021. No known individuals were identified. (Seven associated funerary objects are in the possession of the landowner.)

In 1972, human remains representing, at minimum, one individual were removed from the School Bus Mound site (16AV38), in Avoyelles Parish, LA, during a surface collection conducted by Alan Toth. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1964, human remains representing, at minimum, one individual were removed from the Gunby East site (16CA4) (identified as Boeuf River Site on the LSUMNS site card, and identified as LMS 24–I–31 by the Peabody Museum Lower Mississippi Survey (LMS)), in Caldwell Parish, LA, during a surface collection conducted by William Haag. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1982, human remains representing, at minimum, one individual were removed from the Cottingham Landing site (16CA17) (LMS 25–I–20), in Caldwell Parish, LA, during a surface collection by Robert Neuman and the landowner, A.J. Guyon. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed by an unknown collector from either Little Chenier Mound site (16CM22) or Little Chenier (Ridge) site (16CM30), in Cameron Parish, LA. The human remains belong to three adults. No known individuals were identified. No associated funerary objects are present.

In 1967, human remains representing, at minimum, one individual were removed from the Little Chenier (Ridge) site (16CM30), in Cameron Parish, LA, during a surface collection conducted by Glen Cobb. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1972, human remains representing, at minimum, one individual were removed from the Little Pecan Island site (16CM43), in Cameron Parish, LA, by Robert Neuman during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Elkhorn Plantation site (16CO3) (called the Thomas site in the Baker collection records), in Concordia Parish, LA, by William Baker during an excavation at the site. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1988, human remains representing, at minimum, one individual were removed from the Prairie Lake Mound site (16CO28) (also known as the Glendale Landing Mound site), in Concordia Parish, LA, by Dennis Jones, Malcolm Shuman, and Ann Whitmer. The human remains were recovered from a pothole during mapping of the site for The Atlas. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1938, human remains representing, at minimum, one individual were removed from the Troyville Mounds site (16CT7), in Catahoula Parish, LA, by Norman Haight during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from 16CT42 (called the Open Brake site in the Baker collection records), in Catahoula Parish, LA, by William Baker during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, possibly 1997, human remains representing, at minimum, one individual were removed from 16CT97 (called the South Woods Bayou in the Baker collection records) in Catahoula Parish, LA, by William Baker. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1977, human remains, representing, at minimum, one individual were removed from the Griffin Field Site (16CT98) (LMS 25–J–12), in Catahoula Parish, LA, by William Baker during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, 10 individuals were removed from the Cemetery #2 site (16CT116), in Catahoula Parish, LA, by William Baker during surface collection and excavation. These human remains belong to nine adults and one adolescent. One of the individuals might be male, but the collection is highly fragmented. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Bayou Louis #3 site (16CT128) (called the Plum Mounds site in the Baker collection records), in Catahoula Parish, LA, by William Baker during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

Between 1977 and 1982, human remains representing, at minimum, one individual were removed from 16CT141 (called the Hawkins Shed site in the Baker collection records), in Catahoula Parish, LA, by William Baker during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

Between 1976 and 1984, human remains representing, at minimum, 26 individuals were removed from the Cowpen Slough site (16CT147), in Catahoula Parish, LA, by several unnamed individuals. No known individuals were identified. No associated funerary objects are present. (A pair of antlers was associated with the burials in Feature 8, but the location of the antlers is unknown.)

Possibly in 1937—the date was not recorded in the LSUMNS ledger, but the surrounding entries suggest this date—human remains representing, at minimum, two individuals were

removed from the Knox Place site (16EBR4), in East Baton Rouge Parish, LA, during a surface collection by Fred Kniffen and Walter Beecher. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed from a plowed field in Franklin Parish, LA, by an unknown individual during a surface collection. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

In 1968, human remains representing, at minimum, 12 individuals were removed from the White Oak Landing site, (16FR6), in Franklin Parish, LA, during a surface collection of a plowed field by T.L. Gatton. (The GIS database also lists LMS 24–I–4 and Ford's #74. The site has also received the number 16FR161, but the form for that site indicates that 16FR6 is preferred.) The human remains belong to 12 adults. No known individuals were identified. No associated funerary objects are present.

Between 1969 and 1971, human remains representing, at minimum, 275 individuals were removed from the Morton Shell Mound site (16IB3) (also known as Weeks Island and LMS 33–I–3), on the Weeks Island salt dome, in Iberia Parish, LA. The burials were recovered as part of an intensive research program under the direction of then-LSUMNS Curator of Anthropology Robert Neuman. No known individuals were identified. No associated funerary objects are present.

In 1937, human remains representing, at minimum, one individual were removed from the Blind Hooppole Bayou site (16IB6) in Iberia Parish, LA, by Fred Kniffen and Walter Beecher during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1975, human remains representing, at minimum, two individuals were removed from 16IB107, in Iberia Parish, LA, during a surface collection conducted by Frank Servello and others. The human remains belong to an adult and a juvenile. No known individuals were identified. No associated funerary objects are present.

In 1937, human remains representing, at minimum, one individual were removed from the Bayou Sorrel Mound site (16IV4), in Iberville Parish, LA, by Fred Kniffen and Walter Beecher during a surface collection. The human remains—a mandible fragment with three extremely worn teeth—belong to an older adult. No known individual was identified. No associated funerary objects are present.

In 1937, human remains representing, at minimum, one individual were recovered from the Reed Mounds site (16IV5) (also known as Kniffen's #4), in Iberville Parish, LA, as part of a surface collection by Fred B. Kniffen and Walter F. Beecher. LSUMNS has located six cranial fragments. The LSUMNS ledger also lists five human teeth, but they cannot be located at this time. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1960, human remains representing, at minimum, one individual were removed from the Bruly St. Martin site (16IV6) (also known as the Grand Bayou Site and Kniffen #11) in Iberville Parish, LA, by William G. Haag, as part of a surface collection of the site. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1883, human remains representing, at minimum, one individual were removed from site 16JE000, in Jefferson Parish, LA, by R.W. Shufeldt during surface collection and excavation. The human remains, which are part of the Shufeldt Collection at LSUMNS, belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date (possibly 1935), human remains representing, at minimum, five individuals were removed from the Little Bayou Barataria (16JE1) (Kniffen referred to this site as Bayou Dupont), in Jefferson Parish, LA, by an unknown individual. The human remains belong to five adults. No known individuals were identified. No associated funerary objects are present.

In 1935, and again in 1975, human remains representing, at minimum, two individuals were removed from the Bayou Cutler #1 site (16JE3) (also known as Bayou Cutler and Cheniere Cutler), in Jefferson Parish, LA. The human remains removed in 1935 were part of a surface collection by Fred B. Kniffen (#687). These human remains—a single incisor—belong to an adult. The human remains collected in 1975, presumably from the surface of the site, were discovered in wooden box of the type used by Sherwood Gagliano, Ph.D., to store survey materials. The box was labeled ''Metairie Beach Deposit No. 1,'' and the bones were labeled with ledger numbers identifying them as having come from 16JE3. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

Between the 1930s and 1958, human remains representing, at minimum, eight individuals were collected from the Bonnabel site (16JE6), in Jefferson Parish, LA. LSUMNS ledger records indicate that in 1939, an unnamed individual gave materials from this site to the Museum (#5262). Subsequent surface collections containing human bones were made by Gagliano (1950s (#20480) and 1958 (#19605)) and Saucier and Gagliano (1958 (#20150)). In addition, labels on two bags contain provenience information (#19780 states ''pit A in mound'' and #20480 states ''second mound''). Lastly, a donation of human remains from this site contains no information regarding the collector or the date when the human remains were removed. The human remains belong to eight adults. No known individuals were identified. No associated funerary objects are present.

Sometime in the 1970s (perhaps 1975 or 1977), human remains representing, at minimum, one individual were removed from the Fleming/Berthoud Cemetery (16JE36) (also known as Mavis Grove Plantation), in Jefferson Parish, LA, by Sherwood Gagliano during a surface collection. According to the LSUMNS ledger, the accession number (#20637) was one of a block of numbers given by LSUMNS to Coastal Environments, Inc. (CEI), a cultural resources management firm co-founded by Gagliano. Gagliano took the collection to CEI, where it remained until, in 2001, it was brought to LSUMNS by a graduate student employed at CEI. In 2021, when CEI sent Gagliano's catalogs to LSUMNS, the number was not on those logs. No known individual was identified. No associated funerary objects are present.

In 1952, human remains representing, at minimum, one individual were removed from the Graveyard site (16JE45), in Jefferson Parish, LA, by Kniffen, McIntire, and Saucier during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1969, human remains representing, at minimum, six individuals were removed from the Killeen site (16JE48), in Jefferson Parish, LA, by Robert Neuman and David Morgan. The human remains belong to four adults and two subadults. No known individuals were identified. No associated funerary objects are present.

Between 1938 and 1939, human remains representing, at minimum, 82 individuals were removed from the Crooks Mound site (16LA3), in LaSalle Parish, LA, during a joint excavation project between LSU and the Works Progress Administration (WPA). No known individuals were identified. The

24 associated funerary objects are two projectile points, three plain pottery vessels, 16 decorated pottery vessels, one ear spool, and two quartz crystals.

At an unknown date, human remains representing, at minimum, one individual were removed from the Bradford's Camp site (16LA21) (also known as J. Gibson #2), in LaSalle Parish, LA, by Ed Yule, a resident of the Town of Jena. The human remains belong to an adult. No known individual was identified. The three associated funerary objects are vessels.

At an unknown date, human remains representing, at minimum, one individual were removed from the Temple Mound site (16LF4) (also appearing as ''Grand Temple Mound'' on one site form), in Lafourche Parish, LA, by an unknown collector. The human remains belong to an adult. No known individual was identified. No associated funerary items are present.

In 1935, human remains, representing, at minimum, one individual were removed from the Bayou Chactimahan site (16LF17) (also known as Bowie), in Lafourche Parish, LA, by an unknown collector. The human remains—a mandible—belong to a young-to-middle-aged adult male. No known individual was identified. No associated funerary objects are present.

In 1952, human remains, representing, at minimum, one individual were removed from site 16LF28 (the LSUMNS site card name is Eagle Island Bayou), in LaFourche Parish, LA, by Randolph Bazet during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1973, 1992, and 1994, human remains representing, at minimum, two individuals were removed from the Booth Shell Bank site (16LV6), in Livingston Parish, LA. A portion of the human remains was recovered by Paul Orr in 1973 (Accession #16LV6–8). Another portion was removed by R. Saunders in 1994 during a separate surface collection (Accession #16LV6–45). In 1992, Michael Eldredge, an avocational archeologist, collected materials from the site, among which were human bones. After passing through the Louisiana Office of State Parks, the Eldridge collection was transferred to LDOA sometime between 1993 and 2000. In 2000, LDOA transferred the collection to LSUMNS. At least one of the individuals can be identified as an 18–21-year-old adolescent/young adult. No known individuals were identified. No associated funerary objects are present.

In 1996, human remains, representing, at minimum, two individuals were removed from the Sharp Site (16LV13) in Livingston Parish, LA, during a surface collection by Robert Barilleaux. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

Sometime during 1996–1997, human remains representing, at minimum, one individual were removed from the Sharp Site (16LV13) in Livingston Parish, LA, during field school excavations directed by Dr. Rebecca Saunders of LSU. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1973, human remains representing, at minimum, one individual were removed from the Clio Mound Site (16LV15) (also known as Clio), in Livingston Parish, LA. These fragmentary human remains were excavated from Test Pit #2 by Weinstein and Facundas as part of the research for Weinstein's M.A. thesis. The bone fragments were retrieved from the first 10 cm of the excavation. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Fontenot site (16LV16), in Livingston Parish, LA, by an unknown collector. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Hall Site (16LV33), in Livingston Parish, LA, by an unknown collector, presumably during a surface collection. Numbers associated with the remains follow a format like the one used by LSUMNS (and the State of Louisiana), but there is no accession/catalog record for this site in LSUMNS's records. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

Between 1969 and 1973, human remains representing, at minimum, two individuals were removed from the Burial site (16LV37) (also known as Old Tree), in Livingston Parish, LA. In 1969, Robert Neuman removed human remains during a surface collection (Accession #16LV37–1, 2). Subsequently (1973), Weinstein and Facundus also removed human bone (Accession #16LV37–7). The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

Between 1973 and 1974, human remains representing, at minimum, four individuals were removed from the Bayou Chene Blanc site (16LV43) (also known as Whitehall), in Livingston Parish, LA, by Richard Weinstein, who was following up on the results of his 1974 M.A. thesis research. The human remains belong to four adults. No individuals were identified. No associated funerary objects are present.

In 1932, human remains, representing, at minimum, one individual were removed from the Sevier's Place site (16MA3) (identical with 16MA24 and 16MA45), in Madison Parish, LA, by James Ford during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

During 1969–1970, human remains, representing, at minimum, 77 individuals were removed from the Mt. Nebo site (16MA18) (LMS 23–K–12), in Madison Parish, LA, during excavations conducted by Robert Neuman of LSUMNS. No known individuals were identified. No associated funerary objects are present.

In 1968, human remains, representing, at minimum, one individual were removed from the Batchelor Mound Site (16MA27) (also known as Bull Bayou and LMS 22–K–23), in Madison Parish, LA, by George Percy during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1968, human remains representing, at minimum, four individuals were removed from the L.C. Parker site (16MA33), in Madison Parish, LA, by George Percy during a surface collection. When Percy moved to Florida to become the Florida State Historic Preservation Officer, he took materials from Louisiana with him, including a portion of the collection from 16MA33. Those 16MA33 materials were returned to LSUMNS in 2009, and were added to a pre-existing catalog. The human remains belong to four adults. No known individuals were identified. No associated funerary objects are present.

In 1972 and 1974, human remains representing, at minimum, four individuals were removed from the J.W. Copes site (16MA47), in Madison Parish, LA, during surface collections. The 1972 collector was William Haag; the 1974 collector is unknown. The human remains belong to two adults, one juvenile, and one neonate. No known individuals were identified. No associated funerary objects are present.

In 1973, human remains representing, at minimum, one individual were removed from site 16NA19, in Natchitoches Parish, LA, by Ricky Collins and Artis Durr during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1973, human remains representing, at minimum, one individual were removed from the Sportsman's Inn site (16NA20_16NA105) (also known as the Sportsman Lodge Site, as NSU NA 105 and, in the LSUMNS ledger, as Fort Selden), in Natchitoches Parish, LA, by Robert Neuman during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1939, human remains representing, at minimum, 47 individuals were removed from the ''The Little Woods'' sites (16OR1–5), in Orleans Parish, LA, by Preston Holder, during ''re-excavations'' of a series of discrete shell middens on the southeastern shore of Lake Pontchartrain. The human remains belong to 47 adults. No known individuals were identified. No associated funerary objects are present.

In 1972, 1973, and 1982, human remains representing, at minimum, 69 individuals were removed from the Big Oak Island site (16OR6), in Orleans Parish, LA. No known individuals were identified. No associated funerary objects are present.

In 1939, 1974, and in the 1980s, human remains representing, at minimum, 29 individuals were removed from the Pine Island/Little Oak Island site (16OR7), in Orleans Parish, LA, by, respectively, Preston Holder (during an excavation); Richard Shenkel and Jon Gibson (during excavations); and Richard Shenkel and Douglas Owsley (during surface collection and excavation). No known individuals were identified. No associated funerary objects are present.

In 1970, human remains representing, at minimum, one individual were removed from the Rabbit Island site (16OR16), in Orleans Parish, LA, by Gloria Thom during a surface collection of materials that had been dredged from the site. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1970, human remains representing, at minimum, one individual were removed from the Hospital Foundations/Garcia site (16OR34) (also known as Les Petites Coquilles, as Little Shells, and as Fort Pike Hospital), in Orleans Parish, LA, by Tommy Ryan during a surface collection at the site. (Among Louisiana archeologists, 'Garcia' prevails as the site name.) The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1964, human remains representing, at minimum, one individual were removed from the Linsley Site (16OR40), in Orleans Parish, LA, by Sherwood Gagliano, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1985, human remains representing, at minimum, one individual were removed from the Catfish Point site (16OR61), in Orleans Parish, LA, by Lacefield and Burden, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1935 and also at an unknown date, human remains representing, at minimum, one individual were removed from the Pargoud Landing site (16OU1), in Oachita Parish, LA. The 1935 collectors were Ford and Freeman; the collector of the undated collection is unknown. The human remains belong to an adult female. No known individual was identified. The three associated funerary objects are one globular jar with restricted neck, one lot of bowl sherds, and one lot of jar sherds.

In 2002–2003, human remains representing, at minimum, two individuals were removed from the Bayou Grande Cheniere site (16PL159) (also known as Pelican Mounds), in Plaquemines Parish, LA, by R. Saunders, during excavations conducted in conjunction with an LSU field school. The human remains belong to a 3–4-year-old juvenile and an adult. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from site 16SB00A in St. Bernard Parish, LA, by Sherwood Gagliano. LSUMNS has no other information about these human remains. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1982, human remains representing, at minimum, one individual were removed from dredge spoil at site 16SB00B (the LSUMNS reference name is Trosclair Collection), in St. Bernard Parish, LA, near Fort Beauregard, during a surface collection by H. Trosclair, a local avocational archeologist. The human remains—predominantly long bone fragments—belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1935, human remains representing, at minimum, one individual were removed from the Machias Lake Site (16SB2), in St. Bernard Parish, LA, by Richard B. Russell, a professor in the Department of Geology at LSU. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1936, and over numerous trips between 1976 and 1985, human remains representing, at minimum, 10 individuals were removed from the Mulatto Bayou site (16SB12_16SB18), in St. Bernard Parish, LA, by Eric Lacefield, a local amateur collector. The human remains belong to four adult males, one adult female, and five adults of undetermined sex. No known individuals were identified. No associated funerary objects are present.

Between 1972 and 1984, and at an unknown date, human remains representing, at minimum, seven individuals were removed from site 16SB20 (also known as Grand Pass, as Grand Pass #1 in LSUMNS card records, and as Camp at Grand Pass) in St. Bernard Parish, LA, by Robert Neuman (1970), Brant Savoie (Department of Fish and Wildlife), and Eric Lacefield (1980–1984), during surface collections. The human remains belong to seven adults. No known individuals were identified. No associated funerary objects are present.

In 1972, human remains representing, at minimum, one individual were removed from the Seven Dollar Bay site (16SB33), in St. Bernard Parish, LA, by Robert Neuman, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1952 and 1981, human remains representing, at minimum, eight individuals were removed from the East Bayou site (16SB48), in St. Bernard Parish, LA. In 1952, Treadwell made a surface collection at the site in conjunction with the LSU Delta Survey initiated by McIntire, during which the remains of three individuals were removed (#52–327). Subsequent investigations of 16SB48 are poorly recorded but appear to have occurred in 1981, and to have included both surface collection and excavations, at which time the remains of an additional five individuals were removed. The human remains belong to eight adults. No known individuals were identified. No associated funerary objects are present.

In 1952, human remains representing, at minimum, one individual were removed from the Shotgun Shell site

(16SB52), in St. Bernard Parish, LA, by Robert Treadwell, as part of a surface collection. This collection was made in conjunction with McIntire's survey project, *Prehistoric Indian Settlements of the Changing Mississippi River Delta* (Delta Survey). The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains, representing at minimum, one individual were removed from the Lake of the Second Trees site (16SB61), in St. Bernard Parish, LA, by unknown individuals. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1964 and 1965, human remains representing, at minimum, three individuals were removed from the Lower Vacherie site (16SJ2) (also known as Shell Hill Plantation and, in LSUMNS records, as Foulgoust), in St. Johns Parish, LA, during surface collections by William McIntire and William Haag (1964), and by Mike Zatarain (1965). The human remains belong to one juvenile and two adults. No known individuals were identified. No associated funerary objects are present. (Information in the State site files indicates that mortuary objects were present, but they are not at LSUMNS.)

Between 1974 and 1975, human remains representing, at minimum, 11 individuals were removed from the Bayou Jasmine site (16SJB2), in St. John the Baptist Parish, LA, during a series of surface collections atop deep dredge spoil deposited during highway and interstate construction through the site. Collections were made by professional and avocational collectors in 1974 (by Neuman and Lewis; Weinstein and Neuman; Neuman; Rivet; and Weinstein, Neuman, and Conn) and 1975 (by Ryan and Neuman; Wingate; and Melvin Glory). In addition, excavations conducted at the site in 1975 by Robert Neuman produced a small number of human bones culled from faunal samples belonging to the Tchefuncte component by Kathleen Byrd (#176, 180). The human remains belong to 11 adults. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, six individuals were removed from the Bayou Becnel site (16SJB5), in St. John the Baptist Parish, LA. Although bags containing artifacts and human bones have what appears to be a trinomial accession number like those used in LSUMNS binders, there are no accession records for 16SJB5 in the LSUMNS's records. The human remains belong to six adults. No known individuals were identified. No associated funerary objects are present.

In 1940 and 1957, human remains representing, at minimum, five adult individuals were removed from the Miller Place site (16SM6) (also known as Belle River Landing), in St. Martin Parish, LA. Surface collections were made by Edward Doran in 1940, by Neitzel in 1940, and by Saucier and Gagliano in 1957. The human remains belong to five adults. No known individuals were identified. No associated funerary objects are present.

In 1941, human remains representing, at minimum, 60 individuals were removed from the Lafayette Mounds site (16SM17), in St. Martin Parish, LA. The human remains belong to 60 adults. No known individuals were identified. No associated funerary objects are present.

In 1970, human remains representing, at minimum, two adult individuals were removed from the Mary Barber site (16SM35), in St. Martin Parish, LA, by Robert Neuman during a surface collection. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

In 1975, human remains representing, at minimum, one individual were removed from the Patterson Mound site (16SMY10) (also known as Atchafalaya Basin, as Cocke Mounds, and as Qiteet Kuti'ngi na'mu), in St. Mary Parish, LA, by Frank Servello, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1950, human remains representing, at minimum, two individuals were removed from the Oyster Bayou Site (16SMY11), in St. Mary Parish, LA, by R.J. Russell, during a surface collection. The human remains probably were collected in conjunction with McIntire's Delta Survey. The human remains were catalogued into LSUMNS in 1952. The human remains belong to two adults. No known individuals were identified. No associated funerary objects are present.

In 1952, human remains representing, at minimum, one individual were removed from the Possum Point site (16SMY31), in St. Mary Parish, LA, by an unknown collector. The surface collection was probably done by an individual associated with McIntire's Delta survey. No known individual was identified. No associated funerary objects are present.

Between 1940 and 1941, human remains representing, at minimum, 60 individuals were removed from the Tchefuncte site (16ST1), in St. Tammany Parish, LA. The human remains were recovered as part of excavation projects conducted initially by Clarence Johnson, under the auspices of the Civilian Conservation Corps (CCC) and subsequently by Edwin Doran, through the WPA. No known individuals were identified. No associated funerary objects are present.

In 1937, human remains representing, at minimum, one individual were removed from the Indian Village Landing site (16ST6), in St. Tammany Parish, LA, by James Ford, during a surface collection. The collection was limited to vertebral fragments. No known individual was identified. No associated funerary objects are present.

In 1941, human remains representing, at minimum, one individual were removed from the West Pearl River site (16ST7) (related to 16ST47), in St. Tammany Parish, LA, by Edward Doran, during testing at the site. No known individual was identified. No associated funerary objects are present.

In 1995, human remains representing, at minimum, one individual were removed from the Hoover site (16TA5), in Tangipahoa Parish, LA. This individual was recovered as part of excavations conducted by R. Saunders of LSUMNS. The human remains, which had been interred secondarily and were very poorly preserved, belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1955, human remains representing, at minimum, one individual were removed from the Shackleford Church site (16TE1) (also known as Shackleford Lake; other site numbers are 16TE59 and LMS 24–K–3), in Tensas Parish, LA, by William Haag, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed from the Seabreeze Pass site (16TR17), in Terrebonne Parish, LA, by Rainwater during a surface collection. Sometime in the 1980s, Rainwater donated these human remains, along with artifacts, to LSUMNS. The human remains belong to three adults. No known individuals were identified. No associated funerary objects are present.

In 1952, human remains representing, at minimum, one individual were removed from the Bayou Du Large site (16TR19) (also known as Bayou Mauvais), in Terrebonne Parish, LA, by William McIntire, presumably during a surface collection. The human remains

belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1952 and 1993, human remains representing, at minimum, one individual were removed from the Bayou Sale #2 site (16TR35), in Terrebonne Parish, LA. In 1952, William McIntire removed the remains during a surface collection, and in 1993, R. Saunders removed two molars, also during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1971, human remains representing, at minimum, five individuals were removed from 16TR81 (no State site file name; called Crochet's Island in LSUMNS cards), in Terrebonne Parish, LA, by William Haag, during a surface collection. The human remains belong to four adults and one subadult. No known individuals were identified. No associated funerary objects are present.

In March of 1993, human remains representing, at minimum, one individual were removed from the Bayou Terrebonne #8L site (16TR273), in Terrebonne Parish, LA, by Gerard Riché, during a surface collection. No known individual was identified. No associated funerary objects are present.

In 1950 and again in 1952, human remains representing, at minimum, six individuals were removed from the Veazey site (16VM7_16VM8, also LMS 34–G–4, LMS 34–G- 5), in Vermillion Parish, LA. The human remains were removed during surface collections, first by an unknown individual (possibly R.J. Russell), and later by Roger Saucier. The human remains belong to five adults and one subadult. No known individuals were identified. No associated funerary objects are present.

In 1951, human remains representing, at minimum, four individuals were removed from the Morgan Mounds site (16VM9), in Vermillion Parish, LA, by William McIntire, as part of a surface collection. The human remains belong to three adults and one subadult. No known individuals were identified. No associated funerary objects are present.

In 1951, human remains, representing, at minimum, one individual were removed from the Six Mile Canal site, (16VM14), in Vermillion Parish, LA, by William McIntire, during a surface collection. The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

In 1952 and at an unknown date, human remains representing, at minimum, one individual were removed from the Indian Point site (16VM24), in Vermillion Parish, LA. In 1952, Saucier and Van Lopik recovered a single tooth during a surface collection (#52–133), and at an unknown date, a collector listed in LSUMNS's ledger as ''Ford?'' found a fragment of a mandible (#19920). The human remains belong to an adult. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown site in Louisiana by an individual named ''Moorman.'' The human remains—two teeth—were found among artifacts donated to LSUMNS in 1964. The human remains, which are identified as prehistoric, belong to an adult. No known individual was identified. No associated funerary objects are present.

Determinations Made by Louisiana State University, Museum of Natural Science

Officials of Louisiana State University, Museum of Natural Science have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 1,070 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 30 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Chitimacha Tribe of Louisiana. The determination of affiliation with the Chitimacha is based on the presence of a Lower Mississippi River Valley (LMRV) cultural assemblage or site location within the LMRV culture area. The Chitimacha are the only federally recognized Tribe with direct prehistoric ties to the LMRV culture area.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Rebecca Saunders, Louisiana State University, Museum of Natural Science, 119 Foster Hall, LSU, Baton Rouge, LA 70803, telephone (225) 578–6562 or (225) 588–0909, email *rsaunde@lsu.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Chitimacha Tribe of Louisiana may proceed.

Louisiana State University, Museum of Natural Science is responsible for notifying the Chitimacha Tribe of Louisiana that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25135 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034887; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Texas Archeological Research Laboratory, The University of Texas at Austin, Austin, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Texas Archeological Research Laboratory (TARL) has completed an inventory of human remains and an associated funerary object, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined the lineal descent of a present-day individual from the Native American individual whose human remains are described in this notice. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and this associated funerary object should submit a written request to TARL. If no additional requestors come forward, transfer of control of the human remains and the associated funerary object to the lineal descendant stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and this associated funerary object should submit a written request with information in support of the request to TARL at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Annie Riegert Cummings, Texas Archeological Research Laboratory, 1 University Station R7500, Austin, TX

78712, telephone (512) 471–6006, email *annie.riegert@austin.utexas.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and an associated funerary object under the control of the Texas Archeological Research Laboratory, The University of Texas at Austin, Austin, TX. The human remains and associated funerary object were removed from the Spirit Eye Cave Site, 41PS25, in Presidio County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary object. The National Park Service is not responsible for the determinations in this notice.

Consultation

Archeologist Deborah Gray conducted a detailed assessment of the human remains prior to their acquisition by TARL professional staff in 1998. In 2000, the human remains were further assessed and inventoried by TARL. Between 2000 and 2021, no potential consulting parties were identified, and no Indian Tribes requested to consult on the human remains. In 2021, Mr. Xoxi Nayapiltzin was identified as directly descending from the Native American individual whose human remains are described in this notice, and consultation was conducted with him.

History and Description of the Remains

In 1968, human remains representing, at minimum, one individual were looted by Kenneth Novak and Adrian Benke from the Spirit Eye Cave site (41PS25), previously known as the Novak and Benke site, in Presidio County, TX. The largely complete mummified remains belong to a middle aged-to-old adult female. The one associated funerary object is a piece of yellow ochre.

Due to the looted context, no additional information concerning the burial can be determined with great confidence. Following their removal in 1968, the human remains were advertised in a magazine, *The Shotgun,* and sold to a private buyer in California, Bob Howard. In 1998, during a search of Howard's residence by the California Department of Fish and Game, the mummified remains were recovered from a display case and taken to Wiefels and Son Mortuary, where they were analyzed by Deborah Gray. Mr. Howard told Ms. Gray where the human remains were disinterred and when he acquired them. As possession of human remains in California is illegal, the human remains were first transferred to the Riverside County Coroner's Office and then, upon the recommendation of the Office of the Texas State Archaeologist, to TARL. The human remains arrived at TARL on August 27, 1998 and were accessioned in 1999 under TARL Accession 1999.0155 and under human osteology accession number 3713.

Based on the presence of prehistoric artifacts at the Spirit Eye Cave site (41PS25), the human remains are reasonably believed to date from the prehistoric phase. Initial ancestry estimation was established through biological analysis of the cranium by Deborah Gray. In an attempt aid in repatriation, Dr. Bryon Schroeder of Sul Ross University sampled the mummified human remains after approval for a sampling request. Dr. Meradeth Snow conducted the genetic analysis and determined that this and another individual from Spirit Eye Cave belong to the B2a4a1 lineage. Dr. Snow then compared the genetic results to data from living individuals and from human remains found in removed archeological contexts in the Americas.

Mr. Xoxi Nayapiltzin approached researchers at Sul Ross State University and the Center for Big Bend Studies concerning prehistoric human remains in the Big Bend area on behalf of his family, the Nana Tana family. During this conversation Mr. Nayapiltzin provided his own haplogroup B2a4a1. The genetic distance between them is close as indicated by a single mutation in Mr. Nayapiltzin's own mitogenome sequence. The single mutation indicates that he is much more closely related to the individual belonging to the human remains at TARL than any other individuals used in Dr. Snow's analysis. Dr. Snow has provided TARL with a report supporting the lineal descent of Mr. Nayapiltzin from the Native American individual whose human remains are described in this notice.

During consultation, Mr. Nayapiltzin reported that nine matrilineal generations of the Nana Tana family have resided in Alpine, TX (55 miles from Spirit Eye Cave). Since starting his genealogical research 53 years ago, Mr. Nayapiltzin has located the 1833 baptismal records of his great great-great grandmother in Meoqui, and through additional research, he has traced his lineage in Meoqui back three more generations. This geographical information is consistent with the burial location of the mummified human remains and further supports the already established genetic findings.

Determinations Made by the Texas Archeological Research Laboratory, The University of Texas at Austin

Officials of the Texas Archeological Research Laboratory, The University of Texas at Austin have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described in this notice is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 43 CFR 10.2(b)(1) and 10.14(b), Mr. Xoxi Nayapiltzin is the direct lineal descendant of the Native American individual whose human remains are described in this notice.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and this associated funerary object should submit a written request with information in support of the request to Annie Riegert Cummings, Texas Archeological Research Laboratory, 1 University Station R7500, Austin, TX 78712, telephone (512) 471–6006, email *annie.riegert@austin.utexas.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains and the associated funerary object to Mr. Xoxi Nayapiltzin may proceed.

The Texas Archeological Research Laboratory, The University of Texas at Austin is responsible for notifying Mr. Xoxi Nayapiltzin that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25132 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034885; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California, Davis, Davis, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Davis (UC Davis) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Colusa County, CA.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after December 19, 2022.

ADDRESSES: Megon Noble, NAGPRA Project Manager, University of California, Davis, 412 Mrak Hall, One Shields Avenue, Davis, CA 95616, telephone (530) 752–8501, email *mnoble@ucdavis.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UC Davis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by UC Davis.

Description

Human remains representing, at minimum, 14 individuals were removed from Colusa County, CA. In 1962 and 1963, CA–COL–1 (UC Davis Accession 38) was excavated by Dr. Martin Baumhoff and Walt Brown as a part of a UC Davis Field School. No known individuals were identified. Of the 649 associated funerary objects listed in this notice, 559 objects are present and accounted for in the UC Davis collections and 90 objects are currently missing. The 559 associated funerary objects are 13 *Olivella* beads or shells, one shell pendant, two clamshell beads or clamshell disc beads, one historic bead, one bone bead, two stone beads, one stone ''tinkler,'' 70 projectile points, 85 bone awls, three bone pins, one incised bone (possible whistle), 13 bone tubes, six bone flakers, seven bone wedges, seven bone spatulas, 104 miscellaneous worked bones, 30 chipped stone items (bifaces, debitage, flake tools, and stone scrapers), 14 miscellaneous worked stone items, six miscellaneous worked shells, four groundstone items (including one pestle), one piece of historic metal, three pieces of charcoal or ash, two unmodified rocks, 46 lots of unmodified shell, 10 lots of clay (including baked clay), and 126 lots of animal bone fragments. UC Davis continues to look for the following 90 missing associated funerary objects: 19 *Olivella* beads or shells, one shell pendant, one shell bead (unknown type), six clamshell beads or clamshell disc beads, one stone bead, 11 projectile points, four bone awls, one bone pin, one bone harpoon, one bone tube, 14 misc. worked bones, eight chipped stones, six miscellaneous worked stones, one miscellaneous worked shell, four groundstone items, one piece of charcoal, one miscellaneous ceramic item (possibly an ear plug), one lot of unmodified shell, seven lots of clay, and one lot of animal bone fragments.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, archeological, biological, geographical, historical, linguistic, and oral traditional.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, UC Davis has determined that:

- The human remains described in this notice represent the physical remains of 14 individuals of Native American ancestry.
- The 649 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California; Kletsel Dehe Band of Wintun Indians (*previously* listed as Cortina Indian Rancheria); and the Yocha Dehe Wintun Nation, California (*previously* listed as Rumsey Indian Rancheria of Wintun Indians of California).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after December 19, 2022. If competing requests for repatriation are received, UC Davis must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. UC Davis is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25130 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034876; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Warren Anatomical Museum, Harvard University, Boston, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Archaeology and Ethnology and Warren Anatomical Museum, Harvard University have completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and have determined that there is no cultural affiliation between the human remains

and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Peabody Museum of Archaeology and Ethnology, Harvard University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Peabody Museum of Archaeology and Ethnology, Harvard University at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Warren Anatomical Museum, Harvard University, Boston, MA. The human remains were removed from Essex, Norfolk, and Suffolk Counties, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Peabody Museum of Archaeology and Ethnology and Warren Anatomical Museum professional staff in consultation with representatives of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.); Narragansett Indian Tribe; Wampanoag Tribe of Gay Head (Aquinnah); and two non-federally recognized Indian groups: the Assonet Band of the Wampanoag Nation and the Massachusett-Ponkapoag Tribal Council (hereafter referred to as ''The Consulted Tribes and Groups'').

History and Description of the Remains

Sometime before 1870, human remains representing, at minimum, one individual were removed from an unknown site in the town of Nahant, Essex County, MA, by Dr. Walter Channing. In December of 1883, J. Collins Warren donated the human remains to the Warren Anatomical Museum as part of the J. Mason Warren Collection. The human remains are the nearly complete cranial remains of an adult male. No known individual was identified. No associated funerary objects are present.

Sometime before 1850, human remains representing, at minimum, one individual were removed from an unknown site in the city of Salem, Essex County, MA, by an unknown person and were donated to the Warren Anatomical Museum by an unknown person. The human remains are the nearly complete cranial remains of an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown site in the town of Milton, Norfolk County, MA, by Dr. John Edwards Holbrook. In December of 1883, J. Collins Warren donated the human remains to the Warren Anatomical Museum as part of the J. Mason Warren Collection. The human remains are the nearly complete cranial remains of an adult female. No known individual was identified. No associated funerary objects are present.

In June of 1861, human remains representing, at minimum, four individuals were removed from a burial site ten feet from the eastern edge of Long Island in Boston Harbor, Suffolk County, MA, by Dr. P.A. O'Connell of the United States Army. Dr. O'Connell sent the human remains to Dr. Henry G. Clark, who presented the human remains to the Warren Anatomical Museum in 1862. No known individuals were identified. No associated funerary objects are present.

The burials on Long Island were organized into a burial ground, arranged in rows, and the individuals were consistently buried in a flexed posture with the head directed to the south and without accompanying funerary objects. This contextual information suggests that these interments date to the Late Woodland period or later (*i.e.,* post-1000 B.P.). The history of Long Island strongly indicates that during and after King Philip's War (A.D. 1675–1676) it served as a burial place for a population of New England Native American individuals that included, but was not limited to, the Massachusett and Pawtucket. During King Philip's War, Long Island was used as an internment camp for the so-called ''Praying Indians'' captured from the 14 towns within Massachusett and Pawtucket homelands. The internment of Praying Indians on Long Island, Deer Island, and other Boston Harbor islands ended in 1677, but not before many had died of starvation, disease, and exposure. During later historic periods, several other groups used Long Island for burials, at least some of whom may have included individuals of Native American ancestry. The burial places of these individuals may have been confused with burial places of Native American individuals in recorded histories, remembered histories, and during archeological and other island surveys.

Historical documents and consultation information demonstrate that areas of northeastern Massachusetts are the aboriginal land of the Wampanoag people. These same types of information also demonstrate that portions of Suffolk, Essex, Norfolk, and Middlesex Counties, MA, are the aboriginal land of the Massachusett and Pawtucket peoples, neither of whom are represented by any federally recognized Indian Tribe.

Determinations Made by the Peabody Museum of Archaeology and Ethnology and the Warren Anatomical Museum, Harvard University

Officials of the Peabody Museum of Archaeology and Ethnology and the Warren Anatomical Museum, Harvard University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on osteological analysis, archeological context, and museum records.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of seven individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee

Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah) (hereafter referred to as ''The Tribes'').

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Peabody Museum of Archaeology and Ethnology on behalf of the Warren Anatomical Museum, Harvard University is responsible for notifying The Consulted Tribes and Groups that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25125 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034886; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Vassar College, Poughkeepsie, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Vassar College has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Vassar College. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Vassar College at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Daly, Vassar College, 124 Raymond Avenue, Poughkeepsie, NY 12604, telephone (845) 437–5310, email *brdaly@vassar.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of Vassar College, Poughkeepsie, NY. The human remains were removed from an unknown geographic location.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Vassar College professional staff in consultation with representatives of the Gila River Indian Community of the Gila River Indian Reservation, Arizona and the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona.

An invitation to consult was extended to the Ak-Chin Indian Community (*previously* listed as Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Hopi Tribe of Arizona; Tohono O'Odham Nation of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico.

Hereafter, all the Indian Tribes listed in this section are referred to as ''The Tribes.''

History and Description of the Remains

On an unknown date, human remains representing, at minimum, five individuals were removed from an unknown geographic location. During the 1920s, the human remains (Mandible 1; Mandible 2; Mandible 5; Mandible 7) were acquired by Vassar College's Natural History and Social Museums. After the museums dissolved in the 1960s, the human remains were acquired by the Anthropology and Biology departments. Human remains located in the Biology and Anthropology Department teaching collections were examined for visual and statistical markers of Native American affinities, with results reported on December 21, 2020. The results from the assessments identified these individuals with ''Hohokam'' affinity. No known individuals were identified. No associated funerary objects are present.

Determinations Made by Vassar College

Officials of Vassar College have determined that:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of five individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Brian Daly, Vassar College, 124 Raymond Avenue, Poughkeepsie, NY 12604, telephone (845) 437–5310, email *brdaly@vassar.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

Vassar College is responsible for notifying The Tribes that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25131 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034875; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Archaeology and Ethnology, Harvard University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Peabody Museum of Archaeology and Ethnology, Harvard University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Peabody Museum of Archaeology and Ethnology, Harvard University at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA. The human remains and associated funerary objects were removed from Essex, Middlesex, Norfolk, and Suffolk Counties, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by the Peabody Museum of Archaeology and Ethnology professional staff in consultation with representatives of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.); Narragansett Indian Tribe; Wampanoag Tribe of Gay Head (Aquinnah); and three non-federally recognized Indian groups: the Assonet Band of the Wampanoag Nation; Massachusett-Ponkapoag Tribal Council; and the Nipmuc Nation Tribal Council Inc. (hereafter referred to as ''The Consulted Tribes and Groups'').

History and description of the Remains

Essex County, MA

Sometime prior to 1912, human remains representing, at minimum, one individual were removed by Andrew Lee II from Lee Field, located in Manchester-by-the-Sea. In June of 1912, Lee donated the human remains of this individual to the Peabody Museum through Alice E. Putnam. Descriptions of the burial noted the presence of several skeletons accompanied by a large piece of sheet copper, an iron tomahawk, several bone points, cordage, and other unnamed funerary objects. The funerary objects described in the burial suggest the interment dates to the Historic/Contact Period (*i.e.,* post-500 B.P.). The human remains are hair. No known individual was identified. The two associated funerary objects are one bone point and one vial of fragments of matting and human hair.

Around 1864, human remains representing, at minimum, two individuals were removed by an unknown person from an ''Indian cemetery'' in Marblehead. In 1916, F. H. C. Reynolds donated the human remains to the Peabody Museum. A description of the burial noted that the skeletons were laid in a flexed position; no other contextual information is available. The human remains are nearly complete crania belonging to two adult females. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from a gravel pit in Boxford. In 1917, the town donated these human remains to the Peabody Museum. The human remains are cranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by an unknown person from an unknown site in Salem. In 1919, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum at Harvard University. The human remains are cranial and postcranial fragments belonging to two adults, one male and one of unknown sex. No known individuals were identified. No associated funerary objects are present.

In 1921, human remains representing, at minimum, six individuals were removed by Alfred Vincent Kidder from the Shattuck Farm Site in Andover. In 1921, Kidder and the Department of Archaeology at the Phillips Andover Academy donated these human remains to the Peabody Museum. Kidder described a small celt, a set of antler punches, a bone or antler harpoon head, and four or five small arrowpoints accompanying the burial. These items are not in the collection of the Peabody Museum. The Shattuck Farm Site dates from the Archaic to Historic time periods. The human remains are cranial and postcranial fragments belonging to one male adult, one female adult, three adults of unknown sex, and one child of unknown sex. No known individuals were identified. The one associated funerary object is a stone gouge.

At an unknown date, human remains representing, at minimum, nine individuals were removed by an unknown person from ''Indian graves'' in Manchester-by-the-Sea. In 1922, George A. Gray donated these human remains to the Peabody Museum. Also in 1922, the heirs of John Lee (Sarah Crombie, Emma F. Priest, Mrs. Downing Lee, Mrs. Andrew Lee, and Mary E. Blaisdell) donated the associated funerary objects and the hair of one of these individuals to the Peabody Museum. The site from which these human remains and associated funerary objects were removed is possibly Lee Field, based on the description of a grave in Manchester-by-the-Sea discovered about fourteen inches below the surface and containing four skeletons lying side-by-side with their heads to the west. Based on the associated funerary objects and copper stains present on some of the human remains, this interment most likely dates to the Historic/Contact Period (*i.e.,* post-500 B.P.). The human remains are the nearly complete cranium and hair belonging to an adult male; cranial

fragments belonging to one adult male and one adult of unknown sex; and cranial and postcranial fragments belonging to one adult male, three adults of unknown sex, one subadult of unknown sex, and one child of unknown sex. No known individuals were identified. The 33 associated funerary objects are five fragments of wooden spoons, six broken bone arrowpoints, one broken terracotta tobacco pipe, one lot of fragments of a beaver incisor, one lot of fragments of brass plate, six fragments of textile, six fragments of cordage, six red fox bones, and one mammal long bone.

In 1904, human remains representing, at minimum, two individuals were removed by Dr. Francis B. Harrington from graves located at ''Indian Ridge,'' on Harrington's estate in Ipswich. In 1927, Harrington's wife donated these human remains to the Peabody Museum. Copper staining on the human remains, as well as European items accompanying the burial, indicate a post-Contact date for the interment (*i.e.,* A.D. post-1600). The human remains are cranial and postcranial fragments belonging to two adults of unknown sex. No known individuals were identified. The four associated funerary objects are one ceramic and brass or copper elbow pipe, one broken bracelet strand with loose beads, one necklace of white and blue glass beads, and one brass brazier. The brazier most likely dates to the latter half of the sixteenth century and was possibly obtained from a Spanish or Portuguese ship visiting the area.

Around 1944, human remains representing, at minimum, one individual were removed by Frank W. Snow from sand under a building on Plum Island. In 1946, Snow sent these human remains to Harvard University's Department of Legal Medicine, which donated the human remains to the Peabody Museum through Alan R. Moritz that same year. The human remains are the nearly complete cranium and postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Danvers. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. Copper staining on the cranium indicates the individual was interred during the post-Contact/Early Historic Period or later (*i.e.,* A.D. post-1614). The human remains are the partial cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Andover. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. Based on an osteological analysis of the human remains, this individual was of mixed Native American and African/African American ancestry, indicating the individual lived during the post-Contact/Early Historic Period or later (*i.e.,* A.D. post-1614). The human remains are the partial cranium belonging to a subadult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Andover. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from a site in Annisquam, a village in Gloucester. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are the nearly complete cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Beverly. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated the human remains to the Peabody Museum through Ernest S. Dodge. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from Summer Street in Salem. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. Copper staining on the cranium indicates the individual was interred during the post-Contact/Early Historic Period or later (*i.e.,* A.D. post-1614). The human remains are cranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from Turner Street in Salem. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are cranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by an unknown person from Salem Harbor. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are cranial fragments belonging to an adult of unknown sex and the partial cranium belonging to an adult female. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by an unknown person from the vicinity of Fort Lee in Salem. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are the partial cranium belonging to an adult who is probably male and postcranial fragments belonging to an adult female. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by an unknown person from Jessy W. Peabody's land in Middletown. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are the partial cranium and postcranial elements belonging to an adult female and postcranial fragments belonging to an adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one

individual were removed by an unknown person from an unknown site in Essex. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are cranial and postcranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed by an unknown person from Lagrange Street in Salem. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are cranial and postcranial fragments belonging to one adult male, one adult female, and one adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In August of 1892, human remains representing, at minimum, four individuals were removed by the Salem Gas Company from Lagrange Street in Salem. In June of 1916, the Salem Gas Company presented these human remains to the Peabody Museum of Salem, now the Peabody Essex Museum, which in turn donated them to the Peabody Museum in 1950, through Ernest S. Dodge. The human remains are cranial fragments and postcranial elements belonging to one adult male, one adult female, and two subadults of unknown sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed by an unknown person from an unknown site in Salem. In 1950, the Peabody Museum of Salem, now the Peabody Essex Museum, donated these human remains to the Peabody Museum through Ernest S. Dodge. The human remains are partial cranial and postcranial elements belonging to two adult males and one subadult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In October of 1866, human remains representing, at minimum, six individuals were removed by David Moore from Salem. In December of 1953, these human remains were donated anonymously to the Peabody Museum. The human remains are postcranial fragments belonging to an adult of unknown sex, cranial and postcranial fragments belonging to an adult of unknown sex, cranial fragments belonging to two children of unknown sex, the partial cranium and postcranial elements belonging to a child of unknown sex, and postcranial fragments belonging to a fetus of unknown sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, six individuals were removed by an unknown person from an unknown site in Ipswich. In 1957, Richard Ford of the Harvard School of Legal Medicine donated these human remains to the Peabody Museum through Edward E. Hunt. The human remains are cranial and postcranial fragments belonging to five children and one infant, all of unknown sex. No known individuals were identified. No associated funerary objects are present.

In July of 1957, human remains representing, at minimum, one individual were removed by Theodore L. Stoddard of the Robert S. Peabody Foundation from the Belosselsky Estate in Ipswich. In November of 1957, Princess Florence Crane Belosselsky donated these human remains to the Peabody Museum. The human remains were located approximately two feet below the rim of a drumlin, in sand. The individual had been interred in a flexed position on the left side, facing west, with the feet to the north. A stone pestle was found with the burial, but it is not in the collection of the Peabody Museum. No information is available regarding the dating of the interment. The human remains are the partial cranium and postcranial elements belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In 1897, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Nahant. In May of 1959, the Warren Anatomical Museum, Harvard University (WAM) transferred these human remains to the Peabody Museum. The human remains are postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

In 1890, human remains representing, at minimum, one individual were removed by Dr. F. Humphrey from an unknown site in Ipswich. Humphrey presented these human remains to the Robert S. Peabody Institute, which in turn donated them to the Peabody Museum in February of 1963. The human remains are cranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Thomas Clegg from an unknown site in Lawrence. Clegg presented these human remains to the Robert S. Peabody Institute, which in turn donated them to the Peabody Museum in February of 1963. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In 1890, human remains representing, at minimum, one individual were removed by Walter W. Taylor from the bank of the Merrimack River in Lowell. Taylor presented these human remains to the Robert S. Peabody Institute, which in turn donated them to the Peabody Museum in February of 1963. The human remains are the nearly complete cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by some boys from a gravel pit in Ipswich. Dr. Wigglesworth, the medical examiner in Ipswich, presented these remains to Dr. Edwin V. Hill at the Department of Legal Medicine, Harvard Medical School. Hill in turn donated the remains to the Peabody Museum in March of 1964. The human remains are the partial cranium and postcranial fragments belonging to two subadults of unknown sex. No known individuals were identified. No associated funerary objects are present.

In May of 1916, human remains representing, at minimum, two individuals were removed by an unknown person from Lagrange Street in Salem. In April of 1964, these hitherto uncatalogued human remains were found in the Peabody Museum and were accessioned. The human remains are cranial and postcranial fragments belonging to one adult and one subadult of unknown sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by H.C. Perkins from near the mouth of the Merrimack River in Newburyport. In 1867, Perkins donated these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by H.C. Perkins from an unknown site in Beverly. In 1867, Perkins donated these human remains to the Peabody

Museum. The human remains are the partial cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site, possibly George Titcomb's cellar, in Newburyport. In 1867, Edward A. Hale donated these human remains to the Peabody Museum. Copper stains present on the human remains indicate interment sometime during the early Historic period or later (*i.e.,* A.D. post-1600). The human remains are cranial fragments belonging to a child of unknown sex. No known individual was identified. No associated funerary objects are present.

In 1867, human remains representing, at minimum, one individual were removed by George Peabody Russell from an unknown site in Essex and donated by him to the Peabody Museum the same year. The human remains are cranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by William C. Otis from an unknown site in Nahant. In 1868, Otis donated these human remains to the Peabody Museum. The human remains are the nearly complete cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In 1868, human remains representing, at minimum, two individuals were removed by Jefferies Wyman and J. Elliot Cabot from the Eagle Hill shell heap, 19ES0084, in Ipswich and donated by them to the Peabody Museum the same year. Non-funerary objects found at the site, including shells, animal bones, pottery fragments, small stemmed points, and small triangle points, indicate that the interments date to the Late Archaic through Woodland Periods (5000–500 B.P.). The human remains are cranial fragments belonging to a child of unknown sex and postcranial fragments belonging to an adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In October of 1876, human remains representing, at minimum, three individuals were removed by Joseph Ballard for the Peabody Academy of Science from an ''Indian grave'' in Saugus. The Peabody Academy of Science, now the Peabody Essex Museum, in turn donated these human remains to the Peabody Museum the same year. Based on the associated funerary objects, this interment dates to the post-Contact period or later (*i.e.,* A.D. post-1600). The human remains are the nearly complete crania belonging to one adult male and one adult female and the partial cranium belonging to an adult male. No known individuals were identified. The 66 associated funerary objects are one pair of iron scissors, one iron jackknife with a molded brass handle, one bone implement, one broken bone implement, and 62 shell beads.

In 1874 and 1876, human remains representing, at minimum, 20 individuals were removed by the Essex Institute for the Peabody Academy of Science from Beesom's Pasture in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. The burials are described as being in a flexed position, and based on the positioning of the individuals, all the decedents likely were interred at the same time. A dark red ochre-like substance was also found on the human remains. The associated funerary objects, which are not in the collection of the Peabody Museum, include the remains of a bearskin pouch, copper tubular beads, and pottery fragments. Based on the associated funerary objects and the description of the burials at the site, these remains were likely interred during the Late Woodland Period or later (*i.e.,* post-1000 B.P.). The human remains are the partial cranium belonging to an adult male; postcranial fragments belonging to 13 adults of unknown sex; the partial cranium and postcranial elements belonging to one adult male and one adult of unknown sex; postcranial fragments belonging to an adult male; and cranial and postcranial fragments belonging to one adult female, one adult male, and one adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In 1876 and at an unknown date, human remains representing, at minimum, nine individuals were removed by D. R. Bickford from his lawn in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. The human remains are the nearly complete cranium belonging to an adult female; cranial fragments belonging to two adults who are probably male; cranial fragments belonging to one adult of unknown sex, one subadult of unknown sex, and one child of unknown sex; and postcranial elements belonging to two adult females and one subadult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In 1876, human remains representing, at minimum, one individual were removed by James Kimball from the corner of Essex and Cambridge Streets in Salem. That same year, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Based on an osteological analysis of these remains, this individual was of mixed Native American and African/African American ancestry and therefore lived during the post-Contact or early Historic Period or later (*i.e.,* A.D. post-1614). The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In 1876, human remains representing, at minimum, four individuals were removed by James Kimball from the corner of Essex and Cambridge Streets in Salem. That same year, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. The human remains are the partial cranium belonging to one adult male, cranial and postcranial fragments belonging to one adult male, one subadult of unknown sex, and cranial and postcranial fragments belonging to one child of unknown sex. No known individuals were identified. No associated funerary objects are present.

In 1872, human remains representing, at minimum, three individuals were removed by C. Cooke of the Peabody Academy of Science from the Pine Grove shell heap, 19ES0226, in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Non-funerary items from the site not in the collection of the Peabody Museum include bifacial stone points, an adze, pendants, stone tools, chipping waste, and a pestle. These items indicate that interment took place during the pre-Contact Period, possibly in the Late Archaic Period (5000–3000 B.P.). The human remains are the partial cranium belonging to one adult male and postcranial fragments belonging to one adult female and one adult who is probably female. No known individuals were identified. No associated funerary objects are present.

In 1872, human remains representing, at minimum, 16 individuals were removed by C. Cooke of the Peabody Academy of Science from Linden Street in Salem. In 1876, the Peabody Academy of Science, now the Peabody

Essex Museum, donated these human remains to the Peabody Museum. The human remains are postcranial fragments belonging to 11 adults of unknown sex and cranial and postcranial fragments belonging to one adult male, three adult females, and one adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In January of 1874, human remains representing, at minimum, two individuals were removed by W. B. Wyman from a location near the Pine Grove shell heap in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Non-funerary items from the Pine Grove shell heap not in the collection of the Peabody Museum include bifacial stone points, an adze, pendants, stone tools, chipping waste, and a pestle. These items indicate that interment took place during the pre-Contact Period, possibly in the Late Archaic Period (5000–3000 B.P.). The human remains are cranial and postcranial fragments belonging to an adult female and postcranial fragments belonging to an adult male. No known individuals were identified. No associated funerary objects are present.

In November of 1874, human remains representing, at minimum, one individual were removed by the Essex Institute for the Peabody Academy of Science from Wyman's Pasture in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Copper staining on the human remains indicate the individual was interred during the Historic/Contact Period (*i.e.,* post-500 B.P.). The human remains are cranial and postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In 1872, human remains representing, at minimum, one individual were removed by Frederic Ward Putnam and the Peabody Academy of Science from the Eagle Hill shell heap, 19ES0084, in Ipswich. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Non-funerary objects found at the site, including shells, animal bones, pottery fragments, small stemmed points, and small triangle points, indicate that the interments date to the Late Archaic through Woodland Periods (5000–500 B.P.). The human remains are cranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

In 1872, human remains representing, at minimum, one individual were removed by C. Cooke of the Peabody Academy of Science from the Wyman's Crossing shell heap in Marblehead. In 1876, the Peabody Academy of Science, now the Peabody Essex Museum, donated these human remains to the Peabody Museum. Non-funerary items from the site, which include stone tools, stone chips, animal bones, and charred wood, indicate the human remains were interred during the Late Archaic Period (5000–3000 B.P.). The human remains are postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by A.J. Colburn from Peter's Falls in West Andover. In February of 1877, the Peabody Museum purchased these human remains. The human remains are the partial cranium and postcranial elements belonging to an adult male. No known individual was identified. The one associated funerary object is a metal button. The metal button post-dates the arrival of Europeans and indicates the human remains were interred during the Historic/Contact Period (*i.e.,* post-500 B.P.).

In 1878, human remains representing, at minimum, one individual were removed by Henry Coleman from an unknown site in Swampscott. In May of 1879, Coleman donated these human remains to the Peabody Museum. The human remains are the nearly complete cranium belonging to an adult who is probably female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by a Mr. Ober from ''Indian Hill,'' located on Beverly Cove, in Beverly. Today, this site is the location of the Beverly Cemetery. In July of 1879, the Peabody Museum purchased these human remains as part of the Ober Collection. Objects found at the site not associated with the burial include atlatl fragments, a full-grooved axe, plain and grooved gouges, and temporally diagnostic bifaces such as Atlantic, Orient Fishtails, and Neville points. The stone implements and projectile point types support a Late to Transitional Archaic Period date for the interment (5000–3000 B.P.). The human remains are the nearly complete cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Salem. In July of 1881, Cordelia A. Studley donated these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult who is probably female. No known individual was identified. No associated funerary objects are present.

In January of 1968, human remains representing, at minimum, one individual were removed by Douglas S. Byers near or on Launching Road in Andover, after they were unearthed by a bulldozer working on construction of a new road. That same month, Byers donated these human remains to the Peabody Museum. The human remains are cranial and postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

Middlesex County, MA

Sometime in the 1950s, human remains representing, at minimum, one individual were removed by Malcolm Brooks Davis from a location somewhere between Spy Pond and Menotomy Rocks Park, in Arlington. In October of 1975, John Blackwell donated these human remains to the Peabody Museum. The human remains are the nearly complete cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

About 1895, human remains representing, at minimum, two individuals were removed by R. L. Richardson from burials at the Fresh Pond ice houses in Cambridge. In 1913, Richardson's wife donated these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult male and postcranial fragments belonging to an adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In 1913, human remains representing, at minimum, one individual were removed by Samuel J. Guernsey, as part of a Peabody Museum Expedition, from a stone-lined grave in Watertown. Artifacts found in the immediate vicinity, not associated with the burial indicate these human remains were interred during the Transitional Archaic Period (3500–2500 B.P.). The human remains are cranial and postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

In 1913, human remains representing, at minimum, one individual were removed by Samuel J. Guernsey, as part of a Peabody Museum Expedition, from a grave in Watertown. A description of the burial noted that there were acorns at the bottom of the pit, and the human remains rested against the side of the pit and were nearly all decayed. Artifacts found in the immediate vicinity, not associated with the burial indicate these human remains were interred during the Transitional Archaic Period (3500–2500 B.P.). The human remains are cranial and postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, 14 individuals were likely removed by George or Cheston Sawtelle from an unknown site in the vicinity of Lowell. Subsequently, these human remains formed part of the Sawtelle Collection at the Robert S. Peabody Institute. In 1951, the Robert S. Peabody Institute donated the human remains to the Peabody Museum through Douglas S. Byers. The human remains are cranial and postcranial fragments belonging to one child, three subadults, and four adults, all of unknown sex; cranial fragments belonging to two adults of unknown sex; cranial fragments belonging to an adult male; cranial fragments belonging to two adult females; and cranial fragments belonging to an individual of unknown age and sex. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, five individuals were removed by an unknown person from a grave in Winchester. An unknown person likely donated these human remains to the Peabody Museum in 1892. The human remains are the partial cranium and postcranial elements belonging to five adults, four of whom are of unknown sex and one who is probably female. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from a sand bank in West Newton. These human remains were likely donated to the Peabody Museum by the West Newton Board of Health in 1895. The human remains are the partial cranium and postcranial elements belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In 1877, human remains representing, at minimum, one individual were removed by James G. Wade from his farm in Wayland. In 1895, Wade donated these human remains to the Peabody Museum. The human remains are the partial cranium and postcranial elements belonging to a subadult who is probably male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed by an unknown person from a sand bank on Washington Street in West Newton. In 1896, the West Newton Board of Health donated these human remains to the Peabody Museum. The human remains are the partial cranium and postcranial elements belonging to an adult female and cranial fragments belonging to a child of unknown sex. No known individuals were identified. No associated funerary objects are present.

In January of 1967, human remains representing, at minimum, one individual were removed by Ramon de Cruz and James Di Tucci from the fill or dump for the Charles Farm located behind a cemetery, in Cambridge. Presumably, these human remains had been bulldozed off the edge of the cemetery. That same month, de Cruz and Di Tucci donated the human remains to the Peabody Museum. The human remains are cranial and postcranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In August of 1967, human remains representing, at minimum, one individual were removed by Roger W. Hamilton and Robert F. Doherty from the fill or dump for the Charles Farm, located behind a cemetery, in Cambridge. Presumably, these human remains had been bulldozed off the edge of the cemetery. In September of 1967, Hamilton and Doherty donated the human remains to the Peabody Museum. The human remains are cranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

Norfolk County, MA

In 1901, human remains representing, at minimum, 14 individuals were removed by William O. Crosby from the Squantum shell heap in Quincy. That same year, Crosby donated these human remains to the Peabody Museum. Although this site is a known Native American shell heap, no information concerning the context or date of these human remains is available. The human remains are cranial and postcranial fragments belonging to two adults who are probably female, four adults of unknown sex, seven children of unknown sex, and one subadult male. No known individuals were identified. No associated funerary objects are present.

In 1927, human remains representing, at minimum, one individual were removed by Augustus Hemenway from the vicinity of Green Street in Canton. That same year, Hemenway gave these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In October of 1937, human remains representing, at minimum, two individuals were removed by Marshall T. Newman of Harvard University's Division of Anthropology from the vicinity of Crabtree Road in Quincy. That same month, the Division of Anthropology gave these human remains to the Peabody Museum. The individuals were interred in a flexed position with the head to the east and with several rolled copper sheet beads around the head. Copper staining on the human remains and the associated copper sheet beads indicate this interment dates to the post-Contact period (*i.e.,* A.D. post-1600). The human remains are the nearly complete cranium and postcranial fragments belonging to an adult male and postcranial fragments belonging to an adult female. No known individuals were identified. The three associated funerary objects are two copper beads with attached human hair and one flat ovate stone.

At an unknown date, human remains representing, at minimum, one individual were removed by the Police Department of Quincy from an unknown site in Quincy. In November of 1954, the Quincy Police Department donated these human remains to the Peabody Museum through Edward E. Hunt. The human remains are the nearly complete cranium and postcranial elements belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Dr. H.B. Inches from an unknown site in Brookline. Inches presented these human remains to the Boston Society for Medical Improvement (BSMI). In 1888–1889, the cabinet of the BSMI was officially transferred to the Warren Anatomical Museum, Harvard University (WAM), and in May of 1959, WAM transferred these human remains to the Peabody Museum. The human remains are the partial cranium

belonging to an adult who is probably male. No known individual was identified. No associated funerary objects are present.

In August of 1898, human remains representing, at minimum, one individual were removed during a Peabody Museum expedition from Hough's Neck in Quincy. These human remains were found with five other skeletons not in the collection of the Peabody Museum and whose locations are unknown. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In October of 1969, human remains representing, at minimum, nine individuals were removed by Dr. Stephen Williams and Dr. Dena Dincauze, as part of a Peabody Museum expedition, from the Burr Lane Cemetery in Canton. These human remains were removed from burials in a known, eighteenth-century ''Praying Indian'' cemetery of the Ponkapoag. The burials in this cemetery exhibited English customs of the eighteenth century, such as securing shrouds with copper pins, using pine coffins, and rectangular graves. Grave markers were likely present, as one footstone was discovered. Objects associated with burials from this site, such as coffin nails, an eighteenth-century kaolin pipe, a fragment of ceramic, a piece of lead shot, and a fragment of shroud cloth with a copper pin adhering, also support an early-mid eighteenth-century date for these interments. A small-handled cup found in the immediate vicinity but not in association with any burials is of a type of English ware in use from 1690–1720. The human remains are postcranial fragments belonging to an adult who is probably male and an adult of unknown sex; the partial cranium and postcranial fragments belonging to an adult female; cranial fragments belonging to an adult of unknown sex; the nearly complete skeletons belonging to an adult female and an adult male; cranial and postcranial fragments belonging to an adult who is probably female; the nearly complete cranium and postcranial fragments belonging to an adult who is probably female; and the partial cranium belonging to an adult of unknown sex. No known individuals were identified. The seven associated funerary objects are one bag of nails, one bag of textile fragments, one clay pipe, one fragment of white-glazed ceramic material, one fragment of lead shot, one lot of shroud cloth fragments with an adhering copper pin, and one lot of iron nails and fragments with adhering wood fragments.

Suffolk County, MA

At an unknown date, human remains representing, at minimum, seven individuals were removed by an unknown person from an unknown burial location, possibly at Bunker Hill in Charlestown. In 1900, an unknown person donated these human remains to the Peabody Museum. The human remains are the partial cranium and postcranial elements belonging to an adult male, an adult female, and five adults of unknown sex. No known individuals were identified. No associated funerary objects are present.

In June of 1861, human remains representing, at minimum, one individual were removed by Dr. P.A. O'Connell of the United States Army from a burial site ten feet from the eastern edge of Long Island in Boston Harbor. O'Connell sent these human remains to Dr. Henry G. Clark, who in turn presented them to the Warren Anatomical Museum, Harvard University (WAM) in 1862. In 1916, the Peabody Museum received the human remains via an exchange with WAM. The Long Island burial site was an organized burial ground, with the burials arranged in rows. Individuals were consistently buried in a flexed posture with the head directed to the south and without accompanying funerary objects. This contextual information suggests these interments date to the Late Woodland period or later (*i.e.,* post-1000 B.P.). The history of Long Island strongly indicates that during and after King Philip's War (A.D. 1675–1676), it served as a burial place for a population of New England Native American individuals that included, but was not limited to, the Massachusett and Pawtucket. During King Philip's War, Long Island was used as an internment camp for so-called ''Praying Indians'' captured from the 14 towns within Massachusett and Pawtucket homelands. The internment of Praying Indians on Long Island, Deer Island, and other Boston Harbor islands ended in 1677, but not before many of them had died of starvation, disease, and exposure. During later historic periods, several other groups used Long Island for burials, at least some of whom may have included individuals of Native American ancestry. The burial places of these individuals may have been confused with burial places of Native American individuals in recorded histories, remembered histories, and during archeological and other island surveys. The human remains are the partial cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In November of 1921, human remains representing, at minimum, one individual were removed by Frank N. Belcher from the Belcher estate in Winthrop. That same year Belcher donated these human remains to the Peabody Museum. Belcher described the burial as ''on the southeast slope of a sand and gravel soil, about 4 feet deep.'' The human remains are cranial and postcranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from Washington Street in Boston. In May of 1959, the Warren Anatomical Museum, Harvard University (WAM) transferred these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In 1878, human remains representing, at minimum, one individual were removed by A.A. Tapley from the G.A. Tapley Farm in Revere. That same year, A.A. Tapley donated these human remains to the Peabody Museum. The human remains are the partial cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In December of 1881, human remains representing, at minimum, two individuals were removed by E.H. Whorf from an unknown site in Revere. That same year, Walter Faxon donated these human remains to the Peabody Museum. The human remains are the nearly complete skeleton belonging to an adult male and postcranial fragments belonging to an adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In June of 1886, human remains representing, at minimum, one individual were removed by Dr. D.D. Slade from a ''ledgy hillside'' northeast of the Reservoir Gateway in Brighton. That same month, Slade donated these human remains to the Peabody Museum. The human remains were removed from under 3.5 feet of loam. The human remains are the partial cranium and postcranial elements belonging to a subadult female. No known individual was identified. No associated funerary objects are present.

In May of 1888, human remains representing, at minimum, one

individual were removed by William Doogue, Dexter Brackett, and Franklin Otis from the vicinity of the Tremont Street Mall on the Boston Common in Boston. That same month, Doogue, Brackett, and Otis donated these human remains to the Peabody Museum. At the time of removal, clam shells were found in association with the human remains. The human remains are the nearly complete cranium and postcranial fragments belonging to an adult male. No known individual was identified. The one associated funerary object is a clam shell (*Mya arenaria*).

In April of 1888, human remains representing, at minimum, 13 individuals were removed by railroad workers and railroad superintendent C.H. Hammond from the Central Station site, 19SU0003, in Winthrop. In May of 1888, Hammond donated these human remains to the Peabody Museum. The Central Station site dates to ca. 1450–1634. Objects associated with burials at the site, such as copper items and European materials provide a date during the Historic/Contact Period, and a cattle pound built by the town near the burials provides a *terminus ante quem* date of 1634 for the site. The human remains are partial crania belonging to one adult female and one adult male; cranial fragments belonging to one adult who is probably female and one adult of unknown sex; the nearly complete, partially mummified cranium belonging to an adult male; cranial and postcranial elements belonging to three adult males and three adult females; cranial and postcranial fragments belonging to one child of unknown sex; and cranial and postcranial fragments belonging to one adult of unknown sex. No known individuals were identified. The seven associated funerary objects include four objects that are present in the Peabody Museum collections and three objects that are currently missing. The four present associated funerary objects are one bag of copper fragments, one bag of bark cloth fragments, one sheet of copper, and one bag of birchbark mat fragments. The three associated funerary objects currently missing are two lots of copper and bark cloth fragments and one lot of sand.

In 1888 and 1890, human remains representing, at minimum, 14 individuals were removed by Frederic Ward Putnam, as part of a Peabody Museum expedition, from the Central Station site, 19SU0003, in Winthrop. As described above, the Central Station site is dated to ca. 1450–1634. The human remains are the nearly complete skeletons belonging to three adult males, one adult female, one subadult who is probably male, and one child of unknown sex; partial cranium belonging to one infant of unknown sex; cranial and postcranial fragments belonging to two infants of unknown sex and one child of unknown sex; partial cranium belonging to one adult male; cranial and postcranial fragments belonging to one child of unknown sex; and cranial fragments belonging to two adults of unknown sex. No known individuals were identified. The 82 associated funerary objects include 81 objects that are present in the Peabody Museum collections and one object that is currently missing. The 81 present associated funerary objects are one fragmented pottery vessel, six lots of pottery vessel fragments, one pottery vessel, two iron implements, eight copper or brass beads, 11 bone points, one beaver tooth, one beaver tooth fragment, one brass arrowpoint, one lot of copper beads and fragments of string, one lot of bark mat fragments, one shell, one strand of shell beads, 10 beads, two strands of glass beads, 11 shell and blue glass beads, one lot of a clay pipe and its fragments, one bag of textile fragments, two metal spoons, six brass or copper ornaments, four shell beads, one small pottery vessel and three sherds, one stone effigy pestle, one rubbing stone, one antler spoon, and one bone implement. The one associated funerary object currently missing is the fragment of a pottery vessel.

Between 1885 and 1887, human remains representing, at minimum, 28 individuals were removed by the Boston Gas Light Company from Commercial Point in Dorchester, during construction. In 1889, Walter K. Means of the Boston Gas Light Company donated these human remains to the Peabody Museum. The human remains were found at the top of a beach, between two and three feet below the original surface, with streaks of beach gravel and scatterings of clam shells and black ashes visible in the soil. There were no funerary objects found with the human remains, but the partial preservation of some of the human remains due to the action of copper salts suggests that a copper burial object had also been interred. The presence of this cupric staining indicates that the interments post-date the Contact Period and provides a burial date of post-500 B.P. The human remains are cranial and postcranial fragments belonging to an adult of unknown sex; cranial fragments belonging to two adults and one subadult of unknown sex; cranial elements belonging to four children of unknown sex; postcranial fragments belonging to four adults, four subadults, four children, and one infant of unknown sex; postcranial fragments belonging to an adult female; the nearly complete cranium and postcranial elements belonging to an adult female; cranial and postcranial elements belonging to two children and one infant of unknown sex; cranial elements belonging to an adult female; and cranial and postcranial fragments belonging to an adult who is probably female. No known individuals were identified. No associated funerary objects are present.

About 1899, human remains representing, at minimum, one individual were removed by Freeman F. Burr from the Squantum shell heap in Quincy. That same year, Burr donated these human remains to the Peabody Museum. The human remains were located approximately a foot below the level of the shell heap. Based on the non-funerary objects at this site, which include a chipped stone implement; fragments of thin, black, friable, sand-tempered, decorated ceramics; shells; a slate slab; charcoal; and fragments of bone, this interment most likely occurred during the Late Archaic to Late Woodland periods (5000–500 B.P.). The human remains are the nearly complete skeleton belonging to one infant of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were likely removed by an unknown person from Revere. In 1892, G. Arthur Tapley donated these human remains were donated to the Peabody Museum. The human remains are partial cranial elements belonging to an adult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Chelsea. The human remains were likely donated to the Peabody Museum by Jefferies Wyman in 1867. The human remains are cranial elements belonging to an adult female. No known individual was identified. No associated funerary objects are present.

Between 1880 and 1899, human remains representing, at minimum, one individual were removed by George B. Frazar from a burial place in Winthrop. In 1899, Frazar sold these human remains to the Peabody Museum. The burial place in question is likely the Central Station site (19SU0003), also known as the Winthrop Cemetery or The Pound, which was discovered and destroyed during railroad depot

construction between 1888 and 1890. As described above, the Central Station site is dated to ca. 1450–1634. The human remains are cranial elements belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In April of 1971, human remains representing, at minimum, one individual were removed by Dr. Dena Dincauze, as part of a Peabody Museum expedition, from a shell midden on Peddock's Island (19PL0003 and 19–SU–3a) in Boston Harbor. The shell midden above the human remains was five to six inches deep; no shells were found below the human remains in the burial pit. The burial pit was lined with black organic matter, and red ochre stain was observed in the northeast corner of the pit, on some of the bones. Three fieldstone slabs of Cambridge slate were in the north and northeast areas of the pit, beside and over the head. The human remains had been tightly bundled, almost certainly had been defleshed, and were at least partially articulated at the time of burial. Human remains from this site have been radiocarbon dated to 4435 +/ − 225 B.P., or 2600–2900 B.P., which corresponds to the Late Archaic Period (5000–3000 B.P.) for the Peddock's Island area. The red ochre found with the human remains supports this date. The human remains are cranial and postcranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

Between 1969 and 1972, human remains representing, at minimum, one individual were removed by Dr. Dena Dincauze, David Braun, and William Fitzhugh, as part of a Peabody Museum expedition, from Thompson's Island in Boston Harbor. This habitation and midden site covers a large part of the surface of the sandy elevation at the southeastern corner of the island. Occupation most likely began during the Atlantic phase, ca. 4000 B.P., and continued through the Late Woodland Period, ca. 1000–500 B.P. The interment is a shell midden sub-burial, which indicates that it pre-dates at least some of the occupational periods of the site. The burial position was most likely flexed with a northern orientation. No artifacts were found within the burial pit and there were no temporally diagnostic artifacts within the two clam shell strata located directly above the burial. However, in other portions of the site similar clam shell strata contained artifacts ranging from 4000–500 B.P., suggesting that the burial dates to the earlier occupational period of the Late Archaic. The human remains are cranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

Historical documents and other information obtained through consultation show that areas of northeastern Massachusetts were aboriginally occupied by the Wampanoag people. These types of sources also show that portions of Suffolk, Essex, Norfolk, and Middlesex Counties, MA, were aboriginally occupied by the Massachusett and Pawtucket peoples, neither of whom are represented by any federally recognized Indian Tribe.

Determinations Made by the Peabody Museum of Archaeology and Ethnology, Harvard University

Officials of the Peabody Museum of Archaeology and Ethnology, Harvard University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on osteological analysis, archeological context, and museum records.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 277 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 207 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah) (hereafter referred to as ''The Tribes'').
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Peabody Museum of Archaeology and Ethnology, Harvard University is responsible for notifying The Consulted Tribes and Groups that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25136 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034877; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Archaeology and Ethnology, Harvard University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary object and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary object should submit a written request to the Peabody Museum of Archaeology and Ethnology, Harvard University. If no additional requestors come forward, transfer of control of the human remains and associated funerary object to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these

human remains and associated funerary object should submit a written request with information in support of the request to the Peabody Museum of Archaeology and Ethnology, Harvard University at the address in this notice by December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA. The human remains and associated funerary object were removed from Barnstable, Bristol, Dukes, and Plymouth Counties, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary object. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by the Peabody Museum of Archaeology and Ethnology professional staff in consultation with representatives of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.); Narragansett Indian Tribe; Wampanoag Tribe of Gay Head (Aquinnah); and the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group (hereafter referred to as ''The Consulted Tribes and Group'').

History and Description of the Remains

Barnstable County, MA

In 1901, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Osterville. In 1901 or 1902, Dr. S.W. Driver donated these human remains to the Peabody Museum through Dr. Frederic Ward Putnam. The human remains are postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

In the spring of 1921, human remains representing, at minimum, three individuals were removed by Charles C. Owen from Grand Island in Osterville. In December of 1921, A.A. Marsters donated these human remains to the Peabody Museum. The human remains are cranial and postcranial elements belonging to two adult males and one adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

In March of 1934, human remains representing, at minimum, one individual were removed by Lauchlan M. Crocker, the Sheriff of Barnstable County, from an unknown site in Barnstable. That same month, Crocker donated these human remains to the Peabody Museum. The human remains were recorded as being 12 feet underground. The human remains are cranial and postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Edward H. Rogers from an unknown site in Provincetown. Rogers donated these human remains to the Robert S. Peabody Institute, which in turn donated them to the Peabody Museum in December of 1937. The human remains are the partial cranium and postcranial elements belonging to an adult female. No known individual was identified. The one associated funerary object is a projectile point. As the point's shape most likely falls within the ''Neville'' tradition, it is a modified Neville point. The Neville tradition is associated with the Middle Archaic period in southeastern New England (ca. 8000–6000 B.P.).

In 1947, human remains representing, at minimum, one individual were removed by Ross Moffett from the Hillside site in Truro. That same year, Moffett donated these human remains to the Peabody Museum. The human remains were located in a brownish-black, sandy midden layer. Moffett's descriptions of grit-tempered pottery known as Early Woodland Period Vinette I and Fox Creek style projectile points—these are not in the collections of the Peabody Museum—suggest that this interment most likely dates from the Early to Middle Woodland Period (3000–1000 B.P.). The human remains are the nearly complete skeleton belonging to a subadult male. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Deputy Sheriff Louis Cataldo from the Indian Neck site in Wellfleet. In March of 1966, Cataldo donated these human remains to the Peabody Museum through Dr. Edward Hunt. The human remains are the partial cranium and postcranial elements belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In 1867, human remains representing, at minimum, one individual were removed by Dr. Jeffries Wyman from the Cotuit port shell heap and donated by him to the Peabody Museum. The human remains are postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

In February of 1970, human remains representing, at minimum, one individual were removed by the Bourne Police from an unknown site in Buzzards Bay in Bourne. Deputy Sheriff Cataldo donated these human remains to the Peabody Museum. The human remains were removed from a depth of approximately 30 feet. The human remains are the nearly complete cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

Bristol County, MA

In July of 1945, human remains representing, at minimum, one individual were removed by workmen while excavating a sewer on the property of John Martin in Taunton. That same month, Dr. Alan Richards Moritz of Harvard University's Department of Legal Medicine donated these human remains to the Peabody Museum. The human remains are the partial cranium and postcranial fragments belonging to an adult female. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in New Bedford. These human remains were given to the Robert S. Peabody Institute, which in turn presented them to the Peabody Museum in February of 1963. The human remains are the partial cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

Dukes County, MA

In 1914, human remains representing, at minimum, one individual were removed by Edward Wigglesworth from Wasque Point on Martha's Vineyard. In

July of 1914, Curtis N. Smith donated these human remains to the Peabody Museum. The human remains are cranial and postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Dr. Charles T. Jackson from an ''Indian burial place'' on Martha's Vineyard. Jackson presented these remains to the Boston Society for Medical Improvement (BSMI). In June of 1889, the cabinet of the BSMI was officially transferred to the Warren Anatomical Museum, Harvard University (WAM), and in May of 1959, WAM transferred the human remains to the Peabody Museum. The original inventory of the human remains describes the burial location as full of small shells and notes that many of the bodies in the burial place were interred in an erect posture surrounded by shells. The human remains are the nearly complete cranium belonging to an adult female. No known individual was identified. No associated funerary objects are present.

Plymouth County, MA

In March of 1940, human remains representing, at minimum, one individual were removed by Norman Merry, Arthur Chandler, and Superintendent Sherman from an unknown site in Lakeville. That same month, Dr. Alan Richards Moritz of Harvard University's Department of Legal Medicine donated these human remains to the Peabody Museum. The human remains are postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by Dr. Charles T. Jackson from a refuse heap in Plymouth. In November of 1943, the Boston Society of Natural History donated these human remains to the Peabody Museum through Dr. Frederic T. Lewis. The human remains are postcranial fragments belonging to an adult of unknown sex. No known individual was identified. No associated funerary objects are present.

In May of 1946, human remains representing, at minimum, one individual were removed by Dr. Raymond G. Vinal from an unknown site in Norwell. Vinal turned these human remains over to the Massachusetts State Police, who delivered them to Harvard University's Department of Legal Medicine. That same month, Dr. Alan Richards Moritz of the Department of Legal Medicine donated these human remains to the Peabody Museum. The human remains were found buried 2.5–3 feet beneath the ground in gravel resembling hard-packed sand. The human remains are cranial and postcranial fragments belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In April of 1947, human remains representing, at minimum, two individuals were removed by Dr. Maurice Robbins and William Bell Taylor from the Taylor Farm Site, 19Pl165, in North Middleboro. In May of 1947, Robbins donated these human remains to the Peabody Museum. The human remains are the partial cranium and postcranial elements belonging to two adult females. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed by an unknown person from an unknown site in Middleboro. In December of 1883, J. Collins Warren donated these human remains to the Warren Anatomical Museum, Harvard University (WAM) as part of the J. Mason Warren Collection, and in May of 1959, WAM transferred them to the Peabody Museum. The human remains are the nearly complete cranium belonging to an adult male. No known individual was identified. No associated funerary objects are present.

In August of 1961, human remains representing, at minimum, seven individuals were removed by a member of the Cohannet Chapter of the Massachusetts Archaeological Society named ''Curtis'' from the Wapanucket 8 site in Middleboro. In September of 1961, the Massachusetts Archaeological Society, through Maurice Robbins, donated the human remains to the Peabody Museum. The human remains were found in a burial feature consisting of burned and unburned bones capped by a layer of red paint. Radiocarbon dates, artifacts diagnostic of the Archaic period, and the cremation burial suggest that this site and interment dates to the Late Archaic Period (5000–3000 B.P.). The human remains are cranial and postcranial fragments belonging to two infants of unknown sex, one child of unknown sex, one subadult of unknown sex, one adult male, one adult female, and one adult of unknown sex. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Peabody Museum of Archaeology and Ethnology, Harvard University

Officials of the Peabody Museum of Archaeology and Ethnology, Harvard University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on osteological analysis, archeological context, and museum records.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 27 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described in this notice is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary object and any present-day Indian Tribe.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains and associated funerary object were removed is the aboriginal land of the Mashpee Wampanoag Tribe (*previously* listed as Mashpee Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah) (hereafter referred to as ''The Tribes'').
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary object may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary object should submit a written request with information in support of the request to Jane Pickering, William & Muriel Seabury Howells Director, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu,* by December 19, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary object to The Tribes may proceed.

The Peabody Museum of Archaeology and Ethnology, Harvard University is responsible for notifying The Consulted Tribes and Group that this notice has been published.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25137 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034884; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion Amendment: University of Arkansas Museum Collections, Fayetteville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice; amendment.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Arkansas Museum Collections has amended a Notice of Inventory Completion originally published in the **Federal Register** on November 13, 2018 and subsequently amended in a Notice of Inventory Completion Correction published in the **Federal Register** on May 20, 2022. This notice amends the minimum number of individuals and number of associated funerary objects in collections removed from Cross, Mississippi, and Poinsett Counties, AR.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after December 19, 2022.

ADDRESSES: Dr. Mary Suter, University of Arkansas Museum Collections, Biomass 125, Fayetteville, AR 72701, telephone (479) 575–3456, email *msuter@uark.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of Arkansas Museum Collections. The National Park Service is not responsible for the determinations in this notice. Additional information on the amendments and determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the University of Arkansas Museum Collections.

Amendment

This notice amends the determinations originally published in a Notice of Inventory Completion in the **Federal Register** (83 FR 56371–56374, November 13, 2018) and subsequently amended in a Notice of Inventory Completion Correction published in the **Federal Register** (87 FR 30990–30993, May 20, 2022). Repatriation of the items in the original and amended notices has not occurred. Accordingly, the minimum number of individuals whose human remains were removed from Rose Mound (3CS27) in Cross County, AR, is nine (previously six individuals were listed). In addition, this amendment lists as currently missing human remains representing nine individuals that had been removed from the Golden Lake site (3MS60) in Mississippi County, AR (previously no individuals were listed as missing). Also, this amendment lists as currently missing one additional associated funerary object that had been removed from the Hazel Site (3PO6) in Poinsett County, AR (previously 52 associated funerary objects were listed as missing).

In 1950, 1967, and another unknown date, human remains representing, at minimum, nine individuals were removed from the Rose Mound Site (3CS27) in Cross County, AR. No known individuals were identified. The five associated funerary objects are five fragments of copper.

At an unknown date, human remains representing, at minimum, 105 individuals were removed from the Golden Lake Site (3MS60) in Mississippi County, AR. Of that number, human remains representing nine individuals are currently missing from the collection. The University of Arkansas Museum continues to look for the missing individuals. No known individuals were identified. No associated funerary objects are present.

In 1933, human remains representing, at minimum, 260 individuals were removed from the Hazel Site (3PO6) in Poinsett County, AR. No known individuals were identified. In total, there are 1,319 associated funerary objects, of which 53 objects are currently missing from the collection. The 1,266 associated funerary objects currently accounted for are one abrader, six deer antler tines, one arrow point, one artifact sample, two bone awls, one axe, one basketry fragment, 30 bone beads, two ceramic beads, four crinoid beads, 439 shell beads, 83 animal bones, three bird bones, 118 fish bones, 78 ceramic bottles, 83 ceramic bowls, two non-vessel ceramic objects, two lots of charcoal, two clay lumps, two sheets of copper, one corn cob, nine pieces of daub, three ceramic discs, eight ear plugs, two effigy bottles, 12 effigy bowls, one effigy jar, one shell gorget, 43 ceramic jars, one knife, one antler knife, one bone needle, one copper ornament, one shell pendant, 21 bone pins, three pipes, 35 gar scales, two samples of sediment, 26 mussel shells, four pieces of turtle shell, 219 ceramic sherds, one painted stone, two textiles, three animal teeth, two twigs, and two partial vessels. The University of Arkansas Museum continues to look for the missing 53 (previously identified as 52) associated funerary objects, which are one deer antler tine, one artifact sample, one bird bill awl, one bone awl, three shell beads, two worked bones, eight ceramic bottles, 12 ceramic bowls (previously identified as 11 ceramic bowls), one ceramic non-vessel objects, one lot of charcoal, one sheet of copper, three ear plugs, one effigy bottle, four effigy bowls, one bone needle, one pipe, four mussel shells, one sherd, and six vessels.

Determinations (as Amended)

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the University of Arkansas Museum Collections has determined that:

- The human remains represent the physical remains of 374 individuals of Native American ancestry.
- The 1,324 objects are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Quapaw Nation (previously listed as The Quapaw Tribe of Indians).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after December 19, 2022. If competing requests for repatriation are received, the University of Arkansas Museum Collections must determine the most

appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of Arkansas Museum Collections is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, § 10.10, § 10.13, and § 10.14.

Dated: November 9, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–25129 Filed 11–17–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2022–0053]

Notice of Availability of a Draft Environmental Impact Statement for Empire Offshore Wind, LLC's Proposed Wind Energy Facility Offshore New York

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: BOEM announces the availability of the draft environmental impact statement (DEIS) for the construction and operations plan (COP) submitted by Empire Offshore Wind, LLC (Empire Wind) for its proposed Empire Wind Project (Project) offshore New York. The DEIS analyzes the potential environmental impacts of the Project as described in the COP (the proposed action) and the alternatives to the proposed action. This notice of availability (NOA) announces the start of the public review and comment period, as well as the dates and times for public hearings on the DEIS. After BOEM holds the public hearings and addresses comments provided, BOEM will publish a final environmental impact statement (EIS). The EIS will inform BOEM's decision whether to approve, approve with modifications, or disapprove the COP.

DATES: Comments must be received no later than January 17, 2023. BOEM will conduct three virtual public hearings. BOEM's virtual public hearings will be held at the following times (eastern time).

- Wednesday, December 7, 2022; 5 p.m.
- Tuesday, December 13, 2022; 5 p.m.
- Thursday, December 15, 2022; 1 p.m.

Registration for the virtual public hearings may be completed here: *https://www.boem.gov/renewable-energy/state-activities/empire-wind-farm-deis-project-page-virtual-meetings* or by calling (703) 787–1520. Registration for the virtual hearings is required. Meeting information will be sent to registrants via their email address provided during registration.

ADDRESSES: The DEIS and detailed information about the Project, including the COP, can be found on BOEM's website at: *https://www.boem.gov/renewable-energy/state-activities/empire-wind.* Comments can be submitted in any of the following ways:

- Orally or in written form during any of the public hearings identified in this NOA.
- In written form by mail or any other delivery service, enclosed in an envelope labeled ''Empire Wind COP DEIS'' and addressed to Program Chief, Office of Renewable Energy, Bureau of Ocean Energy Management, 45600 Woodland Road, VAM–OREP, Sterling, VA 20166.
- Through the *regulations.gov* web portal: Navigate to *https://www.regulations.gov* and search for Docket No. BOEM–2022–0053. Click on the ''Comment'' button below the document link. Enter your information and comment, then click ''Submit Comment.''

For more information about submitting comments, please see ''*Information on Submitting Comments*'' under the **SUPPLEMENTARY INFORMATION** heading below.

FOR FURTHER INFORMATION CONTACT: Jessica Stromberg, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166, (703) 787–1722 or *jessica.stromberg@boem.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Action: Empire Wind seeks approval to construct, operate, and maintain the Project: two wind energy farms and their associated export cables on the Outer Continental Shelf (OCS) offshore New York. The Project would be developed within the range of design parameters outlined in the Empire Wind COP, subject to applicable mitigation measures. Empire Wind proposes to develop the lease area in two wind farms, known as Empire Wind 1 (EW 1) and Empire Wind 2 (EW 2) (collectively, the Project). EW 1 and EW 2 will be electrically isolated and independent from each other. Empire Wind proposes to construct and operate up to 147 wind turbines and up to 2 offshore substations with 2 cable routes under the terms of Renewable Energy Lease OCS–A 0512. The lease area is located 14 miles from Long Island, New York, and 19.5 miles from Long Branch, New Jersey. The onshore components of the Project will include up to three export cable landfall areas in New York (one for EW 1 and up to two for EW 2) and two onshore substations. The EW 1 onshore substation will be in Brooklyn, New York; and the EW 2 Onshore Substation A in Oceanside, New York, or the EW 2 Onshore Substation C in Island Park, New York.

Alternatives: BOEM considered 30 alternatives when preparing the DEIS and carried forward 7 alternatives for further analysis in the DEIS. These seven alternatives include six action alternatives and a no action alternative. BOEM rejected 23 alternatives because they did not meet the purpose and need for the proposed action or did not meet screening criteria, which are presented in DEIS appendix C. The screening criteria included consistency with law and regulations; technical and economic feasibility; environmental impact; and geographic considerations.

Availability of the DEIS: The DEIS, Empire Wind COP, and associated information are available on BOEM's website at: *https://www.boem.gov/renewable-energy/state-activities/empire-wind.* BOEM has distributed digital copies of the DEIS to all parties listed in DEIS appendix K, which also includes the location of all libraries receiving a copy. If you need a flash drive or paper copy, BOEM will provide one upon request, as long as copies are available. You may request a flash drive or paper copy of the DEIS by calling (703) 787–1520.

Cooperating Agencies: The following 15 Federal agencies, Tribal Nations, and State and city governmental entities participated as cooperating agencies in the preparation of the DEIS: Bureau of Safety and Environmental Enforcement; U.S. Environmental Protection Agency; National Marine Fisheries Service; U.S. Army Corps of Engineers; U.S. Coast Guard; U.S. Fish and Wildlife Service; Department of Defense; Department of the Navy; Maritime Administration; National Park Service; the Shinnecock Indian Nation; New York State Department of Environmental Conservation; New York State Energy Research & Development Authority; New York State Department of State; and New York City.

Information on Submitting Comments: BOEM does not consider anonymous comments. Please include your name and address as part of your

comment. BOEM makes all comments, including the names and addresses of respondents, available for public review online and during regular business hours. Individual respondents may request that BOEM withhold their names, addresses, or any other personal identifiable information (PII) included in their comment from the public record; however, BOEM cannot guarantee that it will be able to do so. If you wish your name, address, or other PII to be withheld, you must state your request prominently in a cover letter and explain the harm that you fear from its disclosure, such as unwarranted privacy invasion, embarrassment, or injury. Even if BOEM withholds your information in the context of this notice, your submission is subject to the Freedom of Information Act (FOIA) and any relevant court orders. If your submission is requested under the FOIA or such court order, your information will only be withheld if a determination is made that one of the FOIA's exemptions to disclosure applies or if such court order is challenged. Such a determination will be made in accordance with the Department's FOIA regulations and applicable law.

Please label privileged or confidential information as ''Contains Confidential Information,'' and consider submitting such information as a separate attachment. Information that is not labeled as privileged or confidential may be regarded by BOEM as suitable for public release.

All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be made available for public inspection in their entirety.

Authority: 42 U.S.C. 4231 *et seq.* (NEPA, as amended) and 40 CFR 1506.6.

Dated: November 11, 2022.

Karen Baker,

Chief, Office of Renewable Energy Programs, Bureau of Ocean Energy Management.

[FR Doc. 2022–25034 Filed 11–17–22; 8:45 am]

BILLING CODE 4340–98–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–671–672 and 731–TA–1571–1573 (Final)]

Oil Country Tubular Goods From Argentina, Mexico, Russia, and South Korea

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of oil country tubular goods from Argentina and Mexico provided for in subheadings 7304.29, 7305.20, and 7306.29 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''); by reason of imports of oil country tubular goods from Russia that have been found by Commerce to be sold in the United States at LTFV and subsidized by the government of Russia; and by reason of imports of oil country tubular goods from South Korea that have been found by Commerce to be subsidized by the government of South Korea.[2] [3]

Background

The Commission instituted these investigations effective October 6, 2021, following receipt of petitions filed with the Commission and Commerce by Borusan Mannesmann Pipe U.S., Inc., Baytown, Texas; PTC Liberty Tubulars LLC, Liberty, Texas; U.S. Steel Tubular Products, Inc., Pittsburgh, Pennsylvania; Welded Tube USA, Inc., Lackawanna, New York; and the United States Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC, Pittsburgh, Pennsylvania. The final phase of the investigations was scheduled by the Commission following notification of a preliminary determination by Commerce that imports of oil country tubular goods from Russia were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and preliminary determinations by Commerce that imports of oil country tubular goods from Argentina, Mexico, and Russia were sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)).[4] Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 9, 2022 (87 FR 35246). The Commission conducted its hearing on September 22, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 14, 2022. The views of the Commission are contained in USITC Publication 5381 (November 2022), entitled *Oil Country Tubular Goods from Argentina, Mexico, Russia, and South Korea: Investigation Nos. 701–TA–671–672 and 731–TA–1571–1573 (Final).*

By order of the Commission.

Issued: November 14, 2022.

Jessica Mullan,

Attorney Advisor.

[FR Doc. 2022–25109 Filed 11–17–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Summary of Commission Practice Relating to Administrative Protective Orders

AGENCY: International Trade Commission.

ACTION: Summary of commission practice relating to administrative protective orders.

SUMMARY: Since February 1991, the U.S. International Trade Commission (''Commission'') has published in the **Federal Register** reports on the status of its practice with respect to breaches of

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 87 FR 59041, 59045, 59047, 59054, and 59056 (September 29, 2022).

[3] The Commission also finds that imports subject to Commerce's affirmative critical circumstances determinations are not likely to undermine seriously the remedial effect of the antidumping duty orders on oil country tubular goods from Mexico and Russia.

[4] 87 FR 28801, 28804, and 28808 (May 11, 2022) (antidumping duty preliminary determinations) and 87 FR 14249 (March 14, 2022) (countervailing duty preliminary determination for Russia). Commerce preliminarily determined that countervailable subsidies were not being provided to producers and exporters of oil country tubular goods from South Korea. 87 FR 14248 (March 14, 2022) (countervailing duty preliminary determination for South Korea).

its administrative protective orders (''APOs'') under the Tariff Act of 1930 in response to a direction contained in the Conference Report to the Customs and Trade Act of 1990. Over time, the Commission has added to its report discussions of APO breaches in Commission proceedings other than under title VII and violations of the Commission's rules, including the rule on bracketing business proprietary information (the ''24-hour rule''). This notice provides a summary of APO breach investigations completed during fiscal year 2022. This summary addresses APO breach investigations related to proceedings under both title VII and section 337 of the Tariff Act of 1930. The Commission intends for this summary to inform representatives of parties to Commission proceedings of the specific types of APO breaches before the Commission and the corresponding types of actions that the Commission has taken.

FOR FURTHER INFORMATION CONTACT: Caitlin Stephens, Office of the General Counsel, U.S. International Trade Commission, telephone (202) 205–2076. Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at (202) 205–1810. General information concerning the Commission is available on its website at *https://www.usitc.gov.*

SUPPLEMENTARY INFORMATION: Statutory authorities for Commission investigations provide for the release of business proprietary information (''BPI'') or confidential business information (''CBI'') to certain authorized representatives in accordance with requirements set forth in the Commission's Rules of Practice and Procedure. Such statutory and regulatory authorities include: 19 U.S.C. 1677f; 19 CFR 207.7; 19 U.S.C. 1337(n); 19 CFR 210.5, 210.34; 19 U.S.C. 2252(i); 19 CFR 206.17; 19 U.S.C. 4572(f); 19 CFR 208.22; 19 U.S.C. 1516a(g)(7)(A); and 19 CFR 207.100—207.120. The discussion below describes APO breach investigations that the Commission completed during fiscal year 2022, including descriptions of actions taken in response to any breaches.

Since 1991, the Commission has published annually a summary of its actions in response to violations of Commission APOs and rule violations. *See* 86 FR 71916 (Dec. 20, 2021); 85 FR 7589 (Feb. 10, 2020); 83 FR 42140 (Aug. 20, 2018); 83 FR 17843 (Apr. 24, 2018); 82 FR 29322 (June 28, 2017); 81 FR 17200 (Mar. 28, 2016); 80 FR 1664 (Jan. 13, 2015); 78 FR 79481 (Dec. 30, 2013); 77 FR 76518 (Dec. 28, 2012); 76 FR 78945 (Dec. 20, 2011); 75 FR 66127 (Oct. 27, 2010); 74 FR 54071 (Oct. 21, 2009); 73 FR 51843 (Sept. 5, 2008); 72 FR 50119 (Aug. 30, 2007); 71 FR 39355 (July 12, 2006); 70 FR 42382 (July 22, 2005); 69 FR 29972 (May 26, 2004); 68 FR 28256 (May 23, 2003); 67 FR 39425 (June 7, 2002); 66 FR 27685 (May 18, 2001); 65 FR 30434 (May 11, 2000); 64 FR 23355 (Apr. 30, 1999); 63 FR 25064 (May 6, 1998); 62 FR 13164 (Mar. 19, 1997); 61 FR 21203 (May 9, 1996); 60 FR 24880 (May 10, 1995); 59 FR 16834 (Apr. 8, 1994); 58 FR 21991 (Apr. 26, 1993); 57 FR 12335 (Apr. 9, 1992); and 56 FR 4846 (Feb. 6, 1991). This report does not provide an exhaustive list of conduct that will be deemed to be a breach of the Commission's APOs. The Commission considers APO breach investigations on a case-by-case basis.

As part of the Commission's efforts to educate practitioners about the Commission's current APO practice, the Secretary to the Commission (''Secretary'') issued in January 2022 a sixth edition of *An Introduction to Administrative Protective Order Practice in Import Injury Investigations* (Pub. No. 5280). This document is available on the Commission's website at *http://www.usitc.gov.*

I. In General

A. Antidumping and Countervailing Duty Investigations

The current APO application form for antidumping and countervailing duty investigations, which the Commission revised in May 2020, requires an APO applicant to agree to:

(1) Not divulge any of the BPI disclosed under this APO or otherwise obtained in this investigation and not otherwise available to him or her, to any person other than—

(i) Personnel of the Commission concerned with the investigation,

(ii) The person or agency from whom the BPI was obtained,

(iii) A person whose application for disclosure of BPI under this APO has been granted by the Secretary, and

(iv) Other persons, such as paralegals and clerical staff, who (a) are employed or supervised by and under the direction and control of the authorized applicant or another authorized applicant in the same firm whose application has been granted; (b) have a need thereof in connection with the investigation; (c) are not involved in competitive decision making for an interested party which is a party to the investigation; and (d) have signed the acknowledgment for clerical personnel in the form attached hereto (the authorized applicant shall also sign such acknowledgment and will be deemed responsible for such persons' compliance with this APO);

(2) Use such BPI solely for the purposes of the above-captioned Commission investigation or for U.S. judicial or review pursuant to the North American Free Trade Agreement the determination resulting from such investigation of such Commission investigation;

(3) Not consult with any person not described in paragraph (1) concerning BPI disclosed under this APO or otherwise obtained in this investigation without first having received the written consent of the Secretary and the party or the representative of the party from whom such BPI was obtained;

(4) Whenever materials (*e.g.,* documents, computer disks or similar media) containing such BPI are not being used, store such material in a locked file cabinet, vault, safe, or other suitable container (N.B.: [S]torage of BPI on so-called hard disk computer media or similar media is to be avoided, because mere erasure of data from such media may not irrecoverably destroy the BPI and may result in violation of paragraph C of this APO);

(5) Serve all materials containing BPI disclosed under this APO as directed by the Secretary and pursuant to section 207.7(f) of the Commission's rules;

(6) Transmit each document containing BPI disclosed under this APO:

(i) With a cover sheet identifying the document as containing BPI,

(ii) With all BPI enclosed in brackets and each page warning that the document contains BPI,

(iii) If the document is to be filed by a deadline, with each page marked ''Bracketing of BPI not final for one business day after date of filing,'' and

(iv) Within two envelopes, the inner one sealed and marked ''Business Proprietary Information—To be opened only by [name of recipient]'', and the outer one sealed and not marked as containing BPI;

(7) Comply with the provision of this APO and section 207.7 of the Commission's rules

(i) Make true and accurate representations in the authorized applicant's application and promptly notify the Secretary of any changes that occur after the submission of the application and that affect the representations made in the application (*e.g.*[,] change in personnel assigned to the investigation),

(ii) Report promptly and confirm in writing to the Secretary any possible breach of this APO, and

(iii) Acknowledge that breach of this APO may subject the authorized applicant and other persons to such sanctions or other actions as the Commission deems appropriate, including the administrative sanctions and actions set out in this APO.

The APO form for antidumping and countervailing duty investigations also provides for the return or destruction of the BPI obtained under the APO on the order of the Secretary, at the conclusion of the investigation, or at the completion of Judicial Review. The BPI disclosed to an authorized applicant under an APO during the preliminary phase of the investigation generally may remain in the applicant's possession during the final phase of the investigation.

The APO further provides that breach of an APO may subject an applicant to:

(1) Disbarment from practice in any capacity before the Commission along with such person's partners, associates, employer, and employees, for up to seven years following publication of a determination that the order has been breached;

(2) Referral to the United States Attorney;

(3) In the case of an attorney, accountant, or other professional, referral to the ethics panel of the appropriate professional association;

(4) Such other administrative sanctions as the Commission determines to be appropriate, including public release of, or striking from the record any information or briefs submitted by, or on behalf of, such person or the party he represents; denial of further access to business proprietary information in the current or any future investigations before the Commission, and issuance of a public or private letter of reprimand; and

(5) Such other actions, including but not limited to, a warning letter, as the Commission determines to be appropriate.

APOs issued in cross-border long-haul trucking (''LHT'') investigations, conducted under the United States-Mexico-Canada Agreement (''USMCA'') Implementation Act, 19 U.S.C. 4571–4574 (19 U.S.C. 4501 note), and safeguard investigations, conducted under the statutory authorities listed in 19 CFR 206.1 and 206.31, contain similar (though not identical) provisions.

B. Section 337 Investigations

APOs in section 337 investigations differ from those in title VII investigations: There is no set form like the title VII APO application, and provisions of individual APOs may differ depending on the investigation and the presiding administrative law judge. However, in practice, the provisions are often similar in scope and applied quite similarly. Any person seeking access to CBI during a section 337 investigation (including outside counsel for parties to the investigation, secretarial and support personnel assisting such counsel, and technical experts and their staff who are employed for the purposes of the investigation) is required to read the APO, file a letter with the Secretary indicating agreement to be bound by the terms of the APO, agree not to reveal CBI to anyone other than another person permitted access by the APO, and agree to utilize the CBI solely for the purposes of that investigation.

In general, an APO in a section 337 investigation will define what kind of information is CBI and direct how CBI is to be designated and protected. The APO will state which persons may have access to CBI and which of those persons must sign onto the APO. The APO will provide instructions on how CBI is to be maintained and protected by labeling documents and filing transcripts under seal. It will provide protections for the suppliers of CBI by notifying them of a Freedom of Information Act request for the CBI and providing a procedure for the supplier to seek to prevent the release of the information. There are provisions for disputing the designation of CBI and a procedure for resolving such disputes. Under the APO, suppliers of CBI are given the opportunity to object to the release of the CBI to a proposed expert. The APO requires a person who discloses CBI, other than in a manner authorized by the APO, to provide all pertinent facts to the supplier of the CBI and to the administrative law judge and to make every effort to prevent further disclosure. Under Commission practice, if the underlying investigation is before the Commission at the time of the alleged breach or if the underlying investigation has been terminated, a person who discloses CBI, other than in a manner authorized by the APO, should report the disclosure to the Secretary. *See* 19 CFR 210.25, 210.34(c). Upon final termination of an investigation, the APO requires all signatories to the APO to either return to the suppliers or, with the written consent of the CBI supplier, destroy the originals and all copies of the CBI obtained during the investigation.

The Commission's regulations provide for the imposition of certain sanctions if a person subject to the APO violates its restrictions. The Commission keeps the names of the persons being investigated for violating an APO confidential unless the sanction imposed is a public letter of reprimand. 19 CFR 210.34(c)(1). The possible sanctions are:

(1) An official reprimand by the Commission.

(2) Disqualification from or limitation of further participation in a pending investigation.

(3) Temporary or permanent disqualification from practicing in any capacity before the Commission pursuant to 19 CFR 201.15(a).

(4) Referral of the facts underlying the violation to the appropriate licensing authority in the jurisdiction in which the individual is licensed to practice.

(5) Making adverse inferences and rulings against a party involved in the violation of the APO or such other action that may be appropriate. 19 CFR 210.34(c)(3).

Commission employees are not signatories to the Commission's APOs and do not obtain access to BPI or CBI through APO procedures. Consequently, they are not subject to the requirements of the APO with respect to the handling of BPI and CBI. However, Commission employees are subject to strict statutory and regulatory constraints concerning BPI and CBI, and they face potentially severe penalties for noncompliance. *See* 18 U.S.C. 1905; title 5, U.S. Code; and Commission personnel policies implementing the statutes. Although the Privacy Act (5 U.S.C. 552a) limits the Commission's authority to disclose any personnel action against agency employees, this should not lead the public to conclude that no such actions have been taken.

II. Investigations of Alleged APO Breaches

The Commission conducts APO breach investigations for potential breaches that occur in title VII, safeguard, and LHT investigations, as well as potential breaches in section 337 investigations that are before the Commission or have been terminated.[1] Administrative law judges handle potential APO breaches in section 337 investigations when the breach occurred and is discovered while the underlying investigation is before the administrative law judge. The Commission may review any decision that the administrative law judge makes

[1] Procedures for investigations to determine whether a prohibited act, such as a breach, has occurred and for imposing sanctions for violation of the provisions of a protective order issued during a North American Free Trade Agreement or USMCA panel or committee proceedings are set out in 19 CFR 207.100–207.120. The Commission's Office of Unfair Import Investigations conducts those investigations initially.

on sanctions in accordance with Commission regulations. *See* 19 CFR 210.25, 210.34(c).

For Commission APO breach investigations, upon finding evidence of an APO breach or receiving information that there is reason to believe that one has occurred, the Secretary notifies relevant Commission offices that the Secretary has opened an APO breach file and the Commission has commenced an APO breach investigation. The Commission then notifies the alleged breaching parties of the alleged breach and provides them with the voluntary option to proceed under a one- or two-step investigatory process. Under the two-step process, which was the Commission's historic practice, the Commission determines first whether a breach has occurred and, if so, who is responsible for it. This is done after the alleged breaching parties have been provided an opportunity to present their views on the matter. The breach investigation may conclude after this first step if: (1) the Commission determines that no breach occurred and issues a letter so stating; or (2) the Commission finds that a breach occurred, but concludes that no further action is warranted and issues a warning letter. If the Commission determines that a breach occurred that warrants further action, the Commission will then determine what sanction, if any, to impose. Before making this determination, the Commission provides the breaching parties with an opportunity to present their views on the appropriate sanction and any mitigating circumstances. The Commission can decide as part of either the first or second step to issue a warning letter. A warning letter is not a sanction, but the Commission will consider a warning letter as part of a subsequent APO breach investigation.

The Commission recognizes that the two-step process can result in duplicative work for the alleged breaching party and Commission staff in some APO breach investigations. For example, parties who self-report their own breach often address mitigating circumstances and sanctions in their initial response to the Commission's letter of inquiry on the breach. But, under the Commission's two-step process, they must await a Commission decision on breach and then submit again their views on mitigating circumstances and sanctions. To streamline this process and accelerate processing times, the Commission offers alleged breaching parties the option to voluntarily elect a one-step APO breach investigation process. Under this process, the Commission will determine simultaneously whether a breach occurred and, if so, the appropriate sanction to impose, if any. Under either process, the alleged breaching party has the opportunity to submit affidavits reciting the facts concerning the alleged breach and mitigating factors pertaining to the appropriate response if a breach is found.

Sanctions for APO violations serve three basic interests: (a) preserving the confidence of submitters of BPI/CBI that the Commission is a reliable protector of BPI/CBI; (b) disciplining breachers; and (c) deterring future violations. As the Conference Report to the Omnibus Trade and Competitiveness Act of 1988 observed: ''[T]he effective enforcement of limited disclosure under [APO] depends in part on the extent to which private parties have confidence that there are effective sanctions against violation.'' H.R. Conf. Rep. 100–576, at 623 (1988).

The Commission has worked to develop consistent jurisprudence, not only in determining whether a breach has occurred, but also in selecting an appropriate response. In determining the appropriate response, the Commission generally considers mitigating factors such as the unintentional nature of the breach, the lack of prior breaches committed by the breaching party, the corrective measures taken by the breaching party, and the promptness with which the breaching party reported the violation to the Commission. The Commission also considers aggravating circumstances, especially whether persons not authorized under the APO had access to and viewed the BPI/CBI. The Commission considers whether there have been prior breaches by the same person or persons in other investigations and whether there have been multiple breaches by the same person or persons in the same investigation.

The Commission's rules permit an economist or consultant to obtain access to BPI/CBI under the APO in a title VII, safeguard, or LHT investigation if the economist or consultant is under the direction and control of an attorney under the APO, or if the economist or consultant appears regularly before the Commission and represents an interested party who is a party to the investigation. *See* 19 CFR 207.7(a)(3)(i)(B) and (C); 19 CFR 206.17(a)(3)(i)(B) and (C); and 19 CFR 208.22(a)(3)(i)(B) and (C). Economists and consultants who obtain access to BPI/CBI under the APO under the direction and control of an attorney nonetheless remain individually responsible for complying with the APO. In appropriate circumstances, for example, an economist under the direction and control of an attorney may be held responsible for a breach of the APO by failing to redact APO information from a document that is subsequently filed with the Commission and served as a public document, or for retaining BPI/CBI without consent of the submitter after the termination of an investigation. This is so even though the Commission may also hold the attorney exercising direction or control over the economist or consultant responsible for the APO breach. In section 337 investigations, technical experts and their staff who are employed for the purposes of the investigation are required to sign onto the APO and agree to comply with its provisions.

The records of Commission investigations of alleged APO breaches in antidumping and countervailing duty cases, section 337 investigations, safeguard investigations, and LHT investigations are not publicly available and are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552. *See, e.g.,* 19 U.S.C. 1677f(g); 19 U.S.C. 1333(h); 19 CFR 210.34(c).

The two types of breaches most frequently investigated by the Commission involve: (1) the APO's prohibition on the dissemination or exposure of BPI or CBI to unauthorized persons; and (2) the APO's requirement that the materials received under the APO be returned or destroyed and that a certificate be filed with the Commission indicating what actions were taken after the termination of the investigation or any subsequent appeals of the Commission's determination. The dissemination of BPI/CBI usually occurs as the result of failure to delete BPI/CBI from public versions of documents filed with the Commission or transmission of proprietary versions of documents to unauthorized recipients. Other breaches have included the failure to bracket properly BPI/CBI in proprietary documents filed with the Commission, the failure to report immediately known or suspected violations of an APO, and the failure to adequately supervise non-lawyers in the handling of BPI/CBI.

Occasionally, the Commission conducts APO breach investigations that involve members of a law firm or consultants working with a firm who were granted access to APO materials by the firm although they were not APO signatories. In many of these cases, the firm and the person using the BPI/CBI mistakenly believed an APO application had been filed for that person. The Commission has determined in all of these cases that the person who was a non-signatory, and therefore did not

agree to be bound by the APO, could not be found to have breached the APO. However, under Commission rule 201.15 (19 CFR 201.15), the Commission may take action against these persons for good cause shown. In all cases in which the Commission has taken such action, it decided that the non-signatory appeared regularly before the Commission, was aware of the requirements and limitations related to APO access, and should have verified their APO status before obtaining access to and using the BPI/CBI. The Commission notes that section 201.15 may also be available to issue sanctions to attorneys or agents in different factual circumstances in which they did not technically breach the APO, but their action or inaction did not demonstrate diligent care of the APO materials, even though they appeared regularly before the Commission and were aware of the importance that the Commission places on the proper care of APO materials.

The Commission has held routinely that the disclosure of BPI/CBI through recoverable metadata or hidden text constitutes a breach of the APO even when the BPI/CBI is not immediately visible without further manipulation of the document. In such cases, breaching parties have transmitted documents that appear to be public documents in which the parties have removed or redacted all BPI/CBI. However, further inspection of the document reveals that confidential information is actually retrievable by manipulating codes in software or through the recovery of hidden text or metadata. In such instances, the Commission has found that the electronic transmission of a public document with BPI/CBI in a recoverable form was a breach of the APO.

The Commission has cautioned counsel to ensure that each authorized applicant files with the Commission within 60 days of the completion of an import injury investigation or at the conclusion of judicial or binational review of the Commission's determination, a certificate stating that, to the signatory's knowledge and belief, all copies of BPI/CBI have been returned or destroyed, and no copies of such materials have been made available to any person to whom disclosure was not specifically authorized. This requirement applies to each attorney, consultant, or expert in a firm who has access to BPI/CBI. One firm-wide certificate is insufficient.

Attorneys who are signatories to the APO in a section 337 investigation should inform the administrative law judge and the Secretary if there are any changes to the information that was provided in the application for access to the CBI. This is similar to the requirement to update an applicant's information in title VII investigations.

In addition, attorneys who are signatories to the APO in a section 337 investigation should send a notice to the Commission if they stop participating in the investigation or the subsequent appeal of the Commission's determination. The notice should inform the Commission about the disposition of CBI obtained under the APO that was in their possession, or the Commission could hold them responsible for any failure of their former firm to return or destroy the CBI in an appropriate manner.

III. Specific APO Breach Investigations

Case 1. The Commission determined that a partner at a law firm breached the APO issued in a title VII investigation when the partner supervised the drafting, revision, and review of a publicly filed document that contained BPI.

Three attorneys, including the partner, were responsible for drafting the document at issue. Despite the firm's instructions to place brackets around any BPI that an attorney added to the draft, one of the non-partner attorneys inadvertently failed to include brackets around a quote in a footnote. The partner completed two full reviews of the document before its filing, but the partner failed to identify the unbracketed BPI in the footnote. The law firm filed the document on the Commission's Electronic Document Information System (EDIS), and it also served the document on all parties on the public service list. The Commission first became aware of this breach through Commission staff, who discovered the exposed BPI and notified the Secretary. The Office of the Secretary notified the partner of the breach, and the law firm filed a corrected version of the public document later that day.

In determining whether to issue a sanction for the breach, the Commission considered mitigating factors, including that: (1) the breach was inadvertent and unintentional; (2) the law firm took prompt corrective actions to mitigate the effect of the breach by correcting its filing, notifying the recipients of the document's error and of its substitute filing, and obtaining the recipient's confirmation of the document's destruction; and (3) the partner had not previously breached an APO in the two-year period preceding the date of the breach. The Commission also considered the following aggravating factors: (1) the Commission was the first to discover and flag the breach; and (2) unauthorized individuals accessed and presumably viewed the CBI.

The Commission issued a private letter of reprimand to the partner after finding that the partner was ultimately responsible for the failure to redact BPI from the public document.

Case 2. The Commission determined that an expert breached the APO issued in a section 337 investigation by submitting expert reports containing CBI in several unrelated actions pending before a federal district court.

The expert drafted and filed before a federal district court six expert reports that contained a sentence from the confidential version of an administrative law judge's initial determination. Two months later, counsel for one of the parties involved in the underlying section 337 investigation, and in the federal district court action, notified the expert that the quoted sentence did not appear in the public version of the initial determination. The expert took immediate steps to replace the page that contained the CBI, but the expert did not notify the Commission until about a month after the breach's discovery. The expert acknowledged the failure to follow firm procedures, which would have required comparison of the draft expert report with the public version of the initial determination.

In determining whether to issue a sanction for the breach, the Commission considered the following mitigating factors: (1) the breach was inadvertent and unintentional; (2) the expert self-reported the breach to the Commission; and (3) the expert had not previously breached an APO in the two-year period preceding the breach. The Commission also considered the following aggravating factors: (1) the expert did not discover the breach; (2) the breach resulted in exposure of CBI to unauthorized individuals; (3) there was a delay of two months between the discovery of the breach and the mitigation of the breach; (4) the expert waited more than one month to report the breach to the Commission; and (5) the expert failed to handle CBI with due diligence and care, and the expert did not follow firm procedures for protecting CBI.

The Commission issued a private letter of reprimand to the expert.

Case 3. The Commission determined that a supervisory attorney at a law firm breached an APO in a title VII investigation when a legal support staff member under the attorney's supervision inadvertently attached a confidential brief from one investigation to a public brief in another investigation and publicly filed both briefs as one

document with the Department of Commerce (Commerce). The Commission also determined that the supervisory attorney breached the APO a second time by providing BPI to that legal support staff member before the staff member had signed an APO acknowledgment for clerical personnel.

After filing the document in Commerce's IA ACCESS website, the legal support staff member served the document on the parties listed on the public brief's service list. None of the served parties were on the APO service list for the confidential brief. Three days later, the law firm received notification from one of the parties on the public brief's service list that the document contained BPI from an unrelated investigation. Upon review of the document, the law firm discovered that the legal support staff member who had filed and served the document had included a copy of a confidential brief from another title VII investigation. The law firm immediately contacted Commerce to request removal of the document from the IA ACCESS website. Commerce indicated to the law firm that multiple individuals had accessed the document while it was posted publicly to that website. The law firm also contacted the parties on the public service list to ask that they destroy any copies.

The law firm immediately notified the Commission of the breach after learning of it. In its correspondence to the Commission, the firm indicated that the breach occurred because of the legal support staff member's failure to follow firm procedures in handling and storing the confidential brief. The firm also indicated that the supervisory attorney had supervised the preparation of the confidential brief and had been aware of staff's inconsistent adherence to the firm's BPI procedures. In addition, over the course of the APO breach investigation, the Commission discovered that the supervisory attorney had provided BPI to the legal support staff member without first having the staff member sign an APO acknowledgment for clerical personnel.

In determining whether to issue a sanction for the breach, the Commission considered mitigating factors, including that: (1) the breach was inadvertent and unintentional; (2) the law firm took prompt action to remedy the breach and prevent further dissemination of BPI; (3) the law firm promptly self-reported the breach to the Commission; (4) the law firm implemented new procedures to prevent similar breaches in the future; and (5) the supervisory attorney had not previously breached an APO in the two-year period preceding the date of the breach. The Commission also considered the following aggravating factors: (1) unauthorized individuals had access to and viewed the BPI; (2) the law firm violated the APO in two different ways; (3) the law firm did not discover either breach; and (4) the supervisory attorney and legal support staff failed to follow the law firm's procedures for protecting BPI.

The Commission also considered whether to find in breach of the APO a second attorney who supervised the preparation of the public brief, and it determined not to do so. The second attorney was an APO signatory in both relevant investigations, but the second attorney had not supervised the preparation of the confidential brief. Further, the second attorney had reviewed the public brief before the legal support staff member had attached the confidential version to it. The Commission determined that the second attorney would have had no reason to suspect that the legal support staff member would attach BPI materials to the public brief after the final review and approval of the brief.

The Commission issued a private letter of reprimand to the supervisory attorney. The Commission did not take any further action against the legal support staff member whose actions contributed to the breach because the staff member had since passed away.

Case 4. The Commission determined that two attorneys at a law firm breached an APO in a title VII investigation when they reviewed, filed in EDIS, and served a public version of a brief that contained unredacted BPI belonging to a third party.

The attorneys served the brief on the parties to the public service list in the investigation, which included individuals who were not authorized under the APO to view BPI, and the brief was publicly posted to EDIS, where at least one unauthorized individual accessed it. In addition, one of the attorneys forwarded copies of the brief to the firm's clients. Two days after filing and serving the brief, the two attorneys received notification from another party to the investigation (after Commission business hours) that the brief contained BPI. The two attorneys immediately reviewed the brief, and they discovered that they had bracketed, but failed to remove, the BPI at issue. That same day, the two attorneys contacted their clients and the parties on the public service list to request that they destroy the brief and contact anyone else to whom they may have forwarded the brief. The next day, the two attorneys notified the Commission of the breach and requested that the Secretary remove the document from public view on EDIS. Over the course of the investigation, the two attorneys confirmed to the Commission that they had received responses (and confirmations of destruction) from all but two individual recipients of the brief. Those two individuals never acknowledged the attorneys' emails nor confirmed destruction of the brief.

In determining whether to issue a sanction for the breach, the Commission considered mitigating factors, including that: (1) the breach was inadvertent and unintentional; (2) the law firm promptly self-reported the breach to the Commission; (3) the law firm took prompt action to remedy the breach and prevent further dissemination of BPI; (4) the law firm implemented new procedures to prevent similar breaches in the future; and (5) neither attorney had previously breach an APO in the two-year period preceding the date of the breach. The Commission also considered the following aggravating factors: (1) unauthorized individuals had access to and presumably viewed the BPI; and (2) the law firm did not discover its own breach.

The Commission determined to issue private letters of reprimand to both attorneys.

Case 5. The Commission determined that an attorney and a paralegal at a law firm breached the APO in a title VII investigation when an economist at the firm accessed BPI materials that the law firm had received under the APO before the Secretary had approved the economist's APO application.

The attorney, who was lead counsel for the investigation, did not confirm that the Secretary had approved the economist's APO application before instructing the economist to access the BPI materials. The economist also failed to confirm that the Secretary had approved the APO application before accessing the BPI materials. The paralegal, who had set up the folder containing the BPI materials in the law firm's system, had failed to restrict access to the folder (in accordance with the firm's procedures) to only authorized individuals whose APO applications had been approved. Upon discovery that the Secretary had not yet approved the economist's APO application, the attorney immediately notified the Commission of the breach and restricted access to the folder containing the BPI materials to approved APO applicants. However, the economist had access to and viewed on several occasions the BPI at issue for approximately two weeks before authorized to do so. The law firm confirmed that the economist was the

only unauthorized individual to access the BPI materials.

In determining whether to issue a sanction for the breach, the Commission considered mitigating factors, including that: (1) the breach was inadvertent and unintentional; (2) the law firm took prompt action to remedy the breach and prevent further dissemination of BPI; (3) the firm immediately self-reported the breach to the Commission; (4) the law firm implemented new procedures to prevent similar breaches in the future; (5) the economist, who was later added to the APO, acted at all times as if bound by the APO, and thus no other unauthorized individuals viewed the BPI materials; and (6) the attorney and the paralegal had not previously breached an APO in the two-year period preceding the date of the breach. The Commission also considered the following aggravating factors: (1) the economist was not an authorized APO signatory at the time of the initial access and viewing of the BPI; and (2) the attorney, the paralegal, and the economist failed to follow the law firm's procedures for protecting BPI.

The Commission determined to issue warning letters to the attorney and the paralegal. The Commission also found that good cause existed to issue a warning letter to the economist under 19 CFR 201.15(a). Though the economist was not a signatory to the APO at the time of the inappropriate access to the BPI, the economist was, or should have been, aware of the requirements and limitations related to APO access. The economist's failure to verify that the Commission had accepted the APO application before using the BPI materials demonstrated a disregard for the Commission's rules protecting the confidentiality of the information that is provided under the APO.

Case 6. The Commission determined that 18 attorneys from one law firm breached the APO issued in a section 337 investigation when the law firm filed in EDIS a public version of a document that contained unredacted CBI in a footnote.

Two supervisory attorneys oversaw the redaction and filing of the public version of the document and 16 attorneys contributed to its review and redaction. Each attorney had the opportunity to discover the presence of the unredacted CBI in the footnote of the document during their respective review, but none did. The firm filed the document in EDIS and served it on the parties. One day later, one of the firm's attorneys, who had an opportunity to review the document before its filing, discovered that the footnote in question contained unredacted CBI. The firm notified the Commission that same day, after the document had been publicly posted to EDIS, and the firm filed a replacement document about a week later.

In determining whether to issue a sanction for the breach, the Commission considered the following mitigating factors: (1) the breach was inadvertent and unintentional; (2) the law firm took prompt action to remedy the breach and prevent further dissemination of CBI; (3) the law firm immediately self-reported the breach to the Commission; and (4) the law firm implemented new procedures to prevent similar breaches in the future. The Commission also considered the aggravating factor that unauthorized persons had access to and presumably viewed CBI.

The Commission issued warning letters to 16 attorneys whose actions contributed to the breach. The Commission also issued private letters of reprimand to the two supervisory attorneys who bore ultimate responsibility for overseeing the redaction and filing of the document at issue.

Case 7. The Commission determined that a supervisory attorney and an associate attorney breached the APO issued in a section 337 investigation when they exposed CBI from the investigation to their client.

The associate attorney, in reporting the work that the attorney had performed for the underlying investigation, noted details of that work in an internal electronic time entry system. The details included references to company names that one of the parties to the investigation considered to be CBI. The firm incorporated the associate attorney's entries from the time entry system into a billing invoice that it sent to its client. The supervisory attorney personally reviewed the billing invoice at issue and approved it for transmittal to the firm's client. Upon receipt of the billing invoice, the client contacted the firm to inquire about the entries that contained CBI, which caused the firm to discover its own breach. The firm requested that its client return the original invoice, and the client immediately did so. The firm notified the party whose CBI was exposed, and after conducting an internal investigation, the firm notified the Commission about two months later.

In determining whether to issue a sanction for the breach, the Commission considered the following mitigating factors: (1) the breach was inadvertent and unintentional; (2) the law firm self-reported the breach to the Commission; (3) the law firm took prompt action to remedy the breach and prevent further dissemination of CBI; (4) the attorneys had not previously breached an APO in the two-year period preceding the date of the breach; and (5) the law firm implemented new measures to prevent future similar breaches in the future. The Commission also considered the following aggravating factors: (1) unauthorized persons had access to and viewed CBI; and (2) the law firm waited nearly two months to notify the Commission of the breach.

The Commission issued a warning letter to the associate attorney whose actions contributed to, but did not directly cause, the breach. It issued a private letter of reprimand to the supervisory attorney.

Case 8. The Commission determined that 16 attorneys from one law firm breached the APO issued in a section 337 investigation when the law firm filed in EDIS 79 public demonstrative exhibits that contained unredacted CBI.

Fifteen attorneys were part of a team that was responsible for preparing and filing demonstrative exhibits following a hearing in the investigation. One senior attorney was responsible for supervising the team's effort. The breach occurred because when, in preparing the demonstrative exhibits for filing, the team failed to follow an instruction to place a ''-C'' designation after the exhibit number where the exhibits contained CBI. Because the team did not include the ''-C'' designation on the exhibits in question, the legal support staff who filed the exhibits in EDIS assumed that they were public and filed them on the public record. Over a year later, the law firm learned that opposing counsel in unrelated federal court litigation accessed the exhibits through EDIS. The law firm promptly notified the Commission and the affected parties whose CBI had been exposed, and the firm spent over 1,000 hours in its efforts to remediate the breach. Following the breach's discovery, the law firm changed its protocols for protecting CBI in section 337 investigations.

In determining whether to issue a sanction for the breach, the Commission considered the following mitigating factors: (1) the breach was inadvertent and unintentional; (2) the law firm discovered its own breach and promptly self-reported it to the Commission; (3) the law firm took prompt action to investigate and remedy the breach; (4) the attorneys had not previously breached an APO in the preceding two years; and (5) the law firm implemented new measures to prevent future similar breaches. The Commission also considered the following aggravating factors: (1) unauthorized persons had access to and viewed CBI; and (2) the

delay in the discovery of the breach left CBI publicly exposed for a period of about 15 months.

The Commission issued a private letter of reprimand to the supervisor of the team responsible for the preparation and filing of the exhibits at issue after finding that the attorney's supervision was inadequate and failed to secure the confidential treatment of the CBI in those exhibits. The Commission issued warning letters to 14 attorneys on the team who contributed to the preparation and filing of the exhibits. The Commission also issued a warning letter to one attorney who did not directly participate in the preparation and filing of the exhibits but permitted legal support staff to use, without supervision, the attorney's credentials to file the exhibits.

Case 9. The Commission found that an associate attorney breached the APO issued in a section 337 investigation when the attorney's actions exposed CBI obtained under the APO to the attorney's client.

The breach occurred when the attorney arranged for the client to access firm files stored on an electronic server by a discovery vendor. The attorney instructed the vendor to provide the client with limited access to certain file locations that stored only public files. However, the attorney did not verify that the vendor had followed the attorney's instructions before granting the client access to the firm's files. The vendor mistakenly granted the client unlimited access, and, as a result, the client inadvertently accessed 14 files containing CBI obtained under the APO. In accordance with the predetermined arrangement, the vendor terminated that client's unlimited access one day later. However, the attorney did not discover the breach until about 14 months later. The attorney reported the breach to the Commission a few days after making the discovery.

In determining whether to issue a sanction for the breach, the Commission considered the following mitigating factors: (1) the breach was inadvertent and unintentional; (2) the law firm discovered its own breach; (3) the law firm took prompt action to investigate and remedy the breach; (4) the attorney had not previously breached an APO in the two-year period preceding the date of the breach; and (5) the law firm self-reported its own breach to the Commission. The Commission also considered the following aggravating factors: (1) unauthorized persons had access to and viewed CBI; and (2) the law firm did not discover its own breach until about 14 months after it occurred. However, the Commission noted that because the client's access to the CBI-containing files was limited to one day, the CBI was not exposed to unauthorized individuals during those 14 months.

The Commission issued a private letter of reprimand to the associate attorney and found that, in the context of this matter, the attorney was obligated to take additional steps to ensure that the client was unable to access the files containing CBI.

Case 10. The Commission determined that an attorney and a paralegal at a law firm breached the APO in a title VII investigation when they publicly filed in EDIS a brief with BPI in recoverable hidden text.

While multiple attorneys reviewed the public version of the brief, the attorney and the paralegal were the only individuals who prepared and reviewed the final .pdf version of the document. Under firm procedures, the paralegal prepared the public version of the document by changing bracketed BPI to white font, converting the document from Microsoft Word to a .pdf file format, and then removing hidden information from the final .pdf file. Following the paralegal's preparation of the final document, the attorney reviewed the .pdf version of the document to ensure that all BPI had been removed from the file. The paralegal then publicly filed the document to EDIS. That same day, while preparing the document for service, another paralegal at the same firm noticed that the document contained BPI in recoverable hidden text. The attorney immediately notified the Commission of the breach and requested that the document be removed from public viewing. However, unauthorized individuals accessed and presumably viewed the brief while it was posted publicly to EDIS.

In determining whether to issue a sanction for the breach, the Commission considered mitigating factors, including that: (1) the breach was inadvertent and unintentional; (2) the law firm discovered its own breach; (3) the law firm took prompt action to remedy the breach and prevent further dissemination of BPI; (4) the law firm immediately self-reported the breach to the Commission; (5) the law firm implemented new procedures to prevent similar breaches in the future; and (6) neither the attorney nor the paralegal had previously breached an APO in the two-year period preceding the date of the breach. The Commission also considered the aggravating factor that unauthorized persons had access to and presumably viewed BPI.

The Commission determined to issue private letters of reprimand to both the attorney and the paralegal. The Commission also considered whether to find in breach other attorneys and legal support staff who reviewed the public version of the brief and approved the bracketing. However, the Commission declined to do so, determining that this breach occurred not because of bracketing issues, but because of a failure to remove properly bracketed BPI from the final .pdf file.

By order of the Commission.

Issued: November 14, 2022.

Jessica Mullan,

Attorney Advisor.

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INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1064 and 1066–1068 (Third Review)]

Frozen Warmwater Shrimp From China, India, Thailand, and Vietnam; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty orders on frozen warmwater shrimp from China, India, Thailand, and Vietnam would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: November 14, 2022.

FOR FURTHER INFORMATION CONTACT: Tyler Berard (202–205–3354) or Keysha Martinez (202–205–2136), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the

Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On August 5, 2022, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (87 FR 54260, September 2, 2022); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in these reviews will be placed in the nonpublic record on March 20, 2023, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with these reviews beginning at 9:30 a.m. on April 11, 2023. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before March 30, 2023. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the reviews, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing.

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on April 4, 2023, if held. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than 4 p.m. on April 10, 2023. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is March 29, 2023. Parties also shall file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is April 20, 2023. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before April 20, 2023. On May 18, 2023, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before May 22, 2023, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C.1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25177 Filed 11–17–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–682 and 731–TA–1592–1593 (Preliminary)]

Certain Freight Rail Couplers and Parts Thereof From China and Mexico

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain freight rail couplers and parts thereof from China and Mexico, provided for in subheadings 8607.30.10 and 7326.90.86 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On September 28, 2022, McConway & Torley LLC, Pittsburgh, Pennsylvania, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of freight rail couplers from China and LTFV imports of freight rail couplers from China and Mexico. Accordingly, effective September 28, 2022, the Commission instituted countervailing duty investigation no. 701–TA–682 and antidumping duty investigation nos. 731–TA–1592–1593 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 5, 2022 (87 FR 60413). The Commission conducted its conference on October 19, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on November 14, 2022. The views of the Commission are contained in USITC Publication 5387 (November 2022), entitled *Certain Freight Rail Couplers and Parts Thereof: Investigation Nos. 701–TA–682 and 731–TA–1592–1593 (Preliminary).*

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25178 Filed 11–17–22; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 87 FR 64440 and 87 FR 64444 (October 25, 2022).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1115]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Berkshire Roots, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 17, 2023.

ADDRESSES: The DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice

does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on October 17, 2022, Berkshire Roots, Inc., 501 Dalton Avenue, Pittsfield, Massachusetts 01201, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract.	7350	I
Marihuana	7360	I

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–25175 Filed 11–17–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–50]

Adley Dasilva, P.A.; Decision and Order

On August 18, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Adley Dasilva, P.A. (Respondent). OSC, at 1, 3. The OSC proposed the revocation of Respondent's Certificate of Registration No. MD4826915 at the registered address of 1941 Southeast Port Saint Lucie Boulevard, Port St. Lucie, Florida 34952. *Id.* at 1. The OSC alleged that Respondent's registration should be revoked because Respondent is ''without authority to handle controlled substances in the State of Florida, the state in which [he is] registered with DEA.'' *Id.* at 1–2 (citing 21 U.S.C. 824(a)(3)).

By letter dated September 2, 2022, Respondent requested a hearing. On September 15, 2022, the Government filed a Motion for Summary Disposition (Government's Motion), which Respondent opposed. On September 28, 2022, the ALJ granted the Government's Motion and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in Florida, the state in which he is registered with DEA, there is no genuine issue of material fact. Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD), at 4–5.

The Agency issues this Decision and Order based on the entire record before it and makes the following findings of fact.

Findings of Fact

On June 8, 2022, the Florida Department of Health issued an Order of Emergency Suspension of License which ordered the immediate suspension of Respondent's Florida P.A. license. Government's Motion Exhibit (GX) B, at 1, 33–34.

According to Florida's online records, of which the Agency takes official notice, Respondent's Florida P.A. license is currently under an ''emergency suspension'' status and Respondent is not authorized to practice medicine in Florida.[1] Florida Department of Health License Verification, *https://mqa-internet.doh.state.fl.us/MQASearch Services* (last visited date of signature of this Order). Accordingly, the Agency finds that Respondent is not currently licensed to engage in the practice of medicine in Florida, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71, 371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[2]

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[2] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617. Moreover, because ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration ''is currently authorized to handle controlled substances in the [S]tate,'' *Hooper,* 76 FR at 71,371 (quoting *Anne Lazar Thorn,* 62 FR 12,847, 12,848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy,* 72 FR 18,273, 18,274 (2007); *Wingfield Drugs,* 52 FR 27,070, 27,071 (1987). Thus, it is of no consequence that Respondent is still challenging the underlying action here. *See* Respondent's Response to Government's Motion; RD, at 4–5. What is consequential is the Agency's finding that Respondent is not currently authorized to dispense controlled substances in Florida, the state in which he is registered with the DEA.

According to Florida statute, ''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.'' Fla. Stat. 893.05(1)(a) (2022). Further, a ''practitioner'' as defined by Florida statute includes ''a physician assistant licensed under chapter 458 or 459.'' [3] *Id.* at 893.02(23).

Here, the undisputed evidence in the record is that Respondent is not currently a licensed practitioner in Florida, and a physician assistant must be a licensed practitioner to dispense a controlled substance in Florida. Thus, because Respondent lacks authority to handle controlled substances in Florida, Respondent is not eligible to maintain a DEA registration based in Florida. Accordingly, the Agency will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MD4826915 issued to Adley Dasilva, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Adley Dasilva, P.A., to renew or modify this registration, as well as any other pending application of Adley Dasilva, P.A., for additional registration in Florida. This Order is effective December 19, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 9, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25103 Filed 11–17–22; 8:45 am]

BILLING CODE 4410–09–P

[3] Chapter 458 regulates medical practice and applies to Respondent. GX B, at 2.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1096]

Bulk Manufacturer of Controlled Substances Application: Vici Health Sciences, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Vici Health Sciences, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 17, 2023. Such persons may also file a written request for a hearing on the application on or before January 17, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 5, 2022, Vici Health Sciences, LLC, 6655 Amberton Drive, Suite N, Elkridge, Maryland 21075, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Ibogaine	7260	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h).	9850	I

The company plans to bulk manufacture the listed controlled substances or their intermediates for sale to its customers. No other activities for these drug codes are authorized for this registration.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–25174 Filed 11–17–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On November 14, 2022, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Illinois in the lawsuit entitled *United States and the State of Illinois* v. *Prairie State Solar, LLC,* Civil Action No. 3:22–cv–02660.

In this case, the United States and the State seek to resolve claims against Defendant Prairie State Solar, LLC under the Clean Water Act. The United States and the State allege Prairie States violated its state stormwater permit during the construction of a large-scale solar farm in Perry County, Illinois. The proposed Consent Decree requires Prairie State to perform injunctive relief measures to ensure compliance until construction is complete and the stormwater permit is terminated. The Consent Decree also requires Prairie State to pay a civil penalty of $225,000, with $157,500 to the United States and $67,500 to the State of Illinois.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and The State of Illinois* v. *Prairie State Solar,* D.J. Ref. No. 90–5–1–1–12558/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.*

We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.50 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy exclusive of exhibits and signature pages, the cost is $10.00.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–25199 Filed 11–17–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On November 14, 2022, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Illinois in the lawsuit entitled *United States and the State of Illinois* v. *Big River Solar, LLC* Civil Action No. 3:22–cv–02659.

In this case, the United States and the State seek to resolve claims against Defendant Big River Solar, LLC, under the Clean Water Act. The United States and the State allege Big River violated of its state stormwater permit, during the construction of a large-scale solar farm in White County, Illinois. The proposed Consent Decree requires Big River to perform injunctive relief measures to ensure compliance until construction is complete and the stormwater permit is terminated. The Consent Decree also requires Big River to pay a civil penalty of $175,000, with $122,500 to the United States, and $52,500 to the State of Illinois.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States State of Illinois* v. *Big River Solar, LLC,* D.J. Ref. No. 90–5–1–1–12558. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $34.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy exclusive of exhibits and signature pages, the cost is $10.00.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–25187 Filed 11–17–22; 8:45 am]

BILLING CODE 4410–15–P

LEGAL SERVICES CORPORATION

Pro Bono Innovation Fund Process for Submitting Pre-Applications for 2023 Grants

AGENCY: Legal Services Corporation.

ACTION: Notice.

SUMMARY: The Legal Services Corporation (LSC) issues this Notice describing the conditions for submitting a Pre-Application for 2023 Pro Bono Innovation Fund grants.

DATES: Pre-applications must be submitted by 11:59 p.m. EST on Friday, January 27, 2023.

ADDRESSES: Letters of Intent must be submitted electronically at *http://lscgrants.lsc.gov.*

FOR FURTHER INFORMATION CONTACT: Mytrang Nguyen, Program Counsel, Office of Program Performance, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007; (202) 295–1564 or *nguyenm@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

Since 2014, Congress has provided an annual appropriation to LSC ''for a Pro Bono Innovation Fund.'' *See, e.g.,* Consolidated Appropriations Act, 2017, Public Law 115–31, 131 Stat. 135 (2017). LSC requested these funds for grants to ''develop, test, and replicate innovative pro bono efforts that can enable LSC grantees to expand clients' access to high quality legal assistance.'' LSC Budget Request, Fiscal Year 2014 at 26 (2013). The grants must involve innovations that are either ''new ideas'' or ''new applications of existing best practices.'' *Id.* Each grant would ''either serve as a model for other legal services providers to follow or effectively replicate a prior innovation. *Id.* The Senate Appropriations Committee explained that these funds ''will support innovative projects that promote and enhance pro bono initiatives throughout the Nation,'' and the House Appropriations Committee directed LSC ''to increase the involvement of private attorneys in the delivery of legal services to [LSC-eligible] clients.'' Senate Report 114–239 at 123 (2016), House Report 113–448 at 85 (2014).

Since its inception, the Pro Bono Innovation Fund has advanced LSC's goal of increasing the quantity and quality of legal services by funding projects that more efficiently and effectively involve pro bono volunteers in serving the critical unmet legal needs of LSC-eligible clients. In 2017, LSC built on these successes by creating three funding categories to better focus on innovations serving unmet and well-defined client needs (Project Grants), on building comprehensive and effective pro bono programs through new applications of existing best practices (Transformation Grants), and on providing continued development support for the most promising innovations (Sustainability Grants). In 2021, LSC created Non-Direct Service Project Grants to fund organizations to develop and implement innovative solutions to pro bono challenges that do not involve providing direct legal services to clients. In 2022, LSC created a new funding category to provide organizations with resources to plan and establish a strong foundation (Planning Grants). Planning Grants will be available on a pilot basis in the 2023 funding cycle to select organizations.

II. Funding Opportunities Information

A. Eligible Applicants

To be eligible for the Pro Bono Innovation Fund's Project, Sustainability, and Transformation grants, Applicants must be current grantees of LSC Basic Field-General, Basic Field-Migrant, or Basic Field-Native American grants. In addition, Sustainability Grant Applicants must

also be a current Pro Bono Innovation Fund grantee with a 2019 grant award.

B. Pro Bono Innovation Fund Purpose and Key Goals

Pro Bono Innovation Fund grants develop, test, and replicate innovative pro bono efforts that can enable LSC grantees to use pro bono volunteers to serve larger numbers of low-income clients and improve the quality and effectiveness of the services provided. The key goals of the Pro Bono Innovation Fund are to:

1. Address gaps in the delivery of legal services to low-income people;
2. Engage more lawyers and other volunteers in pro bono service;
3. Develop, test, and replicate innovative pro bono efforts.

C. Funding Categories

1. Planning Grants

In 2023, LSC is piloting a new grant category, called Planning Grants, to provide select organizations with the resources to assess their pro bono program and develop an action plan and proposal for a 2024 Pro Bono Innovation Fund Transformation grant. Planning Grants are one-time, six-month grants.

2. Project Grants

The goal of Pro Bono Innovation Fund Project Grants is to leverage volunteers to meet a critical, unmet and well-defined client need. Consistent with the key goals of the Pro Bono Innovation Fund, applicants are encouraged to focus on engaging volunteers to increase free civil legal aid for low-income Americans by proposing new, replicable ideas. The Pro Bono Innovation Fund has two Project Grant types, Direct Service and Non-Direct Service. Direct Service projects are focused on engaging volunteers to increase free legal assistance for eligible clients. Non-Direct Service projects propose to strengthen core aspects of pro bono delivery systems and may not result in direct pro bono client services within the grant timeframe (*i.e.,* develop a suite of substantive training materials, create on-demand videos for volunteers, etc.).

Applicants are strongly encouraged to research prior Pro Bono Innovation Fund projects to replicate and improve upon them. LSC is particularly interested in applications that propose to replicate projects LSC has previously funded with ''Sustainability'' Grants. Project Grants can be either 18 or 24 months.

3. Transformation Grants

The goal of Pro Bono Innovation Fund Transformation Grants is to support LSC grantees in comprehensive assessment and restructuring of pro bono programs through new applications of existing best practices in pro bono delivery. Each Transformation Grant will support a rigorous assessment of an LSC grantee's pro bono program and the identification of best practices in pro bono delivery that are best suited to that grantee's needs and circumstances. Transformation Grants are targeted towards LSC grantees whose leadership is committed to restructuring an entire pro bono program and incorporating pro bono best practices into core, high-priority client services with an urgency to create a high-impact pro bono program. This funding opportunity is open to all LSC grantees but is primarily intended for LSC grantees who have been unsuccessful applying for Project Grants or who have never applied for a Pro Bono Innovation Fund grant in the past. Transformation Grants can be either 24 or 36 months.

4. Sustainability Grants

Pro Bono Innovation Fund Sustainability Grants are available to current Pro Bono Innovation Fund grantees who received a 2021 Project grant. The goal of Sustainability Grants is to support further development of the most promising and replicable Pro Bono Innovation Fund projects with an additional 24 months of funding so grantees can leverage new sources of revenue for the project and collect meaningful data to demonstrate the project's results and outcomes for clients and volunteers. Applicants for Sustainability Grants will be asked to propose an ambitious strategy that reduces the Pro Bono Innovation Fund contribution to the project over the Sustainability Grant term.

D. Available Funds and Additional Consideration for 2021 Grants

The amount of funds available for Pro Bono Innovation Fund Grants for FY2023 depends on LSC's final appropriation. LSC currently operates under a Continuing Resolution for FY2023, which funds the Federal government through December 16, 2022. The Continuing Resolution maintains funding for the Pro Bono Innovation Fund at $4,750,000. LSC will make Pro Bono Innovation Fund grant decisions for FY2023 in the summer of 2023. LSC anticipates publicizing the total amount available for Pro Bono Innovation Fund grants when Congress enacts the FY2023 appropriation. LSC will not designate fixed or estimated amounts for the three different funding categories and will make grant awards for the three categories within the total amount of funding available.

E. Grant Terms

Pro Bono Innovation Fund awards can have grant terms of 6, 18, 24, or 36 months, depending on the category of grant.

	6 Months	12 Months	18 Months	24 Months	36 Months
Planning Grants	√	X	X	X	X
Project Grants	X	X	√	√	X
Transformation Grants	X	X	X	√	√
Sustainability Grants	X	X	X	√	X

Applicants invited to submit a Pre-Application for a pilot Planning Grant can apply for a 6-month grant. Applicants for Project Grants can apply for either an 18- or a 24-month grant. Applicants for Transformation Grants can apply for either a 24- or a 36-month grant. Applicants for Sustainability Grants can apply for a 24-month grant only. Applications must cover the full proposed grant term. The grant term is expected to commence on October 1, 2023.

III. Grant Application Process

A. Pro Bono Innovation Fund Grant Application Process

The Pro Bono Innovation Fund application process will be administered in LSC's unified grants management system, GrantEase. Applicants must first submit a Pre-Application to LSC in GrantEase by January 27, 2023 to be considered for a grant. After review by LSC Staff, LSC's President decides which applicants will be asked to submit a full application. Applicants will be notified of approval to submit a full application by early March 2023. Full applications are due to LSC in the GrantEase system on May 1, 2023. Once received, full applications will undergo a rigorous review by LSC staff and other subject matter experts. LSC's President makes the final decision on funding for the Pro Bono Innovation Fund.

B. Late or Incomplete Applications

LSC may consider a request to submit a Pre-Application after the deadline, but only if the Applicant has submitted an email to *probonoinnovation@lsc.gov* explaining the circumstances that caused the delay prior to the Pre-Application deadline. Communication with LSC staff, including assigned Program Liaisons, is not a substitute for sending a formal request and explanation to *probonoinnovation@lsc.gov.* At its discretion, LSC may consider incomplete applications. LSC will determine the admissibility of late or incomplete applications on a case-by-case basis.

C. Multiple Pre-Applications

Applicants may submit multiple Pre-applications under the same or different funding category. If applying for multiple grants, applicants should submit separate Pre-applications for each funding request.

D. Additional Information and Guidelines

Additional guidance and instructions on the Pro Bono Innovation Fund Pre-Application and Application processes, will be available and regularly updated at *https://www.lsc.gov/grants-grantee-resources/our-grant-programs/pro-bono-innovation-fund.*

Dated: November 15, 2022.

Stefanie Davis,

Senior Associate General Counsel.

[FR Doc. 2022–25198 Filed 11–17–22; 8:45 am]

BILLING CODE 7050–01–P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

Sunshine Act Meetings

TIME AND DATE: 9 a.m. to 12:30 p.m. (EST), Wednesday, December 7, 2022.

PLACE: The University of Arizona Washington, DC Center for Outreach and Collaboration, 1301 Pennsylvania Avenue NW, Suite 500, Washington, DC, 20004.

STATUS: This meeting will be open to the public. Members of the public who would like to attend this meeting may request remote access by contacting David Brown at *brown@udall.gov* prior to December 7, 2022, to obtain the teleconference connection information.

MATTERS TO BE CONSIDERED: (1) Call to Order and Chair's Remarks; (2) Trustee Remarks; (3) Executive Director's Remarks; (4) Consent Agenda Approval (Minutes of the April 27, 2022, Board of Trustees Meeting; Board Reports submitted for Data and Information Technology, Education Programs, Finance and Internal Controls, John S. McCain III National Center for Environmental Conflict Resolution, and Udall Center for Studies in Public Policy, including the Native Nations Institute for Leadership, Management, and Policy and The University of Arizona Libraries, Special Collections; and Board takes notice of any new and updated personnel policies and internal control methodologies); (5) The University of Arizona Fiscal Year 2023 Program Work Plan and Funding (including resolutions regarding Allocation of Funds to the Udall Center for Studies in Public Policy and The University of Arizona Libraries, Special Collections and Funds Set Aside for the Native Nations Institute for Leadership, Management, and Policy, a program of the Udall Center for Studies in Public Policy); (6) Udall Foundation Finances; and (7) Other Business (including Presentation of Trustees Awards for Outstanding Accomplishment).

CONTACT PERSON FOR MORE INFORMATION: David P. Brown, Executive Director, 130 South Scott Avenue, Tucson, AZ 85701, (520) 901–8560.

Dated: November 16, 2022.

David P. Brown,

Executive Director, Morris K. Udall and Stewart L. Udall Foundation, and Federal Register Liaison Officer.

[FR Doc. 2022–25327 Filed 11–16–22; 4:15 pm]

BILLING CODE 6820–FN–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Computer and Information Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

NAME AND COMMITTEE CODE: Advisory Committee for Computer and Information Science and Engineering (#1115).

DATE AND TIME: December 16, 2022; 11:00 a.m.–5:00 p.m. (Eastern).

PLACE: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Virtual meeting attendance only; to attend the virtual meeting, please send your request for the virtual meeting link to the following email: *cmessam@nsf.gov.*

TYPE OF MEETING: Open.

CONTACT PERSONS: KaJuana Mayberry, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: (703) 292–8900; email: *kmayberry@nsf.gov.*

PURPOSE OF MEETING: To provide advice, recommendations and counsel on major goals and policies pertaining to Computer and Information Science and Engineering programs and activities.

AGENDA:

- NSF and CISE update
- NSF investments in cybersecurity research
- Infrastructure for computing research

Dated: November 15, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–25215 Filed 11–17–22; 8:45 am]

BILLING CODE 7555–01–P

OFFICE OF PERSONNEL MANAGEMENT

Notice of Federal Long Term Care Insurance Program (FLTCIP)—Suspension of Applications for FLTCIP Coverage

AGENCY: Office of Personnel Management.

ACTION: Notice of Suspension of Applications for FLTCIP Coverage for Currently and Newly Eligible Individuals.

SUMMARY: The U.S. Office of Personnel Management (OPM) is announcing a suspension of applications for Federal Long Term Care Insurance Program (FLTCIP) coverage. During the

suspension period, no applications for FLTCIP coverage will be accepted, and current enrollees may not apply to increase their coverage. Eligible individuals who submit an application for FLTCIP to the program administrator, Long Term Care Partners, LLC, prior to the date that the suspension period begins, will have their application considered. If the Carrier approves the application for coverage, the individual will receive a benefit booklet and schedule of benefits with complete coverage information.

DATES: The suspension period will begin on December 19, 2022. The suspension period will remain in effect for 24 months from the date the suspension period begins.

FOR FURTHER INFORMATION CONTACT: You may call 1–800–LTC–FEDS (1–800–582–3337) (TTY: 1–800–843–3557) or visit *http://www.ltcfeds.com.* For purposes of this **Federal Register** notice only, the contact at OPM is Dyan Dyttmer, Senior Policy Analyst, at *dyan.dyttmer@opm.gov* or (202) 936–0152.

SUPPLEMENTARY INFORMATION: OPM is suspending applications for coverage in FLTCIP to allow OPM and the FLTCIP Carrier to assess the benefit offerings and establish sustainable premium rates that reasonably and equitably reflect the cost of the benefits provided, as required under 5 U.S.C. 9003(b)(2). OPM has issued regulations [CITE FINAL RULE] setting forth the process for suspension of applications in 5 CFR 875.110.

Authority: 5 U.S.C. 9008; Public Law 116–92, 133 Stat. 1198 (5 U.S.C. 8956 note); 5 CFR 875.110.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–24882 Filed 11–17–22; 8:45 am]

BILLING CODE 6325–63–P

OFFICE OF PERSONNEL MANAGEMENT

Chief Human Capital Officers (CHCO) Council; Virtual Public Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The Chief Human Capital Officers (CHCO) Council plans to meet on Tuesday, December 13, 2022. The meeting will start at 9 a.m. EST and will be held by Zoom.

FOR FURTHER INFORMATION CONTACT: CHCO Council email—*chcocouncil@opm.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for the CHCO Council to host their annual public meeting per Public Law 107–296.

The CHCO Council is the principal interagency forum to advise and coordinate the activities of the agencies of its members on such matters as modernization of human resources systems, improved quality of human resources information and legislation affecting human resources operations and organizations.

Persons desiring to attend this public meeting of the Chief Human Capital Officers Council should contact OPM at least 5 business days in advance of the meeting date at the email address shown below. Note: If you require an accommodation, please contact *chcocouncil@opm.gov* no later than December 6, 2022.

U.S. Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–25119 Filed 11–17–22; 8:45 am]

BILLING CODE 6325–46–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–43 and CP2023–43; MC2023–44 and CP2023–44]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 21, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–43 and CP2023–43; *Filing Title:* USPS Request to Add Priority Mail Contract 765 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 10, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* November 21, 2022.

2. *Docket No(s).:* MC2023–44 and CP2023–44; *Filing Title:* USPS Request

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 84 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 10, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Madison Lichtenstein; *Comments Due:* November 21, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–25090 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–45 and MC2023–46; Order No. 6328]

Competitive Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing recent Postal Service filings requesting the removal of Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rate Boxes (PMI RRB) Contracts from the competitive product list and a request for classification changes concerning Global Reseller Expedited Package Contracts. This notice informs the public of the filings, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 8, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Summary of Changes
III. Notice of Commission Action
IV. Ordering Paragraphs

I. Introduction

On November 10, 2022, pursuant to 39 U.S.C. 3642 and 39 CFR 3040.130 *et seq.,* the Postal Service filed a request to remove Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rate Boxes (PMI RRB) Contracts from the Competitive product list.[1] To support this request, the Postal Service filed a copy of the Governors' Decision No. 19–1, an application for nonpublic treatment of the Governors' Decision, a Statement of Supporting Justification in accordance with 39 CFR 3040.132, and proposed changes to the Mail Classification Schedule (MCS). *See* Priority Mail International Regional Rate Boxes Request, Attachments A–D.

Also on November 10, 2022, pursuant to 39 CFR 3040.180 *et seq.,* the Postal Service filed a request for classification changes concerning Global Reseller Expedited Package Contracts.[2] To support this request, the Postal Service filed a copy of the Governors' Decision No. 19–1, an application for nonpublic treatment of the Governors' Decision, and proposed changes to the MCS. *See* Competitive Classification Change Request, Attachments 1–3.

II. Summary of Changes

The Postal Service requests to remove MCS subsection 2510.9 Priority Mail International Regional Rate Boxes—Non-Published Rates and MCS subsection 2510.11 PMI RRB Contracts from the Competitive product list, effective January 22, 2023. *See* Priority Mail International Regional Rate Boxes Request at 1. The Postal Service states that the removal of these MCS subsections conforms with the elimination of Priority Mail Regional Rate Boxes set forth in Governors' Decision No. 22–6, which was included in the Postal Service's Notice of Changes in Rates and Classifications of General Applicability for Competitive Products.[3] The Postal Service asserts the proposed removal satisfies the criteria in 39 CFR 3040.132. Priority Mail International Regional Rate Boxes Request at 3.

The Postal Service also requests to remove all references to PMI RRB from MCS subsection 2510.7 Global Reseller Expedited Package Contracts, effective January 22, 2023. Competitive Classification Change Request at 1–2. The Postal Service states that the proposed removal conforms with the elimination of Priority Mail Regional Rate Boxes set forth in Governors' Decision No. 22–6, which was included in the Postal Service's Notice of Changes in Rates and Classifications of General Applicability for Competitive Products. *Id.* at 1. The Postal Service asserts that the proposed removal will not result in the violation of any of standards in 39 U.S.C. 3633 and 39 CFR part 3035, because ''there are no Global Reseller Expedited Contracts currently in effect that include prices for Priority Mail International Regional Rate Boxes.'' *Id.* at 3. The Postal Service also asserts that the proposed removal will not significantly change the user experience with Global Reseller Expedited Package Contracts and will not significantly impact competitors. *Id.* at 3–4. The Postal Service further asserts that the proposed removal will improve the accuracy of the information in MCS subsection 2510.7. *Id.* at 4.

III. Notice of Commission Actions

The Commission establishes Docket No. MC2023–45 to consider matters raised by the Priority Mail International Regional Rate Boxes Request and Docket No. MC2023–46 to consider matters raised by the Competitive Classification Change Request. *See* 39 CFR 3040.133. The instant dockets involve related issues pertaining to product removal. Accordingly, the Commission will consolidate them. *See* 39 CFR 3010.104.

Pursuant to 39 CFR 3040.133 and 3040.182, the Commission has posted the Priority Mail International Regional Rate Boxes Request and the Competitive Classification Change Request on its website, respectively. The Commission invites comments on the Priority Mail International Regional Rate Boxes Request and the Competitive Classification Change Request. Comments are due no later than December 8, 2022. The filings can be accessed via the Commission's website (*http://www.prc.gov*).

The Commission appoints R. Tim Boone to represent the interests of the general public (Public Representative) in these dockets.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. MC2023–45 to consider matters raised by the Priority Mail International Regional Rate Boxes Request.

[1] Docket No. MC2023–45, Request of the United States Postal Service to Remove Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rate Boxes (PMI RRB) Contracts from the Competitive Product List, November 10, 2022 (Priority Mail International Regional Rate Boxes Request).

[2] Docket No. MC2023–46, Request of the United States Postal Service for Classification Changes Concerning Global Reseller Expedited Package Contracts and Notice of Filing Materials Under Seal, November 10, 2022 (Competitive Classification Change Request).

[3] *Id.* at 1–2 (citing Docket No. CP2023–42, USPS Notice of Changes in Rates and Classifications of General Applicability for Competitive Products, November 10, 2022 (Notice of Changes in Rates and Classifications of General Applicability for Competitive Products)). Docket No. CP2023–42 is pending before the Commission.

2. The Commission establishes Docket No. MC2023–46 to consider matters raised by the Competitive Classification Change Request.

3. The Commission consolidates Docket Nos. MC2023–45 and MC2023–46.

4. Comments by interested persons are due by December 8, 2022.

5. Pursuant to 39 U.S.C. 505, R. Tim Boone is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

6. The Commission directs the Secretary of the Commission to arrange for prompt publication of this notice in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–25181 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2023–12; Order No. 6326]

Market Dominant Product List

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent Postal Service filing requesting to add USPS Connect Local Mail as a new, permanent product to the Mail Classification Schedule and the request's dismissal.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Commission Action
III. Ordering Paragraphs

I. Introduction

On October 11, 2022, the Postal Service filed a request with the Commission pursuant to 39 U.S.C. 3642 and 39 CFR 3045.18 to convert the experimental product offering USPS Connect Local Mail into a permanent product offering on the Mail Classification Schedule.[1] On October 17, 2022, the Commission dismissed the Request without prejudice, allowing the Postal Service to file an amended request if it so chose.[2]

On November 9, 2022, the Postal Service filed a revised request to convert USPS Connect Local Mail into a permanent offering, effective January 22, 2023.[3] In support of its Revised Request, the Postal Service filed the following documents:

- Attachment A—Proposed Changes to the Mail Classification Schedule;
- Attachment B—Market Test Quarterly Data Collection Reports;
- Attachment C—Resolution of the Governors of the United States Postal Service; and
- Attachment D—Statement of Supporting Justification

See Revised Request, Attachments A through D.

The USPS Connect Local Mail market test was initially authorized by the Commission on January 4, 2022.[4] It is currently set to expire on January 8, 2024. Order No. 6080 at 20. USPS Connect Local Mail is a derivative of First-Class Mail that functions as an alternative to long-distance, end-to-end mailing for use by business mailers who wish to send mail locally with regular frequency. Order No. 6080 at 2. The Postal Service asserts that the USPS Connect Local Mail market test has proven successful and that it now wishes to insert the USPS Connect Local Mail product offering into the Mail Classification Schedule under section 1115 (Market Dominant Products: First-Class Mail: First-Class Mail Flats). Revised Request at 2. The Postal Service maintains that the USPS Connect Local Mail product meets all the conditions in 39 U.S.C. 3642 and 39 CFR 3045.18 for adding a non-experimental product based on an experimental product to the product list. *Id.* at 3–6. The Postal Service also, as required by 39 CFR 3045.18(e), filed a separate notice of the instant request in Docket No. MT2022–1.[5] The planned rate for USPS Connect Local Mail is $2.95. Revised Request at 2–3.

II. Commission Action

The Commission reopens Docket No. MC2023–12 to consider the Postal Service's Revised Request. Interested persons may submit comments on whether the Request is consistent with the policies of 39 U.S.C. 3642, 39 CFR 3045.18, and 39 CFR 3040.130 through .135. Comments are due by December 9, 2022.

The Request and related filings are available on the Commission's website (*http://www.prc.gov*). The Commission encourages interested persons to review the Request for further details.

The Commission appoints Mallory L. Smith to serve as Public Representative in this proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. MC2023–12 for consideration of the United States Postal Service Revised Request to Convert USPS Connect Local Mail to a Permanent Offering, filed November 9, 2022.

2. Pursuant to 39 U.S.C. 505, Mallory L. Smith is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments by interested persons are due by December 9, 2022.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–25115 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2023–42; Order No. 6327]

Competitive Price Changes

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recently filed Postal Service document with the Commission concerning changes in rates and classifications of general applicability for competitive products. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 2, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

[1] United States Postal Service Request to Convert USPS Connect Local Mail to a Permanent Offering, October 11, 2022 (Request).

[2] Order Dismissing Without Prejudice Postal Service's Request to Convert USPS Connect Local Mail Market Test to a Permanent Offering, October 17, 2022, at 5–6 (Order No. 6301).

[3] United States Postal Service Revised Request to Convert USPS Connect Local Mail to a Permanent Offering, November 9, 2022 (Revised Request).

[4] Docket No. MT2022–1, Order Authorizing Market Test of Experimental Product—USPS Connect Local Mail, January 4, 2022 (Order No. 6080).

[5] Docket No. MT2022–1, United States Postal Service Notice of Revised Request to Convert USPS Connect Local Mail to a Permanent Offering, November 9, 2022.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction and Overview
II. Initial Administrative Actions
III. Ordering Paragraphs

I. Introduction and Overview

On November 10, 2022, the Postal Service filed notice with the Commission concerning changes in rates and classifications of general applicability for Competitive products.[1] The Postal Service represents that, as required by 39 CFR 3035.102(b) and 39 CFR 3035.104(b), the Notice includes an explanation and justification for the changes, the effective date, and a schedule of the changed rates. *See* Notice at 1–2. The changes are scheduled to take effect on January 22, 2023. *Id.* at 1.

Attached to the Notice is Governors' Decision No. 22–6, which states the new prices are in accordance with 39 U.S.C. 3632 and 3633 and 39 CFR 3035.102.[2] The Governors' Decision provides an analysis of the Competitive products' price and classification changes intended to demonstrate that the changes comply with 39 U.S.C. 3633 and 39 CFR part 3035. Governors' Decision No. 22–6 at 1. The attachment to the Governors' Decision sets forth the classification and price changes and includes draft Mail Classification Schedule language for Competitive products of general applicability.

The Notice also includes an application for non-public treatment of the attributable costs, contribution, and cost coverage data in the unredacted version of the annex to the Governors' Decision, as well as the supporting materials for the data. Notice at 1–2.

Planned price and classification changes. The Governors' Decision includes an overview of the Postal Service's planned price changes which are summarized in the table below.

TABLE I–1—PROPOSED PRICE CHANGES

Product name	Average price increase (percent)
Domestic Competitive Products	
Priority Mail Express	6.6
Retail	6.7
Commercial	6.0
Priority Mail	5.5
Retail	6.8
Commercial	3.6
Parcel Select	5.1
Destination-Entered non-Lightweight	5.1
Destination Delivery Unit	5.6
Destination Sectional Center Facility	4.7
Destination Network Distribution Center	5.0
Lightweight	6.1
Ground[3]	0.0
First-Class Package Service[4]	7.8
Retail	6.9
Commercial	8.0
Retail Ground[5]	6.4
Domestic Extra Services	
Premium Forwarding Service	6.5
Adult Signature Service	
Basic	6.5
Person-Specific	6.9
Competitive Post Office Box	6.5
Package Intercept Service	6.6
Pickup On Demand	6.0
Premium Data Retention and Retrieval Service	0.0
International Competitive Products	
Global Express Guaranteed	4.9
Priority Mail Express International	6.0
Priority Mail International	6.0
International Priority Airmail	3.5
International Surface Air Lift	12.0
Airmail M-Bags	6.4
First-Class Package International Service	6.5
International Ancillary Services and Special Services	
International Ancillary Services	12.2

Source: *See* Governors' Decision No. 22–6 at 2–5.

Further classification changes for Priority Mail, Parcel Select, and certain International Special Services are summarized as follows:

- Commercial Base and Commercial Plus categories of Priority Mail Express and Priority Mail will collapse into one price category labelled ''Commercial.''
- Priority Mail Regional Rate Boxes will be eliminated.
- For several Competitive products ''Zone L 1, 2'', will be split into new ''Zone 1'' and Zone 2 categories and the ''Local Zone'' will be eliminated.
- A new price category under the Competitive Ancillary Services product titled ''Label Delivery Service'' will be introduced.
- Prices for Priority Mail Express International items that are weight-rated and tendered at retail counters will no longer be eligible for the discounted Priority Mail International rate.
- Zones prices that differ by origin ZIP Code for Priority Mail International destined to Canada will be collapsed into a single country group, and the related fee for the International Service Center (ISC) zone chart for such pieces will be eliminated.

Notice at 2–6; Governors' Decision No. 22–6 at 2–5.

II. Initial Administrative Actions

The Commission establishes Docket No. CP2023–42 to consider the Postal Service's Notice. Interested persons may express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3035, and 39 CFR 3040 subparts B and E. Comments are due no later than December 2, 2022. For specific details of the planned price changes, interested persons are encouraged to review the Notice, which is available on the Commission's website at *www.prc.gov.*

Pursuant to 39 U.S.C. 505, Gregory S. Stanton is appointed to serve as Public Representative to represent the interests of the general public in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2023–42 to provide interested persons an opportunity to express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3035, and 39 CFR 3040 subparts B and E.

2. Comments are due no later than December 2, 2022.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Gregory S. Stanton to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–25118 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] USPS Notice of Changes in Rates and Classifications of General Applicability for Competitive Products, November 10, 2022 (Notice). Pursuant to 39 U.S.C. 3632(b)(2), the Postal Service is obligated to publish the Governors' Decision and record of proceedings in the **Federal Register** at least 30 days before the effective date of the new rates.

[2] Notice, Decision of the Governors of the United States Postal Service on Changes in Rates and Classification of General Applicability for Competitive Products (Governors' Decision No. 22–6), at 1 (Governors' Decision No. 22–6).

[3] The Postal Service notes that Parcel Select Ground is slated to be eliminated later in 2023.

[4] The Postal Service notes that First Class Package Service is slated to be expanded later in 2023.

[5] The Postal Service notes that USPS Retail Ground is slated for removal later in 2023.

POSTAL SERVICE

Change in Rates and Classes of General Applicability for Competitive Products

AGENCY: Postal Service™.

ACTION: Notice of a change in rates and classifications of general applicability for competitive products.

SUMMARY: This notice sets forth changes in rates and classifications of general applicability for competitive products.

DATES: *Effective date:* January 22, 2023.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: On November 9, 2022, pursuant to their authority under 39 U.S.C. 3632, the Governors of the Postal Service established prices and classification changes for competitive products. The Governors' Decision and the record of proceedings in connection with such decision are reprinted below in accordance with section 3632(b)(2). Mail Classification Schedule language containing the new prices and classification changes can be found at *www.prc.gov*.

Ruth Stevenson,

Chief Counsel, Ethics and Legal Compliance.

Decision of the Governors of the United States Postal Service on Changes in Rates and Classifications of General Applicability for Competitive Products (Governors' Decision No. 22–6)

November 9, 2022

Statement of Explanation and Justification

Pursuant to authority under section 3632 of title 39, as amended by the Postal Accountability and Enhancement Act of 2006 (''PAEA''), we establish prices and classifications of general applicability for the Postal Service's competitive products. The changes are described generally below, with a detailed description of the changes in the Postal Service's associated draft Mail Classification Schedule change document. That document contains the draft Mail Classification Schedule sections with classification changes in legislative format, and new prices displayed in the price charts.

As shown in the nonpublic annex being filed under seal herewith, the changes we establish should enable each competitive product to cover its attributable costs (39 U.S.C. 3633(a)(2)) and should result in competitive products as a whole complying with 39 U.S.C. 3633(a)(3), which, as implemented by 39 CFR 3035.107(c), requires competitive products collectively to contribute a minimum of 10.4 percent to the Postal Service's institutional costs. Accordingly, no issue of subsidization of competitive products by market dominant products should arise (39 U.S.C. 3633(a)(1)). We therefore find that the new prices and classification changes are in accordance with 39 U.S.C. 3632–3633 and 39 CFR 3035.102 and 104.

I. Domestic Products

A. Priority Mail Express

Overall, the Priority Mail Express price change represents a 6.6 percent increase. The Commercial Base and Commercial Plus price categories, which have had equivalent prices since 2016, will be consolidated into one Priority Mail Express Commercial price category for 2023. Also new for 2023, the zoned prices for the existing ''Local, 1, 2'' Zone will be differentiated. The Local zone will be eliminated, and separate prices will be established for Zone 1 and Zone 2. No other structural changes are proposed. Dimensional weighting, which was introduced for all zones in 2019, will continue in 2023.

Retail prices will increase an average of 6.7 percent. The price for the Retail Flat Rate Envelope, a significant portion of all Priority Mail Express volume, will increase to $28.75, with the Legal Size and Padded Flat Rate Envelopes priced at $28.95 and $29.45, respectively.

The newly consolidated Commercial price category will increase 6.0 percent on average. Commercial prices will, on average, reflect a 12.5 percent discount off of Retail prices. Nonstandard Fees (NSFs) are changing for our full network products for 2023. Priority Mail Express will see an increase in NSFs, while ground products will see a price decrease in NSFs.

B. Priority Mail

On average, the Priority Mail prices will be increased by 5.5 percent. Similar to Priority Mail Express, the Commercial Base and Commercial Plus price categories, which have had equivalent prices since 2019, will be consolidated into one Priority Mail Commercial price category for 2023. Dimensional weighting, which was extended to all zones in 2019, will continue in 2023. New for 2023, the Priority Mail Regional Rate Boxes will be eliminated because of low usage and to avoid product redundancies. Also new for 2023, the zoned prices for the existing ''Local, 1, 2'' Zone will be differentiated. The Local zone will be eliminated, and separate prices will be established for Zone 1 and Zone 2. No other structural changes are proposed.

Retail prices will increase by an average of 6.8 percent. Retail Flat Rate Box prices will be: Small, $10.20; Medium, $17.10; Large, $22.80 and Large APO/FPO/DPO, $21.20.

Thus, the Large APO/FPO/DPO Flat Rate Box will be $1.60 less than the Large Flat Rate Box. The regular Flat Rate Envelope will be priced at $9.65, with the Legal Size and Padded Flat Rate Envelopes priced at $9.95 and $10.40, respectively.

The newly consolidated Commercial price category will increase by 3.6 percent on average. Commercial prices will, on average, reflect a 20.1 percent discount off of Retail prices. Nonstandard Fees (NSFs) are changing for our full network products for 2023. Priority Mail will see an increase in NSFs, while ground products will see a price decrease in NSFs.

C. Parcel Select

On average, Parcel Select prices as a whole will increase 5.1 percent. Prices for destination-entered non-Lightweight Parcel Select, the Postal Service's bulk ground shipping product, will increase 5.1 percent on average. For destination delivery unit (DDU) entered parcels, the average price increase is 5.6 percent. For destination sectional center facility (DSCF) destination entered parcels, the average price increase is 4.7 percent. For destination network distribution center (DNDC) parcels, the average price increase is 5.0 percent. Prices for Parcel Select Lightweight will increase by 6.1 percent on average. Prices for USPS Connect Local, introduced in 2022, will remain unchanged for 2023. Finally, Parcel Select Ground, which is slated to be eliminated later in 2023, will see very minor price adjustments in certain cells, with a zero percent average change. Dimensional weighting, which was introduced for all zones in 2019, will continue in 2023.

New for 2023, the zoned prices for the existing ''Local, 1, 2'' Zone will be differentiated. The Local zone will be eliminated, and separate prices will be established for Zone 1 and Zone 2. No other structural changes are proposed. Nonstandard Fees (NSFs) are changing for our full network products for 2023. Ground products will see a price decrease in NSFs.

D. First-Class Package Service

First-Class Package Service (FCPS) is currently positioned as a lightweight (less than one pound) offering primarily used by businesses for fulfillment purposes. Later in 2023, the Postal Service plans to enhance and expand

the FCPS product up to seventy pounds, but for January 2023, FCPS will remain only a lightweight offering. Overall, FCPS prices will increase 7.8 percent on average, with a 6.9 percent increase for FCPS-Retail and a 8.0 percent increase for FCPS-Commercial. New for 2023, the zoned prices for the existing ''Local, 1, 2'' Zone will be differentiated. The Local zone will be eliminated, and separate prices will be established for Zone 1 and Zone 2. No other structural changes are proposed. Nonstandard Fees (NSFs) are changing for our full network products for 2023. Ground products will see a price decrease in NSFs.

F. USPS Retail Ground

USPS Retail Ground, which is also slated for removal later in 2023 as part of the Postal Service's expansion of FCPS and product simplification efforts, will remain on the competitive product list in January 2023. USPS Retail Ground prices will increase 6.4 percent overall on average. New for 2023, the zoned prices for the existing ''Local, 1, 2'' Zone will be differentiated. The Local zone will be eliminated, and separate prices will be established for Zone 1 and Zone 2. No other structural changes are proposed. Nonstandard Fees (NSFs) are changing for our full network products for 2023. Ground products will see a price decrease in NSFs.

G. Domestic Extra Services

Premium Forwarding Service (PFS) prices will increase 6.5 percent on average in 2023. The retail counter enrollment fee will increase to $25.45. The online enrollment option, introduced in 2014, will increase to $23.40. The weekly reshipment fee will increase to $25.45. PFS Local, which was introduced in 2019 for P.O. Box customers, will have an increased reshipment fee of $25.45. Prices for Adult Signature service will increase to $9.05 for the basic service and $9.35 for the person-specific service. Address Enhancement Service prices will remain the same for 2023. Competitive Post Office Box prices will be increasing 6.5 percent on average, within the existing price ranges. Package Intercept Service will increase to $17.00. The Pickup On Demand fee will increase to $26.50 for 2023. Premium Data Retention and Retrieval Service (USPS Tracking Plus), which was introduced in 2020, will not see a price change in 2023. New for 2023, the Postal Service is introducing a new Label Delivery Service under the Competitive Ancillary Services product, whereby residential and business customers can request return label delivery for a $1.25 fee for certain products.

II. International Products

A. Expedited Services

International expedited services include Global Express Guaranteed (GXG) and Priority Mail Express International (PMEI). Overall, GXG prices will rise by 4.9 percent, and PMEI will be subject to an overall 6.0 percent increase. Commercial Plus prices will be equivalent to Commercial Base.

B. Priority Mail International

The overall increase for Priority Mail International (PMI) will be 6.0 percent. Commercial Plus prices will be equivalent to Commercial Base. For Priority Mail Express International, weight-rated items tendered at retail counters will no longer be offered at prices equivalent to Priority Mail International for certain destinations and weight steps subject to certain requirements and conditions. The zoned prices based on origin ZIP Code for Priority Mail International destined to Canada will be collapsed into a single country group for Priority Mail International to Canada, and the related fee for the International Service Center (ISC) zone chart for Priority Mail International pieces destined to Canada will be eliminated.

C. International Priority Airmail and International Surface Air Lift

Published prices for International Priority Airmail (IPA) and International Surface Air Lift (ISAL) will increase by 3.5 percent and 12.0 percent, respectively.

D. Airmail M-Bags

The published prices for Airmail M-Bags will increase by 6.4 percent.

E. First-Class Package International ServiceTM

The overall increase for First-Class Package International Service (FCPIS) prices will be 6.5 percent. Commercial Plus prices will be equivalent to Commercial Base.

F. International Ancillary Services and Special Services

Prices for several international ancillary services will be increased, with an overall increase of 12.2 percent.

Order

The changes in prices and classes set forth herein shall be effective at 12:01 a.m. on January 22, 2023. We direct the Secretary to have this decision published in the **Federal Register** in accordance with 39 U.S.C. 3632(b)(2) and direct management to file with the Postal Regulatory Commission appropriate notice of these changes.

By The Governors:
/s/

Roman Martinez IV,
Chairman, Board of Governors.

UNITED STATES POSTAL SERVICE OFFICE OF THE BOARD OF GOVERNORS

CERTIFICATION OF GOVERNORS' VOTE ON GOVERNORS' DECISION NO. 22–6

Consistent with 39 U.S.C. 3632(a), I hereby certify that, on November 9, 2022, the Governors voted on adopting Governors' Decision No. 22–6, and that a majority of the Governors then holding office voted in favor of that Decision.

Date: November 9, 2022.
/s/

Michael J. Elston,
Secretary of the Board of Governors.

[FR Doc. 2022–25179 Filed 11–17–22; 8:45 am]

BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot; Extension of Comment Period

AGENCY: White House Office of Science and Technology Policy (OSTP).

ACTION: Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot; extension of comment period.

SUMMARY: On October 28, 2022, the Office of Science and Technology Policy (OSTP) published in the **Federal Register** a document entitled ''Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot.'' This RFI, issued by OSTP in partnership with the Office of the National Coordinator for Health Information Technology (ONC), invited comments on how to optimize data collection for clinical trials carried out across a range of institutions and sites, both in emergency settings and in the pre-emergency phase. OSTP and ONC are seeking input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common application programming interfaces (APIs). OSTP and ONC also seek information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for

example within 6–12 months of the close of comments on the RFI. In response to requests by prospective commenters that they would benefit from additional time to adequately consider and respond to the RFI, OSTP has determined that an extension of the comment period until January 27, 2023 is appropriate.

DATES: The end of the comment period for the document entitled ''Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot,'' published on October 28, 2022 (87 FR 65259), is extended from December 27, 2022 to January 27, 2023.

ADDRESSES: Comments submitted in response to 87 FR 65259 should be submitted electronically to *datacollectionforclinicaltrials@ostp.eop.gov* and should include ''Data Collection for Clinical Trials RFI'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions: Response to this RFI (87 FR 65259) is voluntary. Each responding entity (individual or organization) is requested to submit only one response. Please feel free to respond to one or as many prompts as you choose. Please be concise with your submissions, which must not exceed 10 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders, including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from health information technology (health IT) companies, app developers, clinical trial designers, and users of health IT products. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI (87 FR 65259). Please be aware that comments submitted in response to this RFI (87 FR 65259) may be posted on OSTP's website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Grail Sipes at 202–456–4444 or *datacollectionforclinicaltrials@ostp.eop.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies.[1] On October 28, 2022, OSTP, in partnership with ONC, published in the **Federal Register** a document inviting comments on how to optimize data collection for clinical trials carried out across a range of institutions and sites, both in emergency settings and in the pre-emergency phase (87 FR 65259). OSTP and ONC are seeking input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common APIs. OSTP and ONC also seek information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for example within 6–12 months of the close of comments on the RFI. The RFI was issued to seek input from a broad array of stakeholders on a range of topics related to data capture in the clinical trials context, including ways in which ONC standards and frameworks for interoperability might be leveraged to further the goals of the RFI. The document stated that the comment period would close on December 27, 2022. OSTP has received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the RFI and prepare comments to address the topics listed therein. Therefore, OSTP is extending the end of the comment period for the RFI from December 27, 2022 to January 27, 2023.

Submitted by the White House Office of Science and Technology Policy on November 15, 2022.

Stacy Murphy,

Operations Manager.

[FR Doc. 2022–25166 Filed 11–17–22; 8:45 am]

BILLING CODE 3270–F1–P

[1] *See* Notice of Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials, published October 26, 2022 (87 FR 64821).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–811, OMB Control No. 3235–0767]

Submission for OMB Review; Comment Request; Extension: Rule 204–5

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

The title for the collection of information is: ''Rule 204–5 under the Investment Advisers Act of 1940.'' Rule 204–5 requires an investment adviser to deliver an electronic or paper version of the relationship summary to each retail investor before or at the time the adviser enters into an investment advisory contract with the retail investor. The purpose of the relationship summary is to assist retail investors in making an informed choice when choosing an investment firm and professional, and type of account. Retail investors can use the information required in the relationship summary to determine whether to hire or retain an investment adviser, as well as what types of accounts and services are appropriate for their needs.

We estimate the total collection of information burden for rule 204–5 to be 1,137,413 annual aggregate hours per year, or 124 hours per respondent, for a total annual aggregate monetized cost of $77,344,061, or $8,402 per adviser.

The likely respondents to this information collection are approximately 9,205 investment advisers registered with the Commission that are required to deliver a relationship summary to retail investors pursuant to rule 204–5. We also note

that these figures include the 325 registered broker-dealers that are dually registered as investment advisers.

The requirements of this collection of information are mandatory. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by December 19, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25098 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96307; File No. SR–CboeBYX–2022–026]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

November 14, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 1, 2022, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or BYX) proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/byx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to clarify that fee code X[3] is applicable to certain routed orders that add or remove liquidity. The Exchange proposes to implement these changes effective November 1, 2022.

The Exchange proposes to clarify that fee code X is applicable to routed orders that add or remove liquidity. When certain fee codes were deleted from the Fee Schedule, the Exchange simultaneously proposed to update fee code X to make clear that it applies to all other routed orders that are not otherwise specified under other fee codes in the Fee Schedule.[4] However, the Exchange did not make clear in the fee code table that fee code X is therefore also applicable to orders that both add and remove liquidity.[5] Therefore, the Exchange is now proposing to add such language to the description of fee code X, eliminate the reference to ''Removing'' liquidity in the Standard Rates header for the Routing Liquidity column (which is applicable to fee code X), and make corresponding updates to footnote 8.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Exchange Act of 1934 (the ''Act''),[6] in general, and furthers the objectives of Section 6(b)(4),[7] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities.

The Exchange believes the proposal to modify fee code X to explicitly provide that it is applicable to routed orders that add and remove liquidity on the destination exchange is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Specifically, the proposal is intended only to make a clarifying change to the Fee Schedule and involves no substantive change.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes its proposal to clarify that fee code X is applicable to liquidity adding and removing orders will have no impact on competition as it involves no substantive change, but merely is a clarifying change to the existing Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and paragraph (f) of Rule 19b–4[9] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

[3] Fee code X is appended to routed orders.

[4] *See* Securities Exchange Act No. 90999 (January 27, 2021) 86 FR 7914 (February 2, 2021) (SR-CboeBYX–2021–003).

[5] Under the Transaction Fees section of the Fee Schedule, bullet four provides ''[u]nless otherwise noted, all routing fees or rebates in the Fee Codes and Associated Fees table are for removing liquidity from the destination venue.''

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f).

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBYX–2022–026 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBYX–2022–026. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBYX–2022–026 and should be submitted on or before December 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25089 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–793, OMB Control No. 3235–0738]

Submission for OMB Review; Comment Request; Extension: Rules 13n–4(b)(9), (b)(10) and (d)

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in rules 13n–4(b)(9), (b)(10) and (d) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rules 13n–4(b)(9), (b)(10) and (d) implement Exchange Act sections 13(n)(5)(G) and (H), which conditionally require security-based swap data repositories (SDRs) registered with the SEC to make security-based swap data available to certain regulators and other authorities. The rules in part would condition this access to data on the regulators and other authorities entering into memoranda of understanding or other arrangements with the Commission to address the confidentiality of the data made available. The rules further would require SDRs to create and maintain records regarding such data access. In addition, certain regulators or other authorities that are not otherwise designated by statute or rule may submit applications to the Commission requesting that they be deemed eligible to access the relevant security-based swap data.

Implementation of the statutory data access provisions—including the confidentiality condition and the Commission's authority to designate entities to access such information—will facilitate regulatory oversight of the security-based swap market and its participants, including oversight of systemic and other risks associated with the market. Implementation also will promote compliance with applicable laws and regulations, including but not limited to compliance with the antifraud provisions of the federal securities laws.

Commission Staff estimates that the total annual burden associated with Rules 13n–4(b)(9), (b)(10) and (d) is 11,405 hours and $120,000, calculated as follows:

Commission staff estimates a total of 50 regulators or other authorities will enter into confidentiality arrangements with the Commission to obtain access to security-based swap data pursuant to these provisions. On average, each of those recipients of data is expected to expend 500 hours in connection with negotiating these MOUs or other arrangements, for a one-time aggregate burden of 25,000 hours, with no associated ongoing burdens. This equates to 8,333 hours per year when annualized over three years.

Commission staff estimates that a total of 41 regulators or other authorities (that otherwise are not identified by statute or the rules as being eligible for access) may request that the Commission determine that they be able to access such security-based swap data. On average, each of those entities is expected to expend 40 hours in connection with such requests, for a one-time aggregate burden of 1,640 hours, with no associated ongoing burdens. This equates to 547 hours per year when annualized over three years.

Commission staff also estimates that a total of three SDRs may be expected to incur systems-related costs associated with setting up access to security-based swap data for regulators and other authorities. On average, each of those entities is expected to expend 1,300 hours in connection with providing such connectivity (based on each SDR incurring 26 hours per recipient, over 50 total recipients), for a one-time aggregate burden of 3,900 hours, with no associated no ongoing burdens associated with this requirement. This equates to 1,300 hours when annualized over three years.

In addition, Commission staff estimates that a total of three SDRs may incur costs associated with notifying the Commission when the SDR receives the first request for security-based swap data from a particular entity. On average, each of those SDRs is expected

[10] 17 CFR 200.30–3(a)(12).

to expend 25 hours in connection with this notice requirement (based on each SDR providing 50 notices, at half-hour per notice), for a one-time aggregate burden of 75 hours, with no associated ongoing burdens. This equates to 25 hours per year when annualized over three years.

Commission staff estimates that a total of three SDRs may incur costs associated with the requirement that they maintain records of all information related to initial and subsequent requests for data access. On average, compliance with this provision is expected to require 360 hours initially and 280 hours annually per SDR, for a total burden of 1,080 hours initially and 840 hours annually across three SDRs. This equates to 1,200 hours per year when annualized over three years. Commission staff further estimates that those SDRs each will require $40,000 annually in connection with that requirement, for a total cost of $120,000 annually across three SDRs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by December 19, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*''

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25100 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–506, OMB Control No. 3235–0564]

Submission for OMB Review; Comment Request; Extension: Rule 17a–6

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Section 17(a) of the Investment Company Act of 1940 (the ''Act'') generally prohibits affiliated persons of a registered investment company (''fund'') from borrowing money or other property from, or selling or buying securities or other property to or from, the fund or any company that the fund controls. Rule 17a–6 (17 CFR 270.17a–6) permits a fund, or a company controlled by the fund, and a ''portfolio affiliate'' of the fund (a company that is an affiliated person of the fund because the fund controls the company, or holds five percent or more of the company's outstanding voting securities) to engage in principal transactions that would otherwise be prohibited under section 17(a) of the Act under certain conditions. A fund may not rely on the exemption in the rule to enter into a principal transaction with a portfolio affiliate if certain prohibited participants (*e.g.,* directors, officers, employees, or investment advisers of the fund) have a financial interest in a party to the transaction. Rule 17a–6 specifies certain interests that are not ''financial interests,'' including any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material. A board making this finding is required to record the basis for the finding in its meeting minutes. This recordkeeping requirement is a collection of information under the Paperwork Reduction Act of 1995 (''PRA'').

The rule is designed to permit transactions between funds and their portfolio affiliates in circumstances in which it is unlikely that the affiliate would be in a position to take advantage of the fund. In determining whether a financial interest is ''material,'' the board of the fund should consider whether the nature and extent of the interest in the transaction is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement. The information collection requirements in rule 17a–6 are intended to ensure that Commission staff can review, in the course of its compliance and examination functions, the basis for a board of director's finding that the financial interest of an otherwise prohibited participant in a party to a transaction with a portfolio affiliate is not material.

Based on public filings made with the Commission, we estimate that annually 335 funds and their series (collectively, ''funds'') may rely on rule 17a–6 to engage in otherwise prohibited transactions under section 17(a) of the 1940 Act. This estimate is based on publicly available Form N–CEN filings. Solely for the purposes of this PRA extension, we assume that each of these funds has engaged in one transaction per reporting period that resulted in a paperwork burden pursuant to rule 17a–6. We estimate that compliance with the recordkeeping requirement for rule 17a–6 will impose a burden of .2 hours (12 minutes) for each transaction for which there is a paperwork burden. Therefore, we estimate 67 burden hours to be associated with rule 17a–6 recordkeeping requirements annually, with an associated internal cost of $5,762.

The estimate of burden hours and burden costs is made solely for the purposes of the PRA. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Complying with this collection of information requirement is necessary to obtain the benefit of relying on rule 17a–6. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by December 19, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25101 Filed 11–17–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96305; File No. SR–NYSEARCA–2022–75]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amend the NYSE Arca Equities Fees and Charges

November 14, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 1, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to adopt a new pricing tier, Retail Tier 2. The Exchange proposes to implement the fee changes effective November 1, 2022. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt a new pricing tier, Retail Tier 2. The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for ETP Holders to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the fee changes effective November 1, 2022.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [3]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [4] Indeed, equity trading is currently dispersed across 16 exchanges,[5] numerous alternative trading systems,[6] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly available information, no single exchange currently has more than 17% market share.[7] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange currently has less than 10% market share of executed volume of equities trading.[8]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm's reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which a firm routes order flow. The competition for Retail Orders [9] is even more stark, particularly as it relates to exchange versus off-exchange venues.

The Exchange thus needs to compete in the first instance with non-exchange venues for Retail Order flow, and with the 15 other exchange venues for that Retail Order flow that is not directed off-exchange. Accordingly, competitive forces compel the Exchange to use exchange transaction fees and credits, particularly as they relate to competing for Retail Order flow, because market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

To respond to this competitive environment, the Exchange has established a number of Retail Tiers, *e.g.,* Retail Tier 1, Retail Tier 2, Retail Tier 3 and Retail Step-Up Tier, which are designed to provide an incentive for ETP Holders to route Retail Orders to the Exchange by providing higher credits for adding liquidity correlated to an ETP Holder's higher trading volume in Retail Orders on the Exchange. Under three of these four tiers, ETP Holders also do not pay a fee when such Retail Orders have a time-in-force of Day that remove liquidity from the Exchange.

Proposed Rule Change

The proposed rule change is designed to be available to all ETP Holders on the Exchange and is intended to provide ETP Holders an opportunity to receive enhanced rebates by quoting and trading more on the Exchange.

The Exchange currently provides tiered credits for Retail Orders that provide liquidity on the Exchange. Specifically, Section VII. Tier Rates—Round Lots and Odd Lots (Per Share

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (''Regulation NMS'').

[4] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[5] *See* Cboe U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[6] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[7] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[8] *See id.*

[9] A Retail Order is an agency order that originates from a natural person and is submitted to the Exchange by an ETP Holder, provided that no change is made to the terms of the order to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. *See* Securities Exchange Act Release No. 67540 (July 30, 2012), 77 FR 46539 (August 3, 2012) (SR–NYSEArca–2012–77).

Price $1.00 or Above), provides a credit of $0.0038 per share for Adding under Retail Tier 1, a credit of $0.0036 per share for Adding under Retail Tier 2, a credit of $0.0034 per share for Adding under Retail Tier 3, and a credit of $0.0035 per share for Adding under Retail Step-Up Tier.[10] The Retail Tiers are designed to encourage ETP Holders that provide displayed liquidity in Retail Orders on the Exchange to increase that order flow, which would benefit all ETP Holders by providing greater execution opportunities on the Exchange. In order to provide an incentive for ETP Holders to direct providing displayed Retail Order flow to the Exchange, the credits increase in the various tiers based on increased levels of volume directed to the Exchange.

The Exchange proposes to adopt a new pricing tier, Retail Tier 2,[11] which would provide a credit of $0.0037 per share to ETP Holders that execute an ADV of Retail Orders with a time-in-force of Day that add or remove liquidity during the month that is equal to at least 0.35% of CADV. As with current Retail Tier 1, Retail Tier 2 and Retail Step-Up Tier, under the proposed Retail Tier 2, ETP Holders that qualify for proposed Retail Tier 2 would also not be charged a fee for Retail Orders with a time-in-force of Day that remove liquidity.[12]

With this proposed rule change, the following credits would be available to ETP Holders that provide increased levels of displayed liquidity in Retail Orders on the Exchange:

Tier	Credit for retail adding
Retail Tier 1	$0.0038 (Tape A, Tape B and Tape C).
Retail Tier 2	$0.0037 (Tape A, Tape B and Tape C).
Retail Tier 3	$0.0036 (Tape A, Tape B and Tape C).
Retail Tier 4	$0.0034 (Tape A, Tape B and Tape C).
Retail Step-Up Tier	$0.0035 (Tape A, Tape B and Tape C).

The purpose of the proposed rule change is to encourage greater participation from ETP Holders and promote additional liquidity in Retail Orders. As described above, ETP Holders with liquidity-providing orders have a choice of where to send those orders. The Exchange believes that the proposed new increased credit should encourage more ETP Holders to route their liquidity-providing Retail Order to the Exchange rather than to a competing exchange.

The Exchange does not know how much Retail Order flow ETP Holders choose to route to other exchanges or to off-exchange venues. While the proposed Retail Tier 2 pricing tier would be available to all ETP Holders, no ETP Holder currently qualifies given the pricing tier is new. Without having a view of ETP Holders' activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any ETP Holders sending more of their Retail Orders to the Exchange to qualify for the proposed Retail Order credit. The Exchange cannot predict with certainty how many ETP Holders would avail themselves of this opportunity, but additional liquidity-providing Retail Orders would benefit all market participants because it would provide greater execution opportunities on the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[14] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Fee Change Is Reasonable

As discussed above, the Exchange operates in a highly fragmented and competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15]

Given this competitive environment, the proposal represents a reasonable attempt to attract additional order flow to the Exchange.

As noted above, the competition for Retail Order flow is stark given the amount of retail limit orders that are routed to non-exchange venues. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. This competition is particularly acute for non-marketable, or limit, retail orders, *i.e.,* retail orders that can provide liquidity on an exchange. That competition is even more fierce for retail limit orders that provide *displayed* liquidity on an exchange. With respect to such orders, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees, particularly as they relate to competing for retail orders. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes the proposed change to adopt the Retail Tier 2 pricing tier is reasonable because it would provide ETP Holders with additional incentives to send a greater number of Retail Orders to the Exchange. The Exchange believes that the proposal represents a reasonable effort to provide enhanced order execution opportunities for ETP Holders. All ETP Holders would benefit from the greater amounts of liquidity on the Exchange, which would

[10] *See* Fee Schedule, Retail Tiers table under Section VII. Tier Rates—Round Lots and Odd Lots (Per Share Price $1.00 or Above).

[11] With this proposed rule change to adopt new Retail Tier 2, the Exchange proposes to rename current Retail Tier 2 to Retail Tier 3 and rename current Retail Tier 3 to Retail Tier 4.

[12] Pursuant to footnote (e) under Retail Tiers, ETP Holders that qualify for current Retail Tier 1, Retail Tier 2 and Retail Step-Up Tier are not charged a fee or provided a credit for Retail Orders where each side of the executed order (1) shares the same MPID and (2) is a Retail Order with a time-in-force of Day. *See* Fee Schedule. With the proposed renaming of current Retail Tier 2 to Retail Tier 3, the Exchange also proposes to add Retail Tier 3 to current footnote (e) to reflect its applicability to the renamed tier.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *See supra* note 3.

represent a wider range of execution opportunities. The Exchange notes that market participants are free to shift their order flow to competing venues if they believe other markets offer more favorable fees and credits.

The Exchange believes the proposed change is also reasonable because the increased credit proposed herein would continue to encourage ETP Holders to send Retail Orders to the Exchange to qualify for the proposed pricing tier. As noted above, the Exchange operates in a highly competitive environment, particularly for attracting Retail Order flow that provides displayed liquidity on an exchange. The Exchange believes it is reasonable to continue to provide credits for adding liquidity, in general, and higher credits for Retail Orders that provide displayed liquidity if an ETP Holder meets the requirement for the Retail Tiers.

Further, given the competitive market for attracting Retail Orders, the Exchange notes that with this proposed rule change, the Exchange's pricing for Retail Orders would be comparable to credits currently in place on other exchanges that the Exchange competes with for order flow. For example, Cboe EDGX Exchange, Inc. ('EDGX'') provides its members with a credit of $0.0037 per share for retail orders that add liquidity to that market if an EDGX member adds liquidity in Retail Orders of at least 0.45% of CADV.[16] Additionally, MIAX PEARL, LLC (''MIAX'') provides is member with a similar credit of $0.0037 per share for Retail Orders that add liquidity to that market.[17]

The Exchange believes the proposed change is also reasonable because it is designed to attract higher volumes of Retail Orders transacted on the Exchange by ETP Holders which would benefit all market participants by offering greater price discovery, increased transparency, and an increased opportunity to trade on the Exchange.

On the backdrop of the competitive environment in which the Exchange currently operates, the proposed rule change is a reasonable attempt to increase liquidity on the Exchange and improve the Exchange's market share relative to its competitors.

The Proposed Fee Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that the proposed rule change to adopt new Retail Tier 2 equitably allocates fees and credits among its market participants because it is reasonably related to the value of the Exchange's market quality associated with higher volume in Retail Orders. The Exchange believes that pricing is just one of the factors that ETP Holders consider when determining where to direct their order flow. Among other things, factors such as execution quality, fill rates, and volatility, are important and deterministic to ETP Holders in deciding where to send their order flow.

Further, the Exchange notes that, with this proposed rule change, the difference between the highest credit provided for Retail Orders, $0.0038 per share under Retail Tier 1, and the credit for Retail Orders that do not qualify for any Retail Order pricing tiers, $0.0032 per share, is $0.0006, or 15%, which the Exchange believes is relatively small given the heightened requirements that ETP Holders must meet to qualify for the higher credit. Similarly, with this proposed rule change, the difference in the highest credit for Retail Orders, $0.0038 per share under Retail Tier 1 and the credit provided for Retail Orders to those ETP Holders qualifying for proposed Retail Tier 2, $0.0037 per share, would only be $0.0001 per share, or less than 3%. Therefore, the Exchange believes the proposed new Retail Tier 2 pricing tier is equitably allocated and provides credits that are reasonably related to the value to the Exchange's market quality associated with higher volumes.

Finally, the Exchange believes that the proposed adoption of new Retail Tier 2 is equitable because the magnitude of the proposed credit is not unreasonably high relative to credits paid by other exchanges for orders that provide additional liquidity in Retail Orders.[18] The Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more Retail Orders to the Exchange, thereby improving market-wide quality and price discovery.

The Exchange believes that the proposed rule change equitably allocates its fees and credits because maintaining the proportion of Retail Orders in exchange-listed securities that are executed on a registered national securities exchange (rather than relying on certain available off-exchange execution methods) would contribute to investors' confidence in the fairness of their transactions and would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

The Proposed Fee Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory. In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Moreover, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly situated ETP Holders and all ETP Holders would be similarly subject to the proposed volume requirement to qualify for the proposed new Retail Tier 2. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by the proposed allocation of fees. The Exchange further believes that the proposed change would not permit unfair discrimination among ETP Holders because the general and tiered rates are available equally to all ETP Holders.

As described above, in today's competitive marketplace, order flow providers have a choice of where to direct liquidity-providing order flow, and the Exchange believes the proposed adoption of an increased credit under the proposed new pricing tier will incentivize greater number of ETP Holders to direct their order flow to the Exchange. Lastly, the submission of Retail Orders is optional for ETP Holders in that they could choose whether to submit Retail Orders and, if they do, the extent of its activity in this regard. The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange believes that the proposed rule change would not impose

[16] *See* EDGX Fee Schedule, Fee Codes and Associated Fees, at *https://markets.cboe.com/us/equities/membership/fee_schedule/edgx/*.

[17] *See* MIAX Fee Schedule, at *https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_09012022.pdf*.

[18] *See supra* notes 16–17.

[19] 15 U.S.C. 78f(b)(8).

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [20]

Intramarket Competition. The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed change applies to all ETP Holders equally in that all ETP Holders are eligible for the proposed pricing tier, have a reasonable opportunity to meet the proposed pricing tier's criteria and will all receive the proposed rebate if such criteria is met. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or its competitors. The proposed change is designed to attract additional order flow to the Exchange. The Exchange believes the proposed new pricing tier would continue to incentivize market participants to submit orders that qualify as Retail Order to the Exchange. Greater overall order flow, trading opportunities, and pricing transparency would benefit all market participants on the Exchange by enhancing market quality and would continue to encourage ETP Holders to send their orders to the Exchange, thereby contributing towards a robust and well-balanced market ecosystem. Additionally, the proposed rule change would apply to all ETP Holders equally in that all ETP Holders would be eligible for the proposed pricing tier, have a reasonable opportunity to meet the proposed pricing tier's criteria and would all receive the proposed credit if such criteria is met.

Intermarket Competition. The Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. As noted above, the Exchange's market share of intraday trading (*i.e.,* excluding auctions) is currently less than 10%. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe this proposed fee change would impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [23] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2022–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2022–75, and should be submitted on or before December 9, 2022.

[20] *See supra* note 3.

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b 4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25088 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96311; File No. SR–NASDAQ–2022–063]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Credits at Equity 7, Section 118(a)

November 15, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 4, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's schedule of credits at Equity 7, Section 118(a), as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's schedule of credits, at Equity 7, Section 118(a).[3] Specifically, with respect to its schedule of credits for non-displayed midpoint orders (other than Supplemental Orders) that provide liquidity, the Exchange proposes to add a new supplemental credit in Tapes A, B and C and make conforming changes to its schedule of credits.

The Exchange proposes to provide a new supplemental credit for midpoint orders (excluding buy (sell) orders with midpoint pegging that receive an execution price that is lower (higher) than the midpoint of the NBBO) that provide liquidity to the Exchange. Specifically, the Exchange proposes to provide a supplemental credit of $0.0001 per share executed for midpoint orders (excluding buy (sell) orders with midpoint pegging that receive an execution price that is lower (higher) than the midpoint of the NBBO) if the member executes at least 0.35% of Consolidated Volume through providing midpoint orders and through Midpoint Extended Life Orders (''M–ELO'') during the month, and (ii) executes at least 0.20% of Consolidated Volume through providing midpoint orders during the month.

The proposed credit will be in addition to other credits otherwise available to members for adding non-displayed liquidity to the Exchange, meaning that this supplemental credit is cumulative. Members that receive this new supplemental credit will be entitled to a combined credit (regular and supplemental) up to a maximum of $0.0028 per share executed for midpoint orders. Members that do not receive this new supplemental credit are entitled to a combined credit (regular and supplemental) up to a maximum of $0.0027 per share executed for midpoint orders.

The purpose of the new credit is to provide extra incentive to members that provide non-displayed liquidity to the Exchange to do so through midpoint orders. The Exchange believes that if such incentive is effective, then any ensuing increase in liquidity to the Exchange will improve market quality, to the benefit of all participants.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[5] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposal Is Reasonable

The Exchange's proposed changes to its schedule of credits are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .'' [6]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on November 1, 2022 (SR–NASDAQ–2022–062). The instant filing replaces SR–NASDAQ–2022–062, which was withdrawn on November 4, 2022.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4) and (5).

[6] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

broader forms that are most important to investors and listed companies.'' [7]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange believes it is reasonable to establish a supplemental credit of $0.0001 per share executed for midpoint orders (excluding buy (sell) orders with midpoint pegging that receive an execution price that is lower (higher) than the midpoint of the NBBO) if the member executes at least 0.35% of Consolidated Volume through providing midpoint orders and through M–ELO during the month, and (ii) executes at least 0.20% of Consolidated Volume through providing midpoint orders during the month. This proposal is reasonable because it will provide extra incentive to members that provide non-displayed liquidity to the Exchange to do so through midpoint orders. The Exchange believes that if such incentive is effective, then any ensuing increase in liquidity to the Exchange will improve market quality, to the benefit of all participants.

The Exchange believes that it is reasonable to exclude from the supplemental credit orders with midpoint pegging which execute at prices less aggressive than the midpoint of the NBBO because such orders already receive price improvements, such that members do not require additional inducements to enter these orders on the Exchange.

The Exchange notes that those market participants that are dissatisfied with the proposal are free to shift their order flow to competing venues that offer more generous pricing or less stringent qualifying criteria.

The Proposal Is an Equitable Allocation of Credits

The Exchange believes its proposal will allocate its charges and credits fairly among its market participants.

The Exchange believes that it is an equitable allocation to establish a new transaction credit because the proposal will encourage the addition of non-displayed liquidity to the Exchange through midpoint orders. To the extent that the Exchange succeeds in increasing the levels of liquidity and activity on the Exchange, then the Exchange will experience improvements in its market quality, which stands to benefit all market participants.

Any participant that is dissatisfied with the proposal is free to shift their order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that its proposal is not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it enhances price discovery and improves the overall quality of the equity markets.

The Exchange believes that its proposal to adopt a new credit is not unfairly discriminatory because the credit is available to all members. Moreover, the proposal stands to improve the overall market quality of the Exchange, to the benefit of all market participants, by incentivizing members to increase liquidity adding activity in midpoint orders on the Exchange. Any participant that is dissatisfied with the proposal is free to shift their order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that its proposal will place any category of Exchange participant at a competitive disadvantage.

As noted above, the Exchange's proposal to add a new transaction credit is intended to have market-improving effects, to the benefit of all members. Any member may elect to achieve the level of liquidity in midpoint orders and volume in M–ELO required in order to qualify for the new credit.

The Exchange notes that its members are free to trade on other venues to the extent they believe that the Exchange's fee schedule is not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes.

Intermarket Competition

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its credits and fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own credits and fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which credit or fee changes in this market may impose any burden on competition is extremely limited.

The proposed new credit is reflective of this competition because, as a threshold issue, the Exchange is a relatively small market so its ability to burden intermarket competition is limited. In this regard, even the largest U.S. equities exchange by volume only has 17–18% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. This is in

[7] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

addition to free flow of order flow to and among off-exchange venues which comprises more than 40% of industry volume in recent months.

The Exchange's proposal to add a new transaction credit is pro-competitive in that the Exchange intends for the credit to increase liquidity addition activity in midpoint orders on the Exchange, thereby rendering the Exchange a more attractive and vibrant venue to market participants.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2022–063 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2022–063. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–063 and should be submitted on or before December 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Sherry R. Haywood,

Assistant Secretary.

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[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–817, OMB Control No. 3235–0771]

Proposed Collection; Comment Request; Extension: Rule 3a71–3(d)

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 3a71–3(d), (17 CFR 240.3a71–3(d)), under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 3a71–3 under the Exchange Act provides in part that, for purposes of determining whether they can avail themselves of the *de minimis* exception to the ''security-based swap dealer'' definition, non-U.S. persons must count certain dealing transactions with non-U.S. counterparties that have been ''arranged, negotiated, or executed'' by personnel in the United States. Rule 3a71–3(d) provides an exception from that ''arranged, negotiated, or executed'' counting requirement.

The Commission estimates that up to 24 entities may seek to rely on the exception to the *de minimis* counting requirement of Rule 3a71–3. In connection with the conditions to the exception, each of those up to 24 entities would make use of an affiliated registered security-based swap dealer or registered broker. In general, the registered entity would be required to comply with the collections of information. Applications for ''listed jurisdiction'' status may be submitted by the up to 24 relying entities, but the staff believes that the greater portion of such applications will be submitted by foreign financial authorities.

The Commission estimates that the total annual time burden for Rule 3a71–3(d), for all respondents, is approximately 235,243 hours per year. In addition, the Commission estimates that the total annual cost burden for Rule 3a71–3(d), for all respondents, is approximately $1,242,595 per year. A detailed break-down of the burdens is provided in the supporting statement.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by January 17, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25096 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96306; File No. SR–MEMX–2022–30]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

November 14, 2022

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Excchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members [3] (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on November 1, 2022. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to: (i) modify the Liquidity Provision Tiers by adopting a new Liquidity Provision Tier 4 and modifying the required criteria under Liquidity Provision Tier 2; (ii) increase the fee and modify the required criteria under Liquidity Removal Tier 1; (iii) increase the fee for certain executions of Pegged Orders [4] with a Midpoint Peg [5] instruction (such orders, ''Midpoint Peg Orders'') and a time-in-force (''TIF'') instruction of IOC [6] or FOK [7] that execute at the midpoint of the national best bid and offer (''NBBO''); and (iv) modify the pricing for certain executions of orders in securities priced below $1.00 per share (such orders, ''Sub-Dollar Volume''), each as further described below.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading.[8] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 3.5% of the overall market share.[9] The Exchange in particular operates a ''Maker-Taker'' model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Liquidity Provision Tiers

The Exchange currently provides a standard rebate of $0.0020 per share for executions of orders in securities priced at or above $1.00 per share that add displayed liquidity to the Exchange (such orders, ''Added Displayed Volume''). The Exchange also currently offers Liquidity Provision Tiers 1–4 under which a Member may receive an enhanced rebate for executions of Added Displayed Volume by achieving the corresponding required volume criteria for each tier. The Exchange now proposes to adopt a new tier under the Liquidity Provision Tiers, which, as proposed, would be the new Liquidity Provision Tier 4, and the current Liquidity Provision Tier 4 would be renumbered as Liquidity Provision Tier 5 (hereinafter referred to as such). The rebate for executions of Added Displayed Volume and the required criteria under Liquidity Provision Tier 5 would remain unchanged.

Under the proposed new Liquidity Provision Tier 4, the Exchange would provide an enhanced rebate of $0.0028 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving one of the following two alternative criteria: (1)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 1.5(p).

[4] *See* Exchange Rule 11.6(h).

[5] *See* Exchange Rule 11.6(h)(2).

[6] *See* Exchange Rule 11.6(o)(1).

[7] *See* Exchange Rule 11.6(o)(3).

[8] Market share percentage calculated as of October 31, 2022. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[9] *Id.*

an ADAV [10] that is equal to or greater than 0.10% of the TCV; [11] or (2) a Displayed ADAV [12] (excluding Retail Orders) that is equal to or greater than 750,000 shares and a Step-Up Displayed ADAV [13] (excluding Retail Orders) from October 2022 that is equal to or greater than 30% of the Member's October 2022 Displayed ADAV (excluding Retail Orders).[14] The Exchange proposes to provide Members that qualify for the proposed new Liquidity Provision Tier 4 a rebate of 0.075% of the total dollar volume of the transaction for executions of orders in securities priced below $1.00 per share that add displayed liquidity to the Exchange, which is the same rebate that will be applicable to such executions for all Members after giving effect to the Sub-Dollar Volume pricing changes proposed below. The proposed new Liquidity Provision Tier 4 is designed to encourage Members to maintain or increase their order flow that adds liquidity, including in the form of displayed orders, to the Exchange in order to qualify for the proposed enhanced rebate for executions of Added Displayed Volume, thereby promoting price discovery and contributing to a deeper and more liquid market to the benefit of all market participants.

Currently, under Liquidity Provision Tier 2, the Exchange provides an enhanced rebate of $0.0032 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving an ADAV that is that is equal to or greater than 0.20% of the TCV. Now, the Exchange proposes to modify the required criteria such that a Member would now qualify for such tier by achieving one of the following two alternative criteria: (1) an ADAV that is equal to or greater than 0.20% of the TCV; or (2) an ADAV that is equal to or greater than 15,000,000 shares and a Step-Up ADAV from October 2022 that is equal to or greater than 0.10% of the Member's October 2022 ADAV. Thus, such proposed change would keep the existing criteria intact and add an alternative criteria that includes an overall ADAV threshold and a Step-Up ADAV threshold, which are designed to encourage the submission of additional order flow that adds liquidity to the Exchange. The Exchange notes that, as the proposed change to the required criteria under Liquidity Provision Tier 2 simply provides an alternative criteria and does not change the existing criteria, the Exchange believes that such change would make the tier easier for Members to achieve, and, in turn, while the Exchange has no way of predicting with certainty how the proposed new criteria will impact Member activity, the Exchange expects that more Members will strive to qualify for such tier than currently do, resulting in the submission of additional order flow to the Exchange. The Exchange is not proposing to change the rebate provided for executions of Added Displayed Volume under Liquidity Provision Tier 2.

Liquidity Removal Tier 1

The Exchange currently charges a standard fee of $0.0030 per share for executions of orders in securities priced at or above $1.00 per share that remove liquidity from the Exchange (such orders, ''Removed Volume''). The Exchange also currently offers Liquidity Removal Tier 1 under which qualifying Members are charged a discounted fee of $0.0029 per share for executions of Removed Volume by achieving one of the following two alternative criteria: (1) an ADV [15] that is equal to or greater than 0.45% of the TCV and an ADAV that is equal to or greater than 0.20% of the TCV; or (2) an ADV that is equal to or greater than 1.00% of the TCV.

Now, the Exchange proposes to increase the fee charged for executions of Removed Volume under Liquidity Removal Tier 1 to $0.00295 per share, and to modify the required criteria such that a Member would now qualify for such tier by achieving one of the following two alternative criteria: (1) an ADV that is equal to or greater than 0.50% of the TCV and a Remove ADAV [16] that is equal to or greater than 0.25% of the TCV; or (2) an ADV that is equal to or greater than 1.00% of the TCV.[17] Thus, the proposed change to the required criteria would increase the ADV threshold by 0.05% (*i.e.,* from 0.45% to 0.50%) of the TCV and replace the ADAV threshold with a Remove ADV threshold in the first of such alternative criteria, and it would keep the second of such alternative criteria intact without any change. The proposed changes to increase the ADV threshold and include a Remove ADV threshold in the first of such alternative criteria are designed to encourage Members to maintain or increase their order flow, including in the form of orders that remove liquidity, to the Exchange in order to qualify for the proposed discounted fee for executions of Removed Volume. While the Exchange's overall pricing philosophy generally encourages adding liquidity over removing liquidity, the Exchange believes that providing alternative criteria that are based on different types of volume that Members may choose to achieve, such as the proposed new criteria which includes a Remove ADV threshold, contributes to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members.

The purpose of increasing the fee charged for executions of Removed Volume under such tier as proposed (*i.e.,* by $0.00005 per share), which the Exchange believes is a modest increase and remains commensurate with the proposed new required criteria, is for business and competitive reasons, as the Exchange believes that increasing such

[10] As set forth on the Fee Schedule, ''ADAV'' means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis.

[11] As set forth on the Fee Schedule, ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[12] As set forth on the Fee Schedule, ''Displayed ADAV'' means ADAV with respect to displayed orders.

[13] As set forth on the Fee Schedule, ''Step-Up Displayed ADAV'' means Displayed ADAV in the relevant baseline month subtracted from current Displayed ADAV.

[14] The pricing for Liquidity Provision Tier 4 is referred to by the Exchange on the Fee Schedule under the description ''Added displayed volume, Liquidity Provision Tier 4'' with a Fee Code of ''B4'', ''D4'' or ''J4'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members. The Exchange notes that because the determination of whether a Member qualifies for a certain pricing tier for a particular month will not be made until after the month-end, the Exchange will provide the Fee Codes otherwise applicable to such transactions on the execution reports provided to Members during the month and will only designate the Fee Codes applicable to the achieved pricing tier on the monthly invoices, which are provided after such determination has been made, as the Exchange does for its tier-based pricing today. The Exchange also notes that the pricing for Liquidity Provision Tier 5 is referred to by the Exchange on the Fee Schedule under the description ''Added displayed volume, Liquidity Provision Tier 5'' with a Fee Code of ''B5'', ''D5'' or ''J5'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[15] As set forth on the Fee Schedule, ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day, which is calculated on a monthly basis.

[16] As set forth on the Fee Schedule, ''Remove ADV'' means ADV with respect to orders that remove liquidity.

[17] The pricing for Liquidity Removal Tier 1 is referred to by the Exchange on the Fee Schedule under the existing description ''Removed volume from MEMX Book, Liquidity Removal Tier 1'' with a Fee Code of ''R1'' to be provided by the Exchange on the monthly invoices provided to Members. The Exchange notes that because the determination of whether a Member qualifies for a certain pricing tier for a particular month will not be made until after the month-end, the Exchange will provide the Fee Codes otherwise applicable to such transactions on the execution reports provided to Members during the month and will only designate the Fee Codes applicable to the achieved pricing tier on the monthly invoices, which are provided after such determination has been made, as the Exchange does for its tier-based pricing today.

fee would generate additional revenue to offset some of the costs associated with the Exchange's current transaction pricing structure, which provides various rebates for liquidity-adding orders, and the Exchange's operations generally.

The Exchange notes that it is also proposing to change the fee charged under Liquidity Removal Tier 1 for executions of Removed Sub-Dollar Volume (as defined below), as further described below.

Midpoint Peg IOC/FOK Orders

As noted above, the Exchange currently charges a standard fee of $0.0030 per share for executions of Removed Volume. The Exchange also currently charges a discounted fee of $0.0026 per share for executions of Midpoint Peg Orders in securities priced at or above $1.00 per share with a TIF instruction of IOC or FOK that execute at the midpoint of the NBBO and remove liquidity from the Exchange upon entry (such orders, ''Midpoint Peg IOC/FOK Orders''). Charging a discounted fee for executions of Midpoint Peg IOC/FOK Orders is intended to incentivize the submission of such orders and, in turn, attract additional contra-side orders designed to execute at the midpoint to be posted on the Exchange, and is therefore designed to deepen liquidity and increase execution opportunities at the midpoint on the Exchange, thereby improving the Exchange's market quality to the benefit of all Members and enhancing its attractiveness as a trading venue.

Now, the Exchange proposes to increase the fee charged for executions of Midpoint Peg IOC/FOK Orders to $0.0027 per share.[18] The purpose of increasing the fee for executions of Midpoint Peg IOC/FOK Orders as proposed (*i.e.,* by $0.0001 per share), which the Exchange believes is a modest increase and remains commensurate with the market quality benefits that such discounted fee is intended to achieve, is for business and competitive reasons, as the Exchange believes that increasing such fee would generate additional revenue to offset some of the costs associated with the Exchange's current transaction pricing structure, which provides various rebates for liquidity-adding orders, and the Exchange's operations generally.

Pricing for Certain Sub-Dollar Volume

Currently, the Exchange charges a fee of 0.25% of the total dollar value of the transaction for executions of Sub-Dollar Volume that remove liquidity from the Exchange (such orders, ''Removed Sub-Dollar Volume''). This fee is applicable to all executions of Removed Sub-Dollar Volume (except Retail Orders with a TIF of Day, GTT or RHO that remove liquidity from the Exchange upon entry [19]) and is applicable to all Members (including those that qualify for any of the Exchange's volume tiers). Now, the Exchange proposes to increase the fee charged to all Members (including those that qualify for any of the Exchange's volume tiers) for all executions of Removed Sub-Dollar Volume (except Retail Orders with a TIF of Day, GTT or RHO that remove liquidity from the Exchange upon entry) to 0.28% of the total dollar value of the transaction. The purpose of increasing the fee for such executions of Removed Sub-Dollar Volume is for business and competitive reasons, as the Exchange believes that increasing such fee would generate additional revenue to offset some of the costs associated with the Exchange's current transaction pricing structure, which provides various rebates for liquidity-adding orders, and the Exchange's operations generally. The Exchange notes that despite the increase proposed herein, which the Exchange believes is modest, the proposed fee for such executions of Removed Sub-Dollar Volume (*i.e.,* 0.28% of the total dollar value of the transaction) remains lower than, and competitive with, the standard fee charged by other equity exchanges for executions of orders in securities priced below $1.00 per share that remove liquidity.[20]

Currently, the Exchange provides a rebate of 0.10% of the total dollar value of the transaction for executions of Sub-Dollar Volume that add displayed liquidity to the Exchange (such orders, ''Added Displayed Sub-Dollar Volume''). This fee is applicable to all executions of Added Displayed Sub-Dollar Volume and is applicable to all Members (including those that qualify for any of the Exchange's volume tiers). Now, the Exchange proposes to reduce the rebate provided to all Members (including those that qualify for any of the Exchange's volume tiers) for all executions of Added Displayed Sub-Dollar Volume to 0.075% of the total dollar value of the transaction. The purpose of reducing the rebate for executions of Added Displayed Sub-Dollar Volume is for business and competitive reasons, as the Exchange believes that reducing such rebate would decrease the Exchange's expenditures with respect to its transaction pricing in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging added displayed liquidity. The Exchange notes that despite the reduction proposed herein, which the Exchange believes is modest, the proposed rebate for executions of Added Displayed Sub-Dollar Volume (*i.e.,* 0.075% of the total dollar value of the transaction) remains higher than, and competitive with, the rebates offered by other equity exchanges for executions of orders in securities priced below $1.00 per share that add displayed liquidity.[21]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[22] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[23] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of

[18] The pricing for executions of Midpoint Peg IOC/FOK Orders is referred to by the Exchange on the Fee Schedule under the description ''Removed volume from MEMX Book, Midpoint Peg (IOC/FOK)'' with a Fee Code of ''Rm'' assigned by the Exchange.

[19] Such orders have different pricing that is referred to by the Exchange on the Fee Schedule under the description ''Removed volume from MEMX Book upon entry, Retail Order (Day/GTT/RHO)'' with a Fee Code of ''Rr0'' assigned by the Exchange.

[20] *See, e.g.,* the Cboe BZX Exchange, Inc. (''Cboe BZX'') equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*), which reflects a standard fee of 0.30% of the total dollar value of the transaction for executions of orders in securities priced below $1.00 per share that remove liquidity from Cboe BZX; the Cboe EDGX Exchange, Inc. (''Cboe EDGX'') equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*), which reflects a standard fee of 0.30% of the total dollar value of the transaction for executions of orders in securities priced below $1.00 per share that remove liquidity from Cboe EDGX.

[21] *See, e.g.,* the Cboe BZX equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*), which reflects that no rebate is provided (*i.e.,* a free execution) for executions of orders in securities priced below $1.00 per share that add displayed liquidity to Cboe BZX.

[22] 15 U.S.C. 78f.

[23] 15 U.S.C. 78f(b)(4) and (5).

the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [24]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to Added Displayed Volume, Removed Volume and Sub-Dollar Volume, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct additional order flow, including displayed, liquidity-adding and/or liquidity-removing orders, to the Exchange, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants. While the Exchange has proposed increasing its fees for certain executions of Removed Volume and Removed Sub-Dollar Volume, and reducing its rebate for executions of Added Displayed Sub-Dollar Volume, as further discussed below, the Exchange believes that each of such changes represents a modest increase (decrease) from the current fee (rebate) applicable to such executions.

The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes that the proposed new Liquidity Provision Tier 4, the Liquidity Provision Tier 2 as modified by the proposed change to the required criteria under such tier, and the Liquidity Removal Tier 1 as modified by the proposed changes to the fee for executions of Removed Volume and the required criteria under such tier, are reasonable, equitable and not unfairly discriminatory for these same reasons, as such tiers would provide Members with an incremental incentive to achieve certain volume thresholds on the Exchange, are available to all Members on an equal basis, and, as described above, are designed to encourage Members to maintain or increase their order flow, including in the form of displayed, liquidity-adding and/or liquidity removing orders, to the Exchange in order to qualify for an enhanced rebate for executions of Added Displayed Volume or a discounted fee for executions of Removed Volume, as applicable, thereby contributing to a deeper, more liquid and well balanced market ecosystem on the Exchange to the benefit of all Members and market participants. The Exchange also believes that such tiers reflect a reasonable and equitable allocation of fees and rebates, as the Exchange believes that the enhanced rebate for executions of Added Displayed Volume under the proposed new Liquidity Provision Tier 4 and the modified Liquidity Provision Tier 2, as well as the discounted fee for executions of Removed Volume under the modified Liquidity Removal Tier 1, each remains commensurate with the corresponding required criteria under each such tier and is reasonably related to the market quality benefits that each such tier is designed to achieve, as described above.

The Exchange also believes the proposed increased fee for executions of Midpoint Peg IOC/FOK Orders is reasonable, equitable and not unfairly discriminatory because the Exchange believes that the increase (*i.e.,* $0.0001 per share) is modest and that the fee remains commensurate with the market quality benefits that such discounted fee is intended to achieve, as described above, and such fee would continue to be charged uniformly to all executions of such orders for all Members.

Regarding the proposed changes to Sub-Dollar Volume pricing, the Exchange believes the proposed changes to increase the fee for executions of Removed Sub-Dollar Volume (except Retail Orders with a TIF of Day, GTT or RHO that remove liquidity from the Exchange upon entry) and reduce the rebate for executions of Added Displayed Sub-Dollar Volume are reasonable because, as described above, the Exchange believes that each of such changes represents a modest increase (decrease) from the current fee (rebate) applicable to such executions and that such changes would decrease the Exchange's expenditures and generate additional revenue, as applicable, with respect to its transaction pricing in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging added displayed liquidity. The Exchange also believes such proposed changes are reasonable, as the proposed fee for executions of Removed Sub-Dollar Volume (except Retail Orders with a TIF of Day, GTT or RHO that remove liquidity from the Exchange upon entry) and the proposed rebate for executions of Added Displayed Sub-Dollar Volume are competitive with the standard fees and rebates, as applicable, assessed for such executions on other equity exchanges.[25] Additionally, the Exchange believes that the proposed changes to these rates represent an equitable allocation of fees and are not unfairly discriminatory because such rates will continue to apply equally to all Members (including those that qualify for any of the Exchange's volume tiers) for all such executions.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act [26] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is

[24] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[25] *See supra* notes 20–21.

[26] 15 U.S.C. 78f(b)(4) and (5).

intended to incentivize market participants to direct additional order flow, including displayed, liquidity-adding and liquidity-removing orders, to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members and market participants, as well as to generate additional revenue and decrease the Exchange's expenditures with respect to its transaction pricing in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging added displayed liquidity. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [27]

Intramarket Competition

As discussed above, the Exchange believes that the proposal would incentivize Members to submit additional order flow, including displayed, liquidity-adding and liquidity-removing orders, to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for the proposed new Liquidity Provision Tier 4, and thus receive the proposed enhanced rebate for executions of Added Displayed Volume under such tier, would be available to all Members that meet the associated volume requirements in any month. Similarly, the opportunity to qualify for the proposed new alternative criteria under Liquidity Provision Tier 2 and the proposed modified criteria under Liquidity Removal Tier 1, and thus receive the enhanced rebate for executions of Added Displayed Volume or be charged the discounted fee for executions of Removed Volume, respectively, would continue to be available to all Members that meet the associated volume requirements in any month. Additionally, as described above, the Exchange believes that the proposed changes to the fee for executions of Midpoint Peg IOC/FOK Orders, the fee for executions of Removed Sub-Dollar Volume (except Retail Orders with a TIF of Day, GTT or RHO that remove liquidity from the Exchange upon entry) and the rebate for executions of Added Displayed Sub-Dollar Volume are modest, and such fees and rebate will continue to apply to all such executions for all Members as they do today. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Members have numerous alternative venues that they may participate on and direct their order flow to, including 15 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to Added Displayed Volume, Removed Volume and Sub-Dollar Volume, and market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes represent a competitive proposal through which the Exchange is seeking to decrease the Exchange's expenditures and generate additional revenue with respect to its transaction pricing and to encourage the submission of additional order flow to the Exchange through volume-based tiers, which have been widely adopted by exchanges, including the Exchange. Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [28] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *SEC,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[29] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section

[27] *See supra* note 24.

[28] *See supra* note 24.

[29] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

19(b)(3)(A)(ii) of the Act[30] and Rule 19b–4(f)(2)[31] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–30 and should be submitted on or before December 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25087 Filed 11–17–22; 8:45 am]

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[30] 15 U.S.C. 78s(b)(3)(A)(ii).

[31] 17 CFR 240.19b–4(f)(2).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–340, OMB Control No.3235–0375]

Proposed Collection; Comment Request; Extension: Schedule 13E–4F

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Schedule 13E–4F (17 CFR 240.13e–102) may be used by an issuer that is incorporated or organized under the laws of Canada to make a cash tender or exchange offer for the issuer's own securities if less than 40 percent of the class of such issuer's securities outstanding that are the subject of the tender offer is held by U.S. holders. The information collected must be filed with the Commission and is publicly available. We estimate that it takes approximately 2 hours per response to prepare Schedule 13E–4F and that the information is filed by approximately 3 respondents for a total annual reporting burden of 6 hours (2 hours per response × 3 responses).

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by January 17, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25105 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96321; File No. SR–NYSE–2022–51]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Initial and Annual Fees for Exchange Traded Products

November 15, 2022.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 7, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish initial and annual fees for the listing of Exchange Traded Products on the Exchange. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish initial and annual fees for the listing of Exchange Traded Products (''ETPs'') [4] on the Exchange by adopting a new Section 902.12 to the NYSE Listed Company Manual (the ''Manual'').

The proposed changes respond to the current extremely competitive environment for ETP listings in which issuers can readily favor competing venues or transfer their listings if they deem fee levels at a particular venue to be excessive, or discount opportunities available at other venues to be more favorable. The proposed changes are designed to establish a fee structure for the listing of ETPs on the Exchange that would incentivize issuers to list new products and transfer existing products as well as to maintain listings on the Exchange, which the Exchange believes will enhance competition both among issuers and listing venues, to the benefit of investors.

Proposed Rule Change

As proposed, new Section 902.12 of the Manual would set forth initial listing and annual listing fees for listed ETPs. Proposed Section 902.12 would be titled ''Listing Fees for Exchange Traded Products.'' [5] Under the proposed heading, the Exchange would include the following text (new text *italicized*):

> The Listing Fees and Annual Fees set out in this section apply to Exchange Traded Products as defined in NYSE Rule 1.1(l), which defines an ''Exchange Traded Product'' as a security that meets the definition of ''derivative securities product'' in Rule 19b–4(e) under the Securities and Exchange Act of 1934 (the ''Act'').

Below this proposed text, a new heading titled ''Initial Listing Fees'' would be followed by a chart beneath setting forth proposed initial listing fees of $20,000 (for up to and including 10 million shares), $30,000 (for over 10 million up to and including 20 million shares) or $40,000 (for over 20 million shares). As set forth in proposed footnote *, the Exchange would waive the initial listing fees for issuers that transfer their listings from any other national securities exchange. The proposed listing fee waiver would apply to all class of securities of an ETP.

Further, the Exchange proposes a technical original listing fee of $2,500 per application fixed charge, which may include multiple issues of securities. As explained in proposed footnote **, a Technical Original Listing would occur as a result of a change in state of incorporation, reincorporation under the laws of same state, reverse stock split, recapitalization, creation of a holding company or new company by operation of law or through an exchange offer, or similar events affecting the nature of a listed security. As further explained, the proposed fee would apply if the change in the company's status is technical in nature and the shareholders of the original company receive or retain a share-for-share interest in the new company without any change in their equity position or rights. The proposed fee and text is based on the technical original listing fee applicable to ETPs listed on the Exchange's affiliate NYSE Arca, Inc. (''NYSE Arca'').[6]

Finally, under a second new heading titled ''Annual Listing Fees,'' the Exchange proposes that ETPs would be charged annual listing fees at a rate of $0.001025 per share, with a minimum fee of $25,000. As set forth in proposed footnote ***, issuers transferring their listings from another national securities exchange would not be required to pay Annual Fees for the remainder of the calendar year in which the transfer occurs. The proposed waiver of Annual Fees would apply to all classes of securities.

The proposed fees for listed ETPs are the same as the fees currently applicable to listed Closed-End Funds set forth in Section 902.04 of the Manual.[7] Given the structural similarities between Closed-End Funds and ETPs, the Exchange believes that the anticipated costs associated with the listing and regulating ETPs, including costs related to issuer services, listing administration, product development and regulatory oversight, would be similar to Closed-End Funds. Given this correlation, the Exchange believes that applying the same fees to listed ETPs would be reasonable.

Each of the proposed changes described above are not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[8] in general, and furthers the objectives of section 6(b)(4) [9] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges. The Exchange also believes that the proposed rule change is consistent with section 6(b)(5) of the Act,[10] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the

[4] *See* NYSE Rule 1.1(l). As discussed below, proposed Section 902.12 would incorporate the definition of ETP so issuers can easily identify the class of securities that would be subject to the initial and annual listing fees.

[5] The Exchange also proposes a conforming change to Section 902.02 (General Information on Fees) to add ETPs to the list of securities therein.

[6] *See* NYSE Arca Schedule of Fees and Charges for Exchange Services, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Listing_Fee_Schedule.pdf.*

[7] Under Section 902.04, a Closed-End Fund is charged initial listing fees when it first lists a class of common stock according to a tiered schedule. Under this tiered schedule, a Closed-End Fund pays $20,000 (for up to and including 10 million shares), $30,000 (for over 10 million up to and including 20 million shares) or $40,000 (for over 20 million shares). Additionally, under Section 902.04, Closed-End Funds are subject to annual fees at a rate of $0.001025 per share, subject to a $25,000 minimum fee. In addition, a $2,500 fee applies to applications for changes that involve modifications to Exchange records, for example, changes of name, par value, title of security or designation.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f(b)(5).

mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange operates in a highly competitive marketplace for the listing of the various categories of securities, including the ETPs affected by the proposed fees. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS,[11] the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

The Exchange believes that the ever-shifting market share among the exchanges with respect to new listings and the transfer of existing listings between competitor exchanges demonstrates that issuers can choose different listing markets in response to fee changes. Accordingly, competitive forces constrain exchange listing fees. Stated otherwise, changes to exchange listing fees can have a direct effect on the ability of an exchange to compete for new listings and retain existing listings.

Given this competitive environment, the proposal represents a reasonable attempt to establish pricing for ETPs on the Exchange. As noted, ETPs are structurally similar to Closed-End Funds and the Exchange anticipates devoting substantially similar resources to the listing and regulation of ETPs. Therefore, the Exchange believes that it is reasonable and represents an equitable allocation of its fees among market participants to apply the same initial and annual fees to issuers of listed ETPs as the Exchange currently charges issuers of Closed-End Funds.

Further, the Exchange believes it is reasonable to not charge a listing fee upon listing and to not charge an annual fee for the remainder of the calendar year after an ETP transfers to the Exchange because such a transferring ETP would have already paid listing and/or annual listing fees to the predecessor national securities exchange and may incur multiple listing and/or annual fees in the same year in connection with a listing transfer, which may operate as a disincentive to transferring a listing to the Exchange that the issuer has determined is preferable based on the issuer's assessment of the Exchange's services, value and market quality. Due to the very limited anticipated loss of revenue associated with the proposed waiver, the Exchange does not expect the proposed fee waiver to affect its ability to devote the same level of resources to its oversight of its listed issuers that benefit from the waiver as it does for other issuers or, more generally, impact its resource commitment to its regulatory oversight of the listing process or its regulatory programs.

The Proposal is an Equitable Allocation of Fees

The Exchange believes its proposal equitably allocates its fees among its market participants. In the prevailing competitive environment, issuers can readily favor competing venues or transfer listings if they deem fee levels at a particular venue to be excessive, or discount opportunities available at other venues to be more favorable.

The proposed listing and annual fees for ETPs are equitable because the proposed increased annual fees would apply uniformly to all issuers. Moreover, the proposed fees would be equitably allocated among issuers because issuers would qualify for the listed fee based on issuing ETPs and for the annual fee based on the number of shares outstanding and under criteria applied uniformly to all such issuers. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The proposed annual fees would be applicable to all existing and potential ETP issuers uniformly and in equal measure.

In addition, the Exchange believes the proposed waiver of listing and annual fees for ETPs transferring from another national securities exchange represents an equitable allocation of fees because the proposed waivers would apply to all issuers that transfer ETP listings to the Exchange on an equal basis and would enable all issuers transferring ETPs from any other national securities exchange to benefit from the same waivers with respect to listing and/or annual fees for the specified time period. The Exchange believes that the proposed waivers would therefore equitably allocate fees among issuers transferring ETP listings to the Exchange.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, issuers are free to list elsewhere if they believe that alternative venues offer them better value.

The Exchange believes that the proposal is not unfairly discriminatory because the same fee schedule will apply to all issuers of ETPs listed on the Exchange.

In addition, Exchange Listed Products have substantial structural similarities to Closed-End Funds and the Exchange believes it is therefore it is not unfairly discriminatory to offer the same listing fees for ETPs as are currently applicable to Closed-End Fund products. Conversely, ETPs are not similar to any other class of securities listed on the Exchange, so the Exchange does not believe it is unfairly discriminatory to charge different fees for the listed ETPs than it does for any other class of listed securities other than Closed-End Funds.

In addition, the Exchange believes that the proposed waiver of listing and annual fees for ETPs transferring from another national securities exchange is not unfairly discriminatory because the proposed amendment would enable all issuers transferring ETPs from any other national securities exchange to benefit from the same waivers with respect to fees for the specified time period. The proposed waivers would apply to all issuers of securities that transfer ETP listings to the Exchange. Therefore, the Exchange believes there would be no unfair discrimination against issuers of securities transferring ETP listings to the Exchange. Further, the Exchange believes that the proposed waivers are not unfairly discriminatory with respect to issuers that are already listed on the Exchange because, as noted above, issuers transferring ETPs from other markets may already have paid listing and/or annual fees at their predecessor exchange and may incur multiple listing and/or annual fees in the same year in connection with a listing transfer, which may operate as a disincentive to transferring an ETP listing to the Exchange. As also noted, due to the very limited anticipated loss of revenue associated with the proposed waiver, the Exchange does not expect the proposed fee waiver to affect its ability to devote the same level of resources to its oversight of its listed issues that benefit from the waiver as it does for other issuers or, more generally, impact its resource commitment to its regulatory oversight of the listing process or its regulatory programs.

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[12] *See* Regulation NMS Adopting Release, 70 FR at 37499.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to ensure that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed companies. The market for listing services is extremely competitive. Each listing exchange has a different fee schedule that applies to issuers seeking to list securities on its exchange. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed fee changes impose a burden on competition.

Intramarket Competition

The proposed changes are designed to attract listings to the Exchange by establishing listing and annual fees for an ETPs listed under a new rule. The Exchange believes that the proposed changes would incentivize issuers to develop and list new products, transfer existing products to the Exchange, and maintain listings on the Exchange. The proposed fees would be available to all issuers, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition

The Exchange operates in a highly competitive market in which issuers can readily choose to list new securities on other exchanges and transfer listings to other exchanges if they deem fee levels at those other venues to be more favorable. Because competitors are free to modify their own fees in response, and because issuers may change their chosen listing venue, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition. As such, the proposal is a competitive proposal designed to enhance pricing competition among listing venues and implement pricing for ETPs to reflect the revenue and expenses associated with listing on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [14] of the Act and subparagraph (f)(2) of Rule 19b–4 [15] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B) [16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–51 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–51. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–51 and should be submitted on or before December 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25237 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–492, OMB Control No.3235–0549]

Proposed Collection; Comment Request; Extension: Rule 155

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information

[13] *See* 15 U.S.C. 78f(b)(8).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(2).

[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 155 (17 CFR 230.155) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) provides safe harbors for a registered offering of securities from integration in two circumstances: (1) a registered offering that follows an abandoned private offering; and (2) a private offering that follows a withdrawn registered offering. Each of the rule's safe harbors imposes conditions designed to assure that there is a clean break between the abandoned offering and the later offering. In each safe harbor, these conditions include specified disclosure designed to assure that investors understand this break as they consider an investment decision in the later offering. We estimate Rule 155 takes approximately 4 hours per response to prepare and is filed by approximately 600 respondents annually. We estimate that 50% of the 4 hours per response (2 hours per response) is prepared by the filer for a total annual reporting burden of 1,200 hours (2 hours per response × 600 responses).

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by January 17, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25226 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–814, OMB Control No. 3235–0764]

Submission for OMB Review; Comment Request; Extension: Rule 6c–11

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 6c–11 under the Investment Company Act of 1940 (the ''Act'') permits exchange-traded funds (''ETFs'') that satisfy certain conditions to operate without first obtaining an exemptive order from the Commission. The rule was designed to create a consistent, transparent, and efficient regulatory framework for ETFs and facilitate greater competition and innovation among ETFs. Rule 6c–11 requires an ETF to disclose certain information on its website, to maintain certain records, and to adopt and implement written policies and procedures governing its constructions of baskets, as well as written policies and procedures that set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders.

We estimate that the total hour burdens and time costs associated with rule 6c–11, including the burden associated with reviewing and updating website disclosures, recordkeeping, and reviewing and updating policies and procedures, will result in an average aggregate annual burden of 51,156 hours and an average aggregate time cost of $1,248,912.

The requirements of this collection of information are mandatory. If information collected pursuant to rule 6c–11 is reviewed by the Commission's examination staff, it will be accorded the same level of confidentiality accorded to other responses provided to the Commission in the context of its examination and oversight program.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by December 19, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25097 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34752; 812–15251]

Trinity Capital Inc.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 12(d)(3) of the Act.

SUMMARY OF APPLICATION: Applicant requests an order to permit a business development company (''BDC'') to organize, acquire, and wholly-own a portfolio company that intends to operate as an investment adviser registered under the Investment Advisers Act of 1940 (the ''Advisers Act'').

APPLICANT: Trinity Capital Inc. (the ''Company'' or ''Applicant'').

FILING DATES: The application was filed on August 5, 2021, and amended on August 5, 2022 and on November 7, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicant with a copy of the request, by email. Hearing requests should be received by the Commission by 5:30 p.m. on December 12, 2022 and should be accompanied by proof of service on the Applicant, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing

upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicant: Steven L. Brown, Chairman and Chief Executive Officer, Trinity Capital Inc. at*sbrown@trincapinvestment.com.*

FOR FURTHER INFORMATION CONTACT: Harry Eisenstein, Senior Special Counsel, or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended and restated application, dated November 7, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

Applicant's Representations:

1. The Company is a Maryland corporation that operates as an internally managed, closed-end, non-diversified management investment company. The Company has elected to be regulated as a BDC under the Act. The Company's investment objective is to generate current income and, to a lesser extent, capital appreciation through its investments. The Company seeks to achieve its investment objective by making investments consisting primarily of term loans and equipment financings and, to a lesser extent, working capital loans, equity and equity-related investments.

2. The Company intends to organize, acquire, and wholly own the securities of a portfolio company (''Adviser Sub''), which it expects to be formed as a limited liability company under the laws of the State of Delaware and will be a direct or an indirect wholly owned portfolio company of the Company.[1] As discussed below, the Adviser Sub intends to operate as an investment adviser registered with the Commission under the Advisers Act.[2] The Company expects the Adviser Sub to receive fees in connection with its management of one or more privately-offered pooled investment vehicles, registered management investment companies, BDCs, and/or investment accounts (collectively, ''Managed Accounts'') similar to those received by comparable investment advisers.

3. Those Managed Accounts that are not registered managed investment companies or BDCs (such Managed Accounts, ''Private Fund Managed Accounts'') may make equity investments in growth stage portfolio companies via participation rights. Participation rights will generally be negotiated by the Company at the time the Company makes a debt investment in, or enters into an equipment financing agreement with, a growth stage portfolio company. Managed Accounts other than Private Fund Managed Accounts would not participate in such investments.

4. The Company is, and the Adviser Sub will be, directly or indirectly overseen by the Company's six member Board of Directors (the ''Board''), of whom four are not considered ''interested persons'' of the Company within the meaning of section 2(a)(19) of the Act. In its capacity as the Board of the Advisers Sub's parent company, the Board will indirectly oversee the Adviser Sub.

5. The Company has elected to be treated for U.S. federal income tax purposes, and intends to qualify annually, as a regulated investment company (''RIC'') under Subchapter M of the Internal Revenue Code of 1986, as amended (the ''Code''). Applicant states that as a RIC, the Company generally will not pay corporate-level federal income taxes on any net ordinary income or capital gains that it distributes to its stockholders as dividends in accordance with the timing requirements of the Code. To maintain its RIC status, the Company must, among other things, meet specified source-of-income requirements. Applicant states that the Company will satisfy the source-of-income test for purposes of qualifying as a RIC if it derives in each taxable year at least 90% of its gross income from dividends, interest, payments with respect to certain securities loans, gains from the sale of stock or other securities or currencies, net income from certain ''qualified publicly traded partnerships'' (as defined in the Code) or other income derived with respect to its business of investing in such stock, securities or currencies (income from such sources, ''Good RIC Income'').

6. Applicant states that fee income received in connection with the provision of services to the Managed Accounts generally would not constitute Good RIC Income to the Company if it earned such income directly. Therefore, in order for the Company to maintain its RIC status while receiving the income from the provision of advisory services to the Managed Accounts, the Company believes that it is in the best interests of the Company and its shareholders for the Adviser Sub to provide advisory services to and to receive fees from the Managed Accounts instead of the Company providing such services and receiving such fees directly.

7. Under the Advisers Act, an investment adviser is generally required to be registered if it has $100 million or more of regulatory assets under management.[3] An investment adviser may also register under the Advisers Act in compliance with rule 203A–2(c)(1) of the Advisers Act if it expects to be eligible to register an as adviser within 120 days of registering.

Applicant states that the Adviser Sub will register as an investment adviser under the Advisers Act in compliance with rule 203A–2(c)(1) of the Advisers Act after the relief requested in the application is granted to the Company because the Adviser Sub expects to have $100 million or more of regulatory assets under management within 120 days of such registration.

Applicable Law:

1. Section 12(d)(3) makes it unlawful for any registered investment company, and any company controlled by a registered investment company, to acquire any interest in the business of a person who is either an investment adviser of an investment company or an investment adviser registered under the Advisers Act, unless (a) such person is a corporation all the outstanding securities of which are owned by one or more registered investment companies; and (b) such person is primarily engaged in the business of underwriting and distributing securities issued by other persons, selling securities issued

[1] Adviser Sub will be a wholly owned portfolio company of the Company and will also fall within the definition of ''wholly owned subsidiary'' for purposes of section 2(a)(43) of the Act.

[2] Adviser Sub has not yet been formed, but it does not intend to commence operations unless and until the relief requested in the application has been granted.

[3] In addition, an investment adviser to an investment company registered under the Act or to a company that has elected to be a BDC with $25 million or more of regulatory assets under management would also be required to register under the Advisers Act. Applicants state that the Adviser Sub also may act as an investment adviser to an investment company registered under the Act or to a company that has elected to be a BDC with $25 million or more of regulatory assets under management after the relief requested is granted.

by other persons, selling securities to customers, or any one or more of such or related activities, and the gross income of such person normally is derived principally from such business or related activities. Section 60 of the Act states that section 12 shall apply to a BDC to the same extent as if it were a registered closed-end investment company.

2. Section 6(c) of the Act provides that the Commission may exempt any person or transaction from any provision of the Act if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicant's Legal Analysis

1. Applicant represents that the Company will own 100% of the equity interests in the Adviser Sub. However, Applicant states that it is not expected that the Adviser Sub would also be a broker-dealer that is primarily engaged in the business of underwriting and distributing securities issued by other persons. The ownership of the Adviser Sub, at such point as it becomes registered as an investment adviser, could thus cause the Company to be in violation of the provisions of section 12(d)(3) unless the requested Order is issued.[4] In addition, the Company expects that after the relief requested in the application is granted the Adviser Sub will act as an investment adviser to investment companies. To the extent it does so, relief from section 12(d)(3) is also required because the Adviser Sub acting as an investment adviser of an investment company would result in the Company acquiring a security of an investment adviser of an investment company. Therefore, Applicant requests the Order pursuant to section 6(c) of the Act granting an exemption from the provisions of section 12(d)(3) of the Act, to the extent necessary in order to permit the Company to organize, acquire, and wholly own the securities of the Adviser Sub.

2. Applicant states that section 12(d)(3) was intended to: (a) limit the risk of a registered investment company's exposure to the entrepreneurial risks, or general liabilities, that are peculiar to securities-related businesses; and (b) prevent potential conflicts of interest and reciprocal practices between investment companies and securities-related businesses. Applicant submits that the Company's ownership and control of the Adviser Sub does not present the concerns against which section 12(d)(3) was intended to safeguard.

3. Applicant states that much of the concern regarding entrepreneurial risks stemmed from the fact that when section 12(d)(3) was adopted, most securities-related businesses were organized as privately held general partnerships. As a result, an investment in such a company would expose an investment company to the unlimited liabilities of a general partner. Applicant notes that today's financial services industry is subject to a much more robust body of regulation, which contributes to a more conservative risk profile for those companies that comprise the industry. Moreover, Applicant states that the risks presented by the form of organization of a securities-related business are no longer as germane as they were at the time of the adoption of section 12(d)(3) because many formerly closely-held securities-related businesses have reorganized into corporate forms that are characterized by limited liability. Applicant asserts in particular that the Company's shareholders are not exposed to the risk of unlimited liability associated with an interest in the Adviser Sub because they are insulated by a layer of liability protection between the Adviser Sub and the Company, as the Adviser Sub is a separate entity and is structured as a limited liability company, not a partnership.

4. Applicant also submits that the Company will own 100% of the equity interests in the Adviser Sub and, as a result, will exercise total control over the strategic direction of the Adviser Sub, including the power to control the policies that affect the Company and to protect the Company from potential conflicts of interest and reciprocal practices. Moreover, as a wholly owned portfolio company and the sole shareholder of the Adviser Sub, the Adviser Sub and the Company will generally have aligned interests.

5. Applicant states that the Company will adopt policies and procedures with respect to the Adviser Sub designed to ensure that the Company and the Adviser Sub are both being operated and managed in the best interests of the Company's shareholders and that the ownership by the Company of the Adviser Sub is consistent with the purposes fairly intended by the policy and provisions of the Act.[5] Applicant states that the Company and the Adviser Sub will adopt policies and procedures to address potential conflicts of interest, including but not limited to policies and procedures that govern the allocation of expenses, personal securities trading, and insider trading and confidentiality of proprietary information.

6. Applicant notes that the Company and the Managed Accounts may invest in the same securities or different securities of the same issuer to the extent consistent with applicable law, regulatory guidance, or any exemptive order obtained by the Company. The Company and the Adviser Sub will implement policies and procedures that will govern the allocation of investment opportunities when investment advisory personnel of the Company and/or Adviser Sub become aware of investment opportunities that may be appropriate for the Company and one or more Managed Accounts.

7. Applicant asserts that the acquisition by Private Fund Managed Accounts of participation rights negotiated by the Company would not trigger the application of section 57(a) because the Private Fund Managed Accounts are ''downstream'' affiliates of the Company and, as a result, Applicant notes that rule 57b–1 would apply. Applicant agrees that, to the extent the Company's compliance personnel believes a conflict arises out of the sharing of information obtained due to ownership by the Company, on the one hand, and a Managed Account, on the other hand, of different instruments issued by the same issuer, an information wall will be put into place limiting the flow of information between the Company and the applicable Managed Account (and the Adviser Sub as its manager).

8. Applicant states that the Company's proposal to enter into the advisory business through a wholly owned and controlled portfolio company will benefit the Company's shareholders by: (a) allowing them to share in the profits from the new advisory business; (b) allowing that advisory business to be more marketable than if the services were provided by the Company itself; and (c) limiting any potential liabilities arising from Adviser

[4] Rule 12d3–1(a) and (b) under the Act each provides limited relief from the restrictions of section 12(d)(3) if the acquired company derives 15 percent or less of its gross revenues from securities related activities (as defined in the rule) or the acquiring company owns not more than five percent of the outstanding securities of that class of the acquired company's equity securities. The Company does not believe that it may rely on this relief with respect to its investment in Adviser Sub, since the Company expects that a significant portion of the Adviser Sub's gross revenues will be derived from securities related activities and the Company will own all of the outstanding securities of the Adviser Sub.

[5] Applicant represents that the Adviser Sub's borrowings, if any, would be used only for its own legitimate business purposes, and would not be used directly or indirectly by the Company for its business purposes unrelated to the Adviser Sub, and that the Company will adopt procedures to ensure Board oversight of compliance with this representation.

Sub's provision of advisory services. In addition, the growth in the Company's advisory business through the Adviser Sub will enable the Company to add advisory personnel that it could not on its own, such as additional portfolio managers and investment analysts, who will be available to provide advisory services both to the Company and to the Managed Accounts of the Adviser Sub and further enhance the experience and relationships of the Company's investment team. Without the growth of the Company's advisory business through the Adviser Sub, the Company would not have the ability to support such additional advisory personnel. Applicant also states that the Adviser Sub's organization as a wholly owned portfolio company of the Company and registration as an investment adviser would permit the Adviser Sub to operate the business of managing the Managed Accounts as a direct or an indirect wholly owned taxable portfolio company of the Company, thereby protecting the Company's RIC status.

9. Applicant represents that the Company's Board, including a majority of the disinterested directors, found that the Company organizing, acquiring, and wholly owning 100% of the equity interest in the Adviser Sub subsequent to its registration as an investment adviser is in the best interests of the Company and its shareholders. Applicant agrees that the Board will review at least annually the investment advisory business of the Adviser Sub to determine whether such business should be continued and whether the benefits derived by the Company from the Adviser Sub's business warrant the continued ownership of the Adviser Sub. Applicant states that shareholders of the Company will be provided with notice, in advance of, or concurrent with, the Adviser Sub's start of investment advisory activities.

10. Accordingly, Applicant represents that the requested relief is both necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicant's Conditions:

Applicant agrees that the Order of the Commission granting the requested relief shall be subject to the following conditions:

1. The determination to enter into the advisory business through the Adviser Sub has been made by a vote of at least a majority of the Board who are not ''interested persons'' of the Company as defined in section 2(a)(19).

2. The Company will wholly own and control the Adviser Sub. The Company will not have an investment adviser within the meaning of section 2(a)(20). Only persons acting in their capacities as directors, officers or employees of the Company will provide advisory services to the Company.

3. In each of its annual reports to shareholders and in future registration statements, the Company will discuss the existence of the Adviser Sub and the provision by the Adviser Sub of outside advisory services as well as include an assessment of whatever risks, if any, are associated with the existence of the Adviser Sub and its provision of such services.

4. The Adviser Sub will not make any proprietary investment that the Company would be prohibited from making directly under the Company's investment objectives, policies and restrictions or under any applicable law.

5. In assessing compliance with the asset coverage requirements under section 18 of the Act, the Company will deem the assets, liabilities, and indebtedness of the Adviser Sub as its own.

6. The Board will review at least annually the investment advisory business of the Adviser Sub to determine whether such business should be continued and whether the benefits derived by the Company from the Adviser Sub's business warrant the continued ownership of the Adviser Sub and, if appropriate, approve (by a vote of at least a majority of its directors who are not ''interested persons'' as defined in the Act) at least annually such continuation. In determining whether the investment advisory business of the Adviser Sub should be continued and whether the benefits derived by the Company from the Adviser Sub's business warrant the continued ownership of the Adviser Sub, the Board will take into consideration, among other things, the following: (a) the compensation of the officers of the Company and of the Adviser Sub; (b) all investments by and investment opportunities considered for the Company that relate to any investments by or investment opportunities considered for a client of the Adviser Sub; and (c) the allocation of expenses associated with the provision of advisory services between the Company and the Adviser Sub.[6]

For the Commission, by the Division of Investment Management, under delegated authority.

[6] Such expenses may include: administration and operating expenses; investment research expenses; sales and marketing expenses; office space and general expenses; and direct expenses, including legal and audit fees, directors' fees and taxes.

Dated: November 15, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25224 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–115, OMB Control No.3235–0132]

Proposed Collection; Comment Request; Extension: 7a–15 Through 7a–37

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rules 7a–15 through 7a–37 (17 CFR 260.7a–15—260.7a–37) under the Trust Indenture Act of 1939 (15 U.S.C. 77aaa *et seq.*) set forth the general requirements as to form and content of applications, statements and reports that must be filed under the Trust Indenture Act. The respondents are persons and entities subject to requirements of the Trust Indenture Act. Trust Indenture Act Rules 7a–15 through 7a–37 are disclosure guidelines and do not directly result in any collection of information. The rules are assigned only one burden hour for administrative convenience.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by January 17, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25104 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96322; File No. SR–NYSEARCA–2022–76]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31–E

November 15, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31–E regarding Discretionary Pegged Orders. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (1) amend Rule 7.31–E to delete Commentary .03 to end the temporary suspension of the Discretionary Pegged Order, and (2) amend Rule 7.31–E(h)(3) to modify the operation of the Discretionary Pegged Order.

The Discretionary Pegged Order is a non-displayed order to buy (sell) that is pegged to the same side of the PBBO and assigned a working price equal to the lower (higher) of the midpoint of the PBBO (the ''Midpoint Price'') or the limit price of the order.[3] A Discretionary Pegged Order will exercise the least amount of discretion necessary from its working price to its discretionary price (defined as the lower (higher) of the Midpoint Price or the limit price of the order) to trade with contra-side interest. Current Rule 7.31–E(h)(3)(C) provides that a Discretionary Pegged Order will not exercise discretion if the PBBO is determined to be unstable via a ''quote instability calculation'' that assesses the probability of a change to the PBB or PBO. Specifically, as set forth in current Rule 7.31–E(h)(3)(D), the Exchange uses the quote instability calculation along with real-time relative quoting activity of protected quotations to assess the probability of an imminent change to the PBBO (the ''quote instability factor''). When the quoting activity meets predefined criteria described in Rule 7.31–E(h)(3)(D)(i)(A) through (C) and the quote instability factor calculated is greater than the Exchange's quote instability threshold (defined in Rule 7.31–E(h)(3)(D)(i)(D)(2)), the Exchange treats the quote as unstable. The quote stability calculation utilizes quote stability coefficients and quote stability variables, as defined in Rules 7.31–E(h)(3)(D)(i)(D)(1)(a) and (b). In July 2022, the Exchange modified the quote stability calculation to incorporate updated quote stability coefficients that would allow the quote stability calculation to more accurately identify changes to the PBBO.[4]

End of Temporary Suspension

In August 2022, the Exchange added Commentary .03 to Rule 7.31–E to provide for the temporary suspension of the Discretionary Pegged Order.[5] The Exchange determined to temporarily suspend use of the Discretionary Pegged Order to evaluate system performance impacts following the modification of the quote stability coefficients, as described above. Commentary .03 to Rule 7.31–E provides that the Exchange will submit a proposed rule filing to end the temporary suspension and will provide notice of the end of the suspension period by Trader Update.

The Exchange now proposes to end the temporary suspension period, as it has assessed system performance impact and is prepared to resume offering the Discretionary Pegged Order, as modified by this filing. The Exchange also proposes to delete Commentary .03 from 7.31–E to remove text that would no longer have application once the temporary suspension is lifted.

Modification of Discretionary Pegged Orders

The Exchange proposes to amend Rule 7.31–E(h)(3) to modify the operation of Discretionary Pegged Orders following the end of the temporary suspension period. As noted above, the temporary suspension period provided the Exchange with an opportunity to evaluate the impact of the order type on system performance. Based on the Exchange's assessment of such impact, and, specifically, the system resources required to perform the quote stability calculation, the Exchange now proposes to modify Rule 7.31–E(h)(3) to provide that the Discretionary Pegged Order would not be restricted from exercising discretion during periods of quote instability, thereby eliminating the need to perform the quote stability calculation.

As proposed, the Discretionary Pegged Order would operate as defined in Rule 7.31–E(h)(3) and as specified in current Rules 7.31–E(h)(3)(A), (B), and (E), without any changes except that the order would continue to exercise the least amount of price discretion

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 7.31–E(h)(3). As defined in NYSE Arca Rule 1.1, ''PBBO'' means the Best Protected Bid and the Best Protected Offer. Rule 1.1 also defines ''PBB'' as the highest Protected Bid and ''PBO'' as the lowest Protected Offer.

[4] *See* Securities Exchange Act Release No. 95154 (June 24, 2022), 87 FR 39134 (June 30, 2022) (SR–NYSEArca–2022–13) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Amend Rule 7.31–E(h)(3) Relating to Discretionary Pegged Orders).

[5] *See* Securities Exchange Act Release No. 95584 (August 23, 2022), 87 FR 52826 (August 29, 2022) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 7.31–E).

necessary from its working price to its discretionary price to trade with contra-side orders on the NYSE Arca Book without regard to potential quote instability. The Exchange thus proposes to delete the clause beginning with ''except'' in the last sentence of current Rule 7.31–E(h)(3). In addition, because the Exchange proposes to permit Discretionary Pegged Orders to exercise discretion without considering potential quote instability, the Exchange would no longer perform the quote instability calculation to assess the probability of an imminent change to the PBBO or identify periods of quote instability. To effect this change, the Exchange proposes to delete current Rules 7.31–E(h)(3)(C) and (D), including the subparagraphs thereunder. The Exchange also proposes to renumber current Rule 7.31–E(h)(3)(E) as Rule 7.31–E(h)(3)(C) to reflect those deletions.

Although the Discretionary Pegged Order, as modified, would no longer provide price protection during periods of quote instability, the Exchange believes that it would still provide ETP Holders with the flexibility and benefits of an order type that can exercise discretion to trade with contra-side interest. The Exchange notes that the Discretionary Pegged Order, as modified, would operate similarly to order types currently offered by other equities exchanges.[6]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the end of the temporary suspension and availability of the Discretionary Pegged Order, as proposed in this filing, by Trader Update. Subject to effectiveness of this rule filing, the Exchange will implement the changes described herein in the fourth quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to end the temporary suspension of Discretionary Pegged Orders and delete Commentary .03 would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market and a national market system because it would permit the Exchange to resume offering the Discretionary Pegged Order to ETP Holders and remove rule text that would no longer have application following the end of the suspension period. Furthermore, as discussed above, the temporary suspension of the Discretionary Pegged Order allowed the Exchange an opportunity to evaluate system performance impacts. Accordingly, the Exchange believes that the proposed change to modify the operation of the Discretionary Pegged Order, further to such assessment, would remove impediments to, and perfect the mechanism of, a free and open market and a national market system, as well as protect investors and the public interest, by continuing to provide ETP Holders with the benefits of an order type that can exercise discretion to trade with contra-side interest, without a quote instability calculation that would restrict such order from exercising discretion during periods of quote instability. The Exchange also believes that the proposed modification of the Discretionary Pegged Order would remove impediments to, and perfect the mechanism of, a free and open market and a national market system by modifying the Discretionary Pegged Order to function similarly to discretionary orders currently offered by other equities exchanges.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed change would promote competition by ending the temporary suspension of the Discretionary Pegged Order and making the order type once again available to ETP Holders, as proposed. The proposed modification of the Discretionary Pegged Order would also promote competition by permitting the Exchange to offer ETP Holders an order type that can exercise discretion to trade with contra-side interest and would not be restricted from doing so by a quote stability calculation. The Exchange also believes that the proposed modification to the operation of the Discretionary Pegged Order could promote competition because the order type would function similarly to order types currently offered by other equities exchanges.[10]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to allow the Exchange to end the temporary suspension and modify the Discretionary Pegged Order as soon as the technology associated with those proposed changes is available and make the Discretionary Pegged Order available for use by interested ETP Holders. The Exchange states that the proposed changes would allow the Exchange to end the temporary suspension of an approved order type and modify the order type to operate similarly to discretionary orders

[6] *See, e.g.,* Cboe EDGA Exchange, Inc. Rule 11.8(e) (defining the MidPoint Discretionary Order as a limit order to buy or sell that is pegged to the NBBO with discretion to execute at prices up or down to and including the midpoint of the NBBO); Cboe EDGX Exchange, Inc. Rule 11.8(g) (same).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* note 6, *supra.*

[10] *See id.*

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

currently offered by other equities exchanges. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2022–76 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–76. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NYSEARCA–2022–76 and should be submitted on or before December 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–25230 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

[15] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–617, OMB Control No. 3235–0728]

Submission for OMB Review; Comment Request; Extension: Rule 17Ab2–2

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17Ab2–2 (17 CFR 240.17Ab2–2) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Exchange Act Rule 17Ab2–2 establishes procedures for the Commission to make a determination, either of its own initiative or upon application by any clearing agency or member of a clearing agency, whether a covered clearing agency is systemically important in multiple jurisdictions and procedures to determine, if the Commission deems appropriate, whether any of the activities of a clearing agency providing central counterparty services, in addition to clearing agencies registered with the Commission for the purpose of clearing security-based swaps, have a more complex risk profile. In addition, Exchange Act Rule 17Ab2–2 provides a procedure for the Commission to determine whether to rescind any such determinations previously made by the Commission.

Because determinations made by the Commission pursuant to Exchange Act Rule 17Ab2–2 may be made upon the request of a clearing agency, respondent clearing agencies would have the burden of preparing such requests for submission to the Commission.

Commission staff estimates that Rule 17Ab2–2 will impose a PRA burden on registered clearing agencies that seek a determination from the Commission regarding the covered clearing agency's status as systemically important in multiple jurisdictions. Commission staff estimates that two registered clearing agencies or their members on their behalf will apply for a Commission determination, or may be subject to a Commission-initiated determination, regarding whether a registered clearing agency is involved in activities with a more complex risk profile or whether a covered clearing agency is systemically important in multiple jurisdictions.

Commission staff estimates that each respondent clearing agency incurs a one-time burden of 10 hours and a one-time cost of $2,000 to draft and review a determination request submitted to the Commission, for a total of 20 hours and $4,000 for all respondents. The total annualized burden and cost for all respondents are 6.66 hours and $1,333.33.

Any agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a valid OMB control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by December 19, 2022 to (i) >*MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov*< and (ii) David Bottom, Director/Chief Information Officer,

Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25102 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–793, OMB Control No. 3235–0734]

Submission for OMB Review; Comment Request; Extension: Rule 22c–1

Upon Written Request, Copies Available From: Securities and Exchange Commission Office of FOIA Services 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 22c–1 (17 CFR 270.22c–1) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Investment Company Act'' or ''Act'') enables a fund to choose to use ''swing pricing'' as a tool to mitigate shareholder dilution. Rule 22c–1 is intended to promote investor protection by providing funds with an additional tool to mitigate the potentially dilutive effects of shareholder purchase or redemption activity and a set of operational standards that allow funds to gain comfort using swing pricing as a means of mitigating potential dilution.

The respondents to amended rule 22c–1 are open-end management investment companies (other than money market funds or exchange-traded funds) that engage in swing pricing. Compliance with rule 22c–1(a)(3) is mandatory for any fund that chooses to use swing pricing to adjust its NAV in reliance on the rule.

While we are not aware of any funds that have engaged in swing pricing,[1] we are estimating for the purpose of this analysis that 5 fund complexes have funds that may adopt swing pricing policies and procedures in the future pursuant to the rule. We estimate that the total burden associated with the preparation and approval of swing pricing policies and procedures by those fund complexes that would use swing pricing will be 280 hours.[2] We also estimate that it will cost a fund complex $48,188 to document, review and initially approve these policies and procedures, for a total cost of $240,940.[3]

Rule 22c–1 requires a fund that uses swing pricing to maintain the fund's swing policies and procedures that are in effect, or at any time within the past six years were in effect, in an easily accessible place.[4] The rule also requires a fund to retain a written copy of the periodic report provided to the board prepared by the swing pricing administrator that describes, among other things, the swing pricing administrator's review of the adequacy of the fund's swing pricing policies and procedures and the effectiveness of their implementation, including the impact on mitigating dilution and any back-testing performed.[5] The retention of these records is necessary to allow the staff during examinations of funds to determine whether a fund is in compliance with its swing pricing policies and procedures and with rule 22c–1. We estimate a time cost per fund complex of $344.[6] We estimate that the total for recordkeeping related to swing pricing will be 20 hours, at an aggregate cost of $1,720, for all fund complexes that we believe include funds that have adopted swing pricing policies and procedures.[7]

Amortized over a three-year period, we believe that the hour burdens and time costs associated with rule 22c–1, including the burden associated with the requirements that funds adopt policies and procedures, obtain board approval, and periodic review of an annual written report from the swing pricing administrator, and retain certain records and written reports related to swing pricing, will result in an average aggregate annual burden of 113.3 hours, and average aggregate time costs of $82,033.[8] We also estimate that rule 22c–1 imposes a total external cost burden of $2,655 for outside legal services related to compliance with the policies and procedures requirement.[9]

These estimates of average costs are made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

This collection of information is necessary to obtain a benefit and will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by December 19, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25099 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

[1] No funds have engaged in swing pricing as reported on Form N–CEN as of August 15, 2022.

[2] This estimate is based on the following calculation: (48 + 2 + 6) hours × 5 fund complexes = 280 hours.

[3] These estimates are based on the following calculations: 24 hours × $237 (hourly rate for a senior accountant) = $5,688; 24 hours × $545 (blended hourly rate for assistant general counsel ($510) and chief compliance officer ($580)) = $13,080; 2 hours (for a fund attorney's time to prepare materials for the board's determinations) × $400 (hourly rate for a compliance attorney) = $800; 6 hours× $4,770 (hourly rate for a board of 9 directors) = $28,620; ($5,688 + $13,080 +$800 + $28,620) = $48,188; $48,188 × 5 fund complexes = $240,940. The hourly wages used are from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead. The staff has estimated the average cost of board of director time as $4,770 per hour for the board as a whole, based on information received from funds and their counsel.

[4] *See* rule 22c–1(a)(3)(iii).

[5] *See id.*

[6] This estimate is based on the following calculations: 2 hours × $68 (hourly rate for a general clerk) = $136; 2 hours × $104 (hourly rate for a senior computer operator) = $208. $136 + $208 = $344.

[7] These estimates are based on the following calculations: 4 hours × 5 fund complexes = 20 hours. 5 fund complexes ×$344 = $1,720.

[8] These estimates are based on the following calculations: (280 hours (year 1) + (3 ×20 hours) (years 1, 2 and 3)) ÷ 3 = 113.3 hours; ($240,940 (year 1) + (3 × $1,720) (years 1, 2 and 3)) ÷ 3 = $82,033.

[9] This estimated burden is based on the estimated wage rate of $531 per hour for outside legal services and the following calculation: $531 × 5 fund complexes = $2,655.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–389, OMB Control No. 3235–0444]

Proposed Collection; Comment Request; Extension: Rule 10b–10

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 10b–10 (17 CFR 240.10b–10) under the Securities and Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 10b–10 requires broker-dealers to convey specified information to customers regarding their securities transactions. This information includes the date and time of the transaction, the identity and number of shares bought or sold, and whether the broker-dealer acts as agent for the customer or as principal for its own account. Depending on whether the broker-dealer acts as agent or principal, Rule 10b–10 requires the disclosure of commissions, as well as mark-up and mark-down information. For transactions in debt securities, Rule 10b–10 requires the disclosure of redemption and yield information. Rule 10b–10 potentially applies to all of the approximately 3,531 firms registered with the Commission that effect transactions for or with customers.

Based on information provided by registered broker-dealers to the Commission in FOCUS Reports, the Commission staff estimates that on average, registered broker-dealers process approximately 27,151,388,510 order tickets per year for transactions for or with customers. Each order ticket representing a transaction effected for or with a customer generally results in one confirmation. Therefore, the Commission staff estimates that approximately 27,151,388,510 confirmations are sent to customers annually. The confirmations required by Rule 10b–10 are generally processed through automated systems. It takes approximately 30 seconds to generate and send a confirmation. Accordingly, the Commission staff estimates that broker-dealers spend approximately 226,261,571 hours per year complying with Rule 10b–10 (27,151,388,510 × .5 ÷ 60).

The number of confirmations sent and the cost of sending each confirmation varies from firm to firm. Smaller firms generally send fewer confirmations than larger firms because they effect fewer transactions. The Commission staff estimates the cost of producing and sending a paper confirmation, including postage, to be approximately 67 cents. The Commission staff also estimates that the cost of producing and sending a wholly electronic confirmation is approximately 40 cents. Based on informal discussions with industry participants, as well as representations made in requests for exemptive and no-action letters relating to Rule 10b–10, the staff estimates that broker-dealers used electronic confirmations for approximately 35 percent of transactions. Based on these calculations, Commission staff estimates that 17,648,402,532 paper confirmations are mailed each year at a cost of $11,824,429,696. Commission staff also estimates that 9,502,985,979 wholly electronic confirmations are sent each year at a cost of $3,801,194,392. Accordingly, Commission staff estimates that the total annual cost associated with generating and delivering to investors the information required under Rule 10b–10 is approximately $15,625,624,088.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by January 17, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 14, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25095 Filed 11–17–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before December 19, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration;'' ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain*

SUPPLEMENTARY INFORMATION: The SBA Emerging Leaders (EL) initiative was designed to strengthen and grow existing local entrepreneur communities in historically distressed cities. The key goals of the program are to (1) increase small business growth and survival, and (2) promote economic growth in distressed communities by providing employment opportunities as well as necessary goods and services. To achieve these goals, the program offers executives of high-growth small businesses a five-month executive leader education series, free of charge, that provide the networks, resources, and knowledge required to promote a sustainable business growth, create jobs, and contribute to the economic well-

being of local communities. In 2022, the program was revamped under the new name, T.H.R.I.V.E. Emerging Leaders Reimagined. The revised program provides training that customizes content for small businesses' unique needs, increases accessibility through a virtual component, and specifically promotes business ecosystem connections among business owners, government agencies, and the financial community. This information collection is necessary for SBA to understand the progress made by the T.H.R.I.V.E. program toward achieving its goals.

The evaluation will be used to track participants' business growth, to provide guidance to the program training contractor on areas for additional assistance, and to increase SBA's understanding of the program outcome trends. This evaluation aims to examine the program participants' business growth outcomes including revenue, profits, job creation, and business survival. The evaluation also describes the population of program participants—their businesses, business management practices, experiences with the program, and satisfaction with and perceived effectiveness of the program. Over the previous years, the evaluation results have helped to track the program performance outcomes and provide suggestions for program improvements to better facilitate small business growth. The results are also expected to provide suggestions for improving future evaluations.

The following surveys are conducted with the program participants: (1) the application form before the program enrollment, (2) the intake survey before the training, (3) the module feedback form during the training, (4) the feedback survey right after the graduation, and (5) the follow-up survey annually up to three years after graduation. The application form examines the eligibility status of the enrollees, obtains their contact information, and asks for their business goals. The data from the Intake survey is used to determine baseline levels of business outcomes, the use of management practices, and the extent to which the target population for the program is reached. The module feedback form assesses the participants' experience with each of the eight modules of the training program. The feedback survey is used to measure participant satisfaction with the training activities and to suggest training adjustments, if necessary. The annual follow-up survey tracks changes in the small business owner's management practices and business outcomes for three years after graduation from the program. The data collection covers four cohorts of program participants. The given year participants complete the application form, intake survey, module feedback, and feedback survey. The three cohorts of participants who graduated from the program one, two, and three years prior complete the follow-up survey.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Title: The SBA Emerging Leaders (EL) initiative was designed to strengthen and grow existing local entrepreneur communities in historically distressed cities. The key goals of the program are to (1) increase small business growth and survival, and (2) promote economic growth in distressed communities by providing employment opportunities as well as necessary goods and services. To achieve these goals, the program offers executives of high-growth small businesses a five-month executive leader education series, free of charge, that provide the networks, resources, and knowledge required to promote a sustainable business growth, create jobs, and contribute to the economic well-being of local communities. In 2022, the program was revamped under the new name, T.H.R.I.V.E. Emerging Leaders Reimagined. The revised program provides training that customizes content for small businesses' unique needs, increases accessibility through a virtual component, and specifically promotes business ecosystem connections among business owners, government agencies, and the financial community. This information collection is necessary for SBA to understand the progress made by the T.H.R.I.V.E. program toward achieving its goals.

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OMB Control Number: 3245–0394.

Title: T.H.R.I.V.E. Emerging Leaders Reimagined.

Description of Respondents: Existing local entrepreneur communities in historically distressed cities.

Estimated Number of Respondents: 5,644.

Estimated Annual Responses: 5,644.

Estimated Annual Hour Burden: 4,851.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–25193 Filed 11–17–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 11919]

Clean Energy Resources Advisory Committee

ACTION: Announcement of meeting.

SUMMARY: The Department of State will host a virtual, open meeting of the Clean Energy Resources Advisory Committee (CERAC). There will not be an in-person option for this meeting.

DATES: CERAC will meet virtually December 7, 2022 from 11:00 a.m. to 12:30 p.m. (EST).

FOR FURTHER INFORMATION CONTACT: Bureau of Energy Resources, Energy Officer Brian Bedell at (202) 647–7687, or *CERAC@state.gov*.

SUPPLEMENTARY INFORMATION:

Purpose: This Committee will provide input and advice regarding energy minerals and metals, their supply chains, and end uses. This third meeting will focus on investment needs across clean energy supply chains and strategies to accelerate public and private investment to support supply chain security and diversification.

Participation: Members of the public wishing to participate must RSVP by December 5, 2022 via email to *CERAC@state.gov* (subject line: RSVP). The Department will provide login information prior to the meeting. Requests for reasonable accommodation should be submitted no later than December 1, 2022. Reasonable accommodation requests received after that date will be considered but may not be possible to fulfill.

Any written comments should be emailed to *CERAC@state.gov* with ''PUBLIC COMMENT'' as the subject line at least 48 hours before the start of the meeting. During this meeting, there will not be an option for members of the public to make oral statements.

(Authority: 5 U.S.C. app. 10(a) and 22 U.S.C. 2651a)

Brian Bedell,

Energy Officer, Bureau of Energy Resources, Department of State.

[FR Doc. 2022–25083 Filed 11–17–22; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Random Drug and Alcohol Testing Percentage Rates of Covered Aviation Employees for the Period of January 1, 2023, Through December 31, 2023

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA has determined that the minimum random drug and alcohol testing percentage rates for the period January 1, 2023, through December 31, 2023, will remain at 25 percent of safety-sensitive employees for random drug testing and 10 percent of safety-sensitive employees for random alcohol testing.

FOR FURTHER INFORMATION CONTACT: Ms. Vicky Dunne, Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division, Program Policy Branch; Email *drugabatement@faa.gov*; Telephone (202) 267–8442.

Discussion: Pursuant to 14 CFR 120.109(b), the FAA Administrator's decision on whether to change the minimum annual random drug testing rate is based on the reported random drug test positive rate for the entire aviation industry. If the reported random drug test positive rate is less than 1.00%, the Administrator may continue the minimum random drug testing rate at 25%. In 2021, the random drug test positive rate was 0.728%. Therefore, the minimum random drug testing rate will remain at 25% for calendar year 2023.

Similarly, 14 CFR 120.217(c), requires the decision on the minimum annual random alcohol testing rate to be based on the random alcohol test violation rate. If the violation rate remains less than 0.50%, the Administrator may continue the minimum random alcohol testing rate at 10%. In 2021, the random alcohol test violation rate was 0.114%. Therefore, the minimum random alcohol testing rate will remain at 10% for calendar year 2023.

SUPPLEMENTARY INFORMATION: If you have questions about how the annual random testing percentage rates are determined, please refer to the Code of Federal Regulations Title 14, section 120.109(b) (for drug testing), and 120.217(c) (for alcohol testing).

Issued in Washington, DC.

Susan Northrup,

Federal Air Surgeon.

[FR Doc. 2022–25173 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2022–0037]

Agency Information Collection Activity Under OMB Review: Public Transportation Emergency Relief Program

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

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describe the nature of the information collection and their expected burdens.

DATES: Comments must be submitted on or before December 19, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue SE, Mail Stop TAD–10, Washington, DC 20590 (202) 366–0354 or *tia.swain@dot.gov*.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, Section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue

two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On August 24, 2022, FTA published a 60-day notice (87 FR 52109) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received one anonymous non-significant comment not associated with information collection or burden. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Public Transportation Emergency Relief Program.

OMB Control Number: 2132–0575.

Background: Since the authorization of the Public Transportation Emergency Relief Program in 2012, Congress has appropriated funds three times for transit agencies affected by disaster.

The first appropriation of funds for the program was in 2013 following Hurricane Sandy, for which the President declared a major disaster for areas of 12 States and the District of Columbia. Under the Disaster Relief Appropriations Act (Pub. L. 113–2), Congress provided $10.9 billion for FTA's Emergency Relief Program for recovery, relief, and resilience efforts in the counties specified in the disaster declaration. Approximately $10.0 billion remained available after implementation of the Balanced Budget and Emergency Deficit Control Act of 2011 (Pub. L. 112–25) and after intergovernmental transfers to other bureaus and offices within DOT. FTA has allocated the full amount in multiple tiers for response, recovery and rebuilding; for locally prioritized resilience projects, and for competitively selected resilience projects.

The second appropriation of funds for the Emergency Relief Program was in 2018 following Hurricanes Harvey, Irma, and Maria, for which the President declared major disasters in areas of Florida, Georgia, Louisiana, Puerto Rico, South Carolina, Texas, and the U.S. Virgin Islands. Under the Bipartisan Budget Act of 2018 (Pub. L. 115–123), Congress provided $330 million for FTA's Emergency Relief Program for transit systems affected by Hurricanes Harvey, Irma, and Maria. On May 31, 2018 FTA allocated $277.5 million for response, recovery, rebuilding, and resilience projects.

The third appropriation of funds for the Emergency Relief Program was in 2019. Under the Additional Supplemental Appropriations for Disaster Relief Act of 2019, Congress appropriated $10.5 million for FTA's Emergency Relief Program for transit systems affected by major declared disasters occurring in calendar year 2018.

On March 13, 2020, FTA announced that expanded eligibility of federal assistance is available under FTA's Emergency Relief Program to help transit agencies respond to the coronavirus (COVID–19) in states where the Governor has declared an emergency. This includes allowing all transit providers, including those in large urban areas, to use federal formula funds for emergency-related capital and operating expenses, and raises the cap on the federal government's share of those expenses.

Respondents: States, local governmental authorities, Indian tribes and other FTA recipients impacted by Hurricane Sandy which affected mid-Atlantic and northeastern states in October 2012; Hurricane Harvey which affected areas of Texas and Louisiana in August 2017; and Hurricanes Irma and Maria which affected the southeastern states and the territories of the Puerto Rico and the U.S. Virgin Islands in September 2017, and by major declared disasters occurring in calendar year 2018.

Estimated Annual Number of Respondents: 26.

Estimated Total Annual Burden: 4,680 hours.

Frequency: Annually.

Nadine Pembleton,

Deputy Associate Administrator, Office of Administration.

[FR Doc. 2022–25205 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2022–0035]

Agency Information Collection Activity Under OMB Review: Transit Research, Development, Demonstration, Deployment and Training Projects

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

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describe the nature of the information collection and their expected burdens.

DATES: Comments must be submitted on or before December 19, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue. SE, Mail Stop

TAD–10, Washington, DC 20590 (202) 366–0354 or *tia.swain@dot.gov.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On August 24, 2022, FTA published a 60-day notice (87 FR 52111) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received no comments after issuing this 60-day notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Transit Research, Development, Demonstration, Deployment and Training Projects

OMB Control Number: 2132–0546

Background: 49 U.S.C. Section 5312(a) authorizes the Secretary of Transportation to make grants or contracts for research, development, demonstration, and deployment projects, and for evaluation of technology of national significance to public transportation, that the Secretary determines will improve mass transportation service or help transportation service meet the total urban transportation needs at a minimum cost. In carrying out the provisions of this section, the Secretary is also authorized to request and receive appropriate information from any source. The information collected is submitted as part of the application for grants and cooperative agreements and is used to determine eligibility of applicants. Collection of this information also provides documentation that the applicants and recipients are meeting program objectives and are complying with FTA Circular 6100.1D and other federal requirements.

Respondents: Federal Government Departments, agencies, and instrumentalities of the Government, including Federal laboratories; State and local governmental entities; providers of public transportation; private or non-profit organizations; institutions of higher education; and technical and community colleges.

Estimated Annual Number of Respondents: 175 respondents.

Estimated Annual Number of Responses: 775 responses.

Estimated Total Annual Burden: 20,550 hours.

Frequency: Every Two Years.

Nadine Pembleton,

Deputy Associate Administrator, Office of Administration.

[FR Doc. 2022–25209 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2022–0036]

Agency Information Collection Activity Under OMB Review: Bus Testing Program

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

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describe the nature of the information collection and their expected burdens.

DATES: Comments must be submitted on or before December 19, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue SE, Mail Stop TAD–10, Washington, DC 20590 (202) 366–0354 or *tia.swain@dot.gov*.

SUPPLEMENTARY INFORMATION:

The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On August 24, 2022, FTA published a 60-day notice (87 FR 52210) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received no comments after issuing this 60-day notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30-day notice informs the regulated

community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Bus Testing Program.

OMB Control Number: 2132–0550.

Background: 49 U.S.C. 5318(a) provides that Federal funds appropriated or otherwise made available under 49 U.S.C. chapter 53 [FTA funding] may not be obligated or expended for the acquisition of a new bus model unless a bus of that model has been tested for maintainability, reliability, safety, performance (including braking performance), structural integrity, fuel economy, emissions, and noise.

At this time, there is one active Bus Testing Center operated by the Thomas D. Larson Pennsylvania Transportation Institute of the Pennsylvania State University (LTI). LTI operates and maintains the Center under a cooperative agreement with FTA and establishes and collects fees for the testing of the vehicles at the facility. Upon completion of the testing of the vehicle at the Center with a passing test score, a draft Bus Testing Report is provided to the manufacturer of the new bus model. If the manufacturer approves the Report for publication, the bus model becomes eligible for FTA funding. 49 CFR 665.7 requires a recipient of FTA funds to certify that a bus model has been tested at the bus testing facility, that the bus model received a passing score, and that the recipient has a copy of the applicable Bus Testing Report(s) on a bus model before final acceptance of any buses of that model. Recipients are strongly encouraged to review the Bus Testing Report(s) relevant to a bus model before final acceptance and/or selection of that bus model.

Respondents: Bus manufacturers and recipients of FTA funds.

Estimated Annual Number of Responses: 60.

Estimated Total Annual Burden: 2,131 hours.

Frequency: On occasion.

Nadine Pembleton,

Deputy Associate Administrator, Office of Administration.

[FR Doc. 2022–25207 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against a Proposed Public Transportation Project—Silver Line Project

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA) regarding the construction of the Silver Line Project, formerly known as the Cotton Belt Corridor Regional Rail Project. The purpose of this notice is to publicly announce FTA's environmental decisions on the subject project and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: A claim seeking judicial review of FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before April 17, 2023.

FOR FURTHER INFORMATION CONTACT: Kathryn Loster, Assistant Chief Counsel, Office of Chief Counsel, (312) 705–1269, or Saadat Khan, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–9647. FTA is located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions subject to 23 U.S.C. 139(l) by issuing certain approvals for the public transportation project listed below. The actions on the project, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA environmental project files for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information. Contact information for FTA's Regional Offices may be found at *https://www.transit.dot.gov*.

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA (42 U.S.C. 4321–4375), section 4(f) requirements (23 U.S.C. 138, 49 U.S.C. 303), section 106 of the National Historic Preservation Act (54 U.S.C. 306108), Endangered Species Act (16 U.S.C. 1531), Clean Water Act (33 U.S.C. 1251), Uniform Relocation and Real Property Acquisition Policies Act (42 U.S.C. 4601), and the Clean Air Act (42 U.S.C. 7401–7671q). This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The project and actions that are the subject of this notice follow:

Project name and location: Silver Line Project, Tarrant, Dallas, and Collin Counties, Texas. *Project Sponsor:* Dallas Area Rapid Transit (DART). *Project description:* The project consists of a 26-mile double-track regional commuter rail line extending from Dallas-Fort Worth International (DFW) Airport to Shiloh Road in Plano. The alignment traverses seven cities: Grapevine, Coppell, Dallas, Carrollton, Addison, Richardson, and Plano. FTA issued a combined Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) on November 9, 2018 for the project. Subsequently, FTA published a notice of limitation on claims against the project on March 19, 2019, per 23 U.S.C. 139(l). Since then, FTA has completed a series of re-evaluations of the project to address changes DART identified resulting from design modifications and stakeholder coordination. This notice only applies to the discrete actions taken by FTA under the re-evaluations, as described below.

Final agency actions: FTA determined for each re-evaluation that neither a Supplemental Environmental Impact Statement nor a Supplemental Environmental Assessment is necessary, and the November 2018 FEIS/ROD remains valid. *Supporting documentation:* Memorandum to File Phase A, concerning the relocation of the Equipment Maintenance Facility, dated October 30, 2020; Memorandum to File Phase B, concerning the Elimination of DFW pocket track, Deferral of DFW North Through Platform, Elimination of Oncor Tower Relocation at Cypress Waters Station, and Addition of new at-grade crossing—Huntington Road, dated December 16, 2021; Memorandum to File Phase C, concerning the Elimination of Adaptive Reuse of White Rock Creek Bridge,

dated April 5, 2022; Memorandum to File Phase D, concerning Freight Infrastructure Improvements, dated April 5, 2022; and Memorandum to File Phase E, concerning Hillcrest Road Design Advancement, dated October 6, 2022. All supporting documentation can be viewed and downloaded from: *https://www.dart.org/about/expansion/silverline.asp.*

Authority: 23 U.S.C. 139(l)(1).

Mark A. Ferroni,

Deputy Associate Administrator for Planning and Environment.

[FR Doc. 2022–25204 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2022–0133]

Agency Request for Renewal of a Previously Approved Information Collection: Department of Transportation's (DOT/Department) ''Individual Complaint of Employment Discrimination'' Form

AGENCY: Departmental Office of Civil Rights, Office of the Secretary, DOT.

ACTION: Notice and request for comments.

SUMMARY: DOT invites public comments about its intention to request the Office of Management and Budget (OMB) approval to renew an information collection used by DOT's Equal Employment Opportunity Complaints and Investigations Division within the Departmental Office of Civil Rights. This collection is a form titled ''Individual Complaint of Employment Discrimination'' (Complaint Form). The Complaint Form is necessary for employees, former employees, and/or applicants for employment to file formal equal employment opportunity (EEO) discrimination complaints against DOT and, in turn, for DOT to process the complaints. The Paperwork Reduction Act of 1995 requires DOT to publish this 60-day notice in the **Federal Register**.

DATES: Written comments should be submitted by January 17, 2023.

ADDRESSES: You may submit comments [identified by Docket No. DOT–OST–2022–0133] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Barbara Dougherty, (202) 366–9850, *barbara.dougherty@dot.gov,* U.S. Department of Transportation/Office of the Secretary/Departmental Office of Civil Rights, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105–0556.

Title: Individual Complaint of Employment Discrimination Form (Form Number: DOT–F 1050–8).

Type of Review: Renewal of a previously approved information collection.

Abstract: DOT uses the Complaint Form to collect information necessary to process EEO discrimination complaints filed by DOT employees, former employees and/or applicants for employment. DOT uses the Complaint Form to obtain information from the individual for processing the individual's EEO discrimination complaint and to identify an attorney or other representative, if appropriate. An individual's filing of an EEO discrimination complaint is solely voluntary. DOT processes the complaints in accordance with the U.S. Equal Employment Opportunity Commission's regulations in Title 29, Code of Federal Regulations, Part 1614, as amended.

Respondents: DOT employees, former employees and/or applicants for employment.

Estimated Number of Respondents: 275 per year.

Frequency: Once.

Estimated Hours Burden: One hour.

Estimated Cost Burden: Zero (there is no cost for obtaining the form and it is submitted electronically).

Estimated Total Burden on Respondents: 275 hours per year (one hour per respondent).

Public Comments Invited: DOT requests comment on any aspect of this information collection, including whether the proposed collection is reasonable for the proper performance of the Department's EEO functions; the accuracy of the estimated burden; methods by which the Department could enhance the quality, utility, and clarity of the information collection; and ways the burdens could be minimized without reducing the quality of the collected information. DOT will summarize and include all comments with its request for OMB's renewed approval.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.

Issued in Washington, DC, on November 14, 2022.

Irene B. Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2022–25056 Filed 11–17–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2022–0002]

Proposed Information Collections; Comment Request (No. 88)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB); Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this document.

DATES: We must receive your written comments on or before January 17, 2023.

ADDRESSES: You may send comments on the information collections described in this document using one of these two methods:

- *Internet*—To submit comments electronically, use the comment form for this document posted on the ''*Regulations.gov*'' e-rulemaking website at *https://www.regulations.gov* within Docket No. TTB–2022–0002.
- *Mail*—Send comments to the Paperwork Reduction Act Officer, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW, Box 12, Washington, DC 20005.

Please submit separate comments for each specific information collection described in this document. You must reference the information collection's title, form or recordkeeping requirement number (if any), and OMB control number in your comment.

You may view copies of this document, the relevant TTB forms, and any comments received at *https://www.regulations.gov* within Docket No. TTB–2022–0002. TTB has posted a link to that docket on its website at *https://www.ttb.gov/rrd/information-collection-notices.* You also may obtain paper copies of this document, the listed forms, and any comments received by contacting TTB's Paperwork Reduction Act Officer at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW, Box 12, Washington, DC 20005; 202–453–1039, ext. 135; or complete the Regulations and Rulings Division contact form at *https://www.ttb.gov/contact-rrd.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of a continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections described below, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this document will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether an information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information has a valid OMB control number.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms, letterhead applications or notices, recordkeeping requirements, questionnaires, or surveys:

OMB Control No. 1513–0002

Title: Personnel Questionnaire—Alcohol and Tobacco Products.

TTB Form Number: TTB F 5000.9.

Abstract: Provisions of chapters 51 and 52 of the Internal Revenue Code (IRC, 26 U.S.C. chapters 51 and 52) and the Federal Alcohol Administration Act (FAA Act; 27 U.S.C. 201 *et seq.*) require all persons who desire to engage in certain alcohol and tobacco activities to obtain a permit or registration from, or file a notice with, the Secretary of the Treasury (the Secretary) before beginning operations. The IRC and FAA Act provide that an applicant must meet certain qualifications. For example, an applicant is not eligible for such permits or approvals if the Secretary finds that the applicant, (including company officers, directors, or principal investors) is not likely to lawfully operate or has certain criminal convictions. Under its delegated IRC and FAA Act authorities, the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations authorize the collection of information from applicants so that TTB can determine if they meet the minimum statutory and regulatory qualifications for alcohol and tobacco permits, registrations, or notices. To assist TTB in making such determinations, applicants use form TTB F 5000.9, Personnel Questionnaire—Alcohol and Tobacco, or its electronic Permits Online (PONL) equivalent, to provide TTB with information regarding their identity and their criminal and business history.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the estimated number of annual respondents, responses, and burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits; Individuals and households.

- *Number of Respondents:* 9,850.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 9,850.
- *Average Per-response Burden:* 51.08 minutes.
- *Total Burden:* 8,386 hours.

OMB Control No. 1513–0016

Title: Drawback on Wines Exported.

TTB Form Number: TTB F 5120.24.

Abstract: In general, the IRC at 26 U.S.C. 5041 imposes Federal excise tax on wine produced or imported into the United States, while section 5362(c) allows domestic wine to be exported, transferred to a foreign trade zone, or used on certain vessels and aircraft without payment of that tax. In the case of taxpaid domestic wine that is subsequently exported, the IRC at 26 U.S.C. 5062(b) provides that exporters of such wine may claim ''drawback'' (refund) of the Federal excise tax paid or determined on the exported wine. Under the TTB regulations in 27 CFR part 28, Exportation of Alcohol, exporters of taxpaid domestic wine use form TTB F 5120.24 to document the wine's exportation and to submit drawback claims for the Federal excise taxes paid on the exported wine. TTB uses the provided information to determine if the exported wine is eligible for drawback.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 40.
- *Average Responses per Respondent:* 4 (four).
- *Number of Responses:* 160.
- *Average Per-response Burden:* 67 minutes.
- *Total Burden:* 179 hours.

OMB Control No. 1513–0031

Title: Specific and Continuing Transportation Bonds—Distilled Spirits or Wines Withdrawn for Transportation to Manufacturing Bonded Warehouse, Class Six.

TTB Form Number: TTB F 5100.12.

Abstract: The IRC at 26 U.S.C. 5214(a)(6) and 5362(c)(4) authorizes the transfer without payment of Federal excise tax of, respectively, distilled spirits and wine from a bonded premises to certain customs bonded warehouses for subsequent exportation. To provide proprietors of manufacturing bonded warehouses with operational flexibility based on individual need, the TTB alcohol export regulations in 27 CFR part 28 allow the filing of either a specific transportation bond using form TTB F 5100.12 to cover a single shipment from a bonded premises to a manufacturing bonded warehouse, or a continuing transportation bond using form TTB F 5110.67 to cover multiple shipments.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 50.
- *Average Responses per Respondent:* 1 (one).

- *Number of Responses:* 50.
- *Average Per-response Burden:* 1 hour.
- *Total Burden:* 50 hours.

OMB Control No. 1513–0056

Title: Distilled Spirits Plants—Transaction and Supporting Records.

TTB Recordkeeping Number: TTB REC 5110/05.

Abstract: In general, the IRC at 26 U.S.C. 5001 imposes Federal alcohol excise tax on distilled spirits produced or imported into the United States. The IRC at 26 U.S.C. 5207 also provides that distilled spirits plant (DSP) proprietors must maintain records related to their production, storage, denaturing, and processing activities and render reports covering those activities ''as the Secretary shall by regulations prescribe.'' Under that IRC authority, the TTB regulations in 27 CFR parts 19, 26, 27, and 28 require DSP proprietors to keep certain usual and customary records related to their production, storage, denaturing, and processing activities. This information collection consists of the transaction and supporting records that are common to all four of those DSP activities. Proprietors use those common records, along with records that are unique to each activity, to document the data provided on their monthly DSP production, storage, denaturing, and processing operations reports. (TTB requirements to keep records unique to each of the four DSP activities, and the four related DSP operations reports, are approved under other OMB control numbers.) TTB personnel may examine the required records to verify the data provided by DSP proprietors in their monthly operations reports as those reports are the basis for determining a DSP proprietor's Federal excise tax liability. This information collection implements the relevant statutory provisions and supports the accurate determination of Federal excise tax.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the estimated number of annual respondents and responses.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 4,800.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 4,800.
- *Average Per-response and Total Burden:* As this information collection consists of usual and customary records kept by respondents during the normal course of business, under 5 CFR 1320.3(b)(2), there is no additional burden on respondents associated with this information collection.

OMB Control No. 1513–0061

Title: Letterhead Applications and Notices Relating to Denatured Spirits.

TTB Recordkeeping Number: TTB REC 5150/2.

Abstract: Under the IRC at 26 U.S.C. 5214, denatured spirits (alcohol to which denaturants have been added to render it unfit for beverage purposes) may be withdrawn from distilled spirits plants free of tax for nonbeverage industrial purposes in the manufacture of certain personal and household products. Since it is possible to recover potable alcohol from denatured spirits and articles made with denatured spirits, the IRC at 26 U.S.C. 5271–5275 sets forth provisions relating to denatured spirits and articles made with denatured spirits. Under those IRC authorities, the TTB regulations in 27 CFR part 20 require specially denatured spirits (SDS) dealers and manufacturers of nonbeverage products made with denatured alcohol to apply for and obtain a permit. In addition, the part 20 regulations that concern this information collection require such permit holders to submit letterhead applications and notices to TTB regarding certain changes to permit information, use of alternate methods and emergency variations from requirements, adoption or use of certain formulas, discontinuance of business, losses in transit, and requests to waive certain sample shipment and invoice requirements. The information collected implements the IRC's statutory provisions regarding denatured spirits.

Current Actions: There are no program changes or adjustments associated with this information collection at this time, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 3,800.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 3,800.
- *Average Per-response Burden:* 30 minutes.
- *Total Burden:* 1,900 hours.

OMB Control No. 1513–0086

Title: Marks on Equipment and Structures (TTB REC 5130.3), and Marks and Labels on Containers of Beer (TTB REC 5130.4).

TTB Recordkeeping Numbers: TTB REC 5130.3 and TTB REC 5130.4.

Abstract: Under the authority of chapter 51 of the IRC, the TTB regulations in 27 CFR part 25, Beer, require brewers to place certain marks, signs, and measuring devices on their equipment and structures, and to place certain brands, labels, and marks on bulk and consumer containers of beer and other brewery products. The required information identifies the use, capacity, and contents of brewery equipment and structures, as well as taxable brewery products and the responsible taxpayer. As such, the required information is necessary to protect the revenue and ensure effective administration of the IRC's provisions regarding brewery operations and products. The required information also identifies the contents of bulk and consumer containers of beer and other brewery products. For the purposes of inventory control, cost accounting, equipment utilization, and product identification, TTB believes that brewers would, in the normal course of business, place the information required under the regulations on their equipment and structures and on their bulk and consumers containers of beer and other brewery products, regardless of any TTB requirement to do so.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the estimated number of annual respondents and responses associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 13,720.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 13,720.
- *Average Per-response and Total Burden:* As this information collection consists of usual and customary marks and labels placed by brewers during the normal course of business, under 5 CFR 1320.3(b)(2), there is no additional burden on respondents associated with this information collection.

OMB Control No. 1513–0110

Title: Recordkeeping for Tobacco Products Removed in Bond from a Manufacturer's Premises for Experimental Purposes—27 CFR 40.232(e).

Abstract: The IRC at 26 U.S.C. 5704(a) provides that manufacturers of tobacco products may remove tobacco products for experimental purposes without payment of Federal excise tax, as prescribed by regulation. Under that authority, the TTB regulations at 27 CFR 40.232(e) require the keeping of certain usual and customary business records regarding the description, shipment, use, and disposition of tobacco products removed for experimental purposes outside of the factory. These records are subject to TTB inspection and are necessary to protect the revenue, as they allow TTB to account for the lawful experimental use and disposition of nontaxpaid tobacco products, and to detect diversion of such products into the domestic market.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 235.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 235.
- *Average Per-response and Total Burden:* As this information collection consists of usual and customary records kept by respondents during the normal course of business, under 5 CFR 1320.3(b)(2), there is no additional burden on respondents associated with this information collection.

OMB Control No. 1513–0111

Title: COLAs Online Access Request

TTB Form Number: TTB F 5013.2.

Abstract: To provide consumers with adequate information as to the identity of alcohol beverages and prohibit consumer deception, the FAA Act at 26 U.S.C. 205, and the TTB regulations in 27 CFR parts 4, 5, and 7 that implement that section, require alcohol beverage bottlers and importers to apply for Certificates of Label Approval (COLAs) for such products introduced into interstate commerce or released from customs custody. Domestic bottlers also must apply for COLA exemptions for certain alcohol beverage products that will not be introduced into interstate or foreign commerce. Respondents may complete and submit COLA and COLA exemption applications electronically using TTB's COLAs Online system. To protect TTB computer systems from cyber threats and misuse, persons desiring to use the COLAs Online system must first receive TTB approval of a COLAs Online Access Request. The collected information identifies the applicant and confirms their authority to act on behalf of a specific alcohol beverage industry member. Applicants submit COLAs Online Access Requests electronically using the COLAs Online User Registration function or its paper equivalent, TTB F 5013.2, COLAs Online Access Request.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the estimated number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 4,200.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 4,200.
- *Average Per-response Burden: 18 minutes*
- *Total Burden:* 1,260 hours.

OMB Control No. 1513–0124

Title: Customer Satisfaction Surveys for Permit Applications, Permits Online (PONL), Formulas Online (FONL), and COLAs Online.

Abstract: As part of TTB's efforts to improve customer service, we survey customers who submit applications for original or amended alcohol or tobacco permits, or for approval of alcohol beverage formulas or certificates of label approval (COLAs). These surveys assist TTB in identifying potential customer needs and problems, along with opportunities for improvement in our applications processes, with particular focus on customer experiences with TTB's various electronic application systems, Permits Online (PONL), Formulas Online (FONL), and COLAs Online.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the estimated number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; and Individuals or households.

- *Number of Respondents:* 16,000.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 16,000.
- *Average Per-response Burden:* 12 minutes.
- *Total Burden:* 3200 hours.

OMB Control No. 1513–0142

Title: CBMA Imports Refund Program—Foreign Producer Registration and Assignment System; CBMA Importer Refund Claims System.

Abstract: The IRC at 26 U.S.C. 5001, 5041, and 5051 imposes Federal excise tax on, respectively, distilled spirits, wine, and beer manufactured in or imported into the United States. Under the Craft Beverage Modernization Act (CBMA), certain limited quantities of those products are eligible for lower excise tax rates (see sections 13801–13808 of the Tax Cuts and Jobs Act of 2017, Pub. L. 115–97). Recent amendments to the IRC and CBMA made by the Taxpayer Certainty and Disaster Tax Relief Act of 2020 (Tax Relief Act; Division EE of Pub. L. 116–260) transferred responsibility for administering those CBMA reduced excise tax rate provisions from Customs and Border Protection (CBP) to the Treasury Department, effective January 1, 2023. In addition, rather than receiving CBMA tax benefits at the time of an import's entry, for entries after that date, U.S. importers are required to pay the full excise tax rate to CBP and then subsequently submit refund claims to Treasury to receive their assigned CBMA tax benefits. Under the IRC at 26 U.S.C. 5001(c), 5041(c), and 5051(a), a U.S. importer will only be eligible for CBMA tax benefits if a foreign producer has elected to assign, and the importer has elected to receive, such benefits in accordance with regulations and procedures issued by the Secretary. Finally, under the new provision at 26 U.S.C. 6038E, foreign producers electing to make such assignments are required to provide the information the Secretary requires by regulation, including information about controlled group structures of such producers.

Under those amended IRC authorities, and authorities delegated to TTB by the Secretary, TTB issued temporary regulations in 27 CFR part 27 establishing procedures for alcohol industry members to take advantage of the CBMA tax benefits (see T.D. TTB–186, 09/23/2022, 87 FR 58021). In particular, the new regulations establish the procedures by which (1) Foreign producers may assign CBMA tax benefits to U.S. importers, and (2) U.S. importers may elect to receive those assignments and submit their CBMA tax benefit refund claims to TTB. This information collection is required to ensure that the IRC provisions regarding

CBMA tax benefit refund claims for U.S. alcohol importers are appropriately applied, which is necessary to protect the revenue.

Current Actions: There are no program changes or adjustments associated with this information collection, which was recently approved by the Office of Management and Budget on an emergency basis, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 26,000.
- *Average Responses per Respondent:* 1.8077.
- *Number of Responses:* 47,000.
- *Average Per-response Burden:* 2 hours.
- *Total Burden:* 94,000 hours.

Dated: November 15, 2022.

Amy R. Greenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2022–25152 Filed 11–17–22; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons and property that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. Additionally, OFAC is publishing updates to the identifying information of one person currently included on the SDN List. OFAC is further publishing the name of one person that has been removed from the SDN List.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

A. On November 14, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked and also identified the following property as blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. ALIEV, Murat Magomedovich (Cyrillic: АЛИЕВ, Мурат Магомедович), Haldenstrasse, Bld 20, Apt. 1.2, Luzern 6006, Switzerland; Bolshoy Afanasyevskiy Lane, Apt. 41, Moscow 119019, Russia; Gesegnetmattstrasse 16/18, Luzern 6006, Switzerland; DOB 24 May 1979; POB Nalchik, Russia; nationality Russia; Gender Male; Passport 753717301 (Russia) issued 15 Sep 2016 expires 15 Sep 2026; alt. Passport 753606344 (Russia) issued 19 Aug 2016 expires 19 Aug 2026; National ID No. 8300091117 (Russia) (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation," 86 FR 20249 (April 19, 2021) (E.O. 14024) for operating or having operated in the financial services sector of the Russian Federation economy.

2. GADZHIEV, Nariman Gadzhievich (a.k.a. GADZHIYEV, Nariman Gadzhiyevich), Tannegg 1, St. Niklausen 6005, Switzerland; Dubai, United Arab Emirates; DOB 31 May 1976; POB Derbent, Russia; nationality Russia; alt. nationality Saint Kitts and Nevis; Gender Male; Passport RE0032776 (Saint Kitts and Nevis) issued 19 Feb 2015 expires 18 Feb 2025 (individual) [RUSSIA-EO14024] (Linked To: KERIMOV, Suleiman Abusaidovich).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, Suleiman Abusaidovich Kerimov, a person whose property and interests in property are blocked pursuant to E.O. 14024.

3. KATZ, Laurin, Switzerland; DOB 15 Jan 1988; POB Zurich, Switzerland; nationality Switzerland; Gender Male (individual) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

4. KERIMOV, Said Suleymanovich (a.k.a. KERIMOV, Said Suleimanovich), Apt 270, Build. 31, Pyatnitskoe Shosse, Moscow 123430, Russia; DOB 06 Jul 1995; POB Moscow, Russia; alt. POB Makhachkala, Republic of Dagestan, Russia; nationality Russia; Gender Male; Passport 724109376 (Russia) issued 17 Apr 2013 expires 17 Apr 2023; National ID No. 4515180935 (Russia); Tax ID No. 773382620676 (Russia) (individual) [RUSSIA-EO14024] (Linked To: KERIMOV, Suleiman Abusaidovich).

   Designated pursuant to section 1(a)(v) of E.O. 14024 for being a spouse or adult child of Suleiman Abusaidovich Kerimov, a person whose property and interests in property are blocked pursuant to section 1(a)(iii) of E.O. 14024.

5. KERIMOVA, Amina Suleymanovna (a.k.a. KERIMOVA, Aminat Suleymanovna), Apt. 270, Build. 31, Pyatnitskoe Shosse, Moscow 123430, Russia; DOB 26 Sep 2003; POB Moscow, Russia; nationality Russia; Gender Female; Passport 724263564 (Russia) issued 26 Apr 2013 expires 26 Apr 2023 (individual) [RUSSIA-EO14024] (Linked To: KERIMOV, Suleiman Abusaidovich).

   Designated pursuant to section 1(a)(v) of E.O. 14024 for being a spouse or adult child of Suleiman Abusaidovich Kerimov, a person whose property and interests in property are blocked pursuant to section 1(a)(iii) of E.O. 14024.

6. KERIMOVA, Firuza Nazimovna (a.k.a. KHANBALAEVA, Firuza Nazimovna), Apt. 270, Build. 31, Pyatnitskoe Shosse, Moscow 123430, Russia; DOB 22 Dec 1967; alt. DOB 22 Oct 1967; POB Makhachkala, Russia; nationality Russia; Gender Female; Passport 724348524 (Russia) issued 06 May 2013 expires 06 May 2023; National ID No. 4512970434 (Russia); Tax ID No. 052901215575 (Russia) (individual) [RUSSIA-EO14024] (Linked To: KERIMOV, Suleiman Abusaidovich).

   Designated pursuant to section 1(a)(v) of E.O. 14024 for being a spouse or adult child of Suleiman Abusaidovich Kerimov, a person whose property and interests in property are blocked pursuant to section 1(a)(iii) of E.O. 14024.

7. KERIMOVA, Gulnara Suleymanovna, Apt. 270, Build. 31, Pyatnitskoe Shosse, Moscow 123430, Russia; DOB 29 Apr 1990; POB Makhachkala, Russia; nationality Russia; Gender Female (individual) [RUSSIA-EO14024] (Linked To: KERIMOV, Suleiman Abusaidovich).

   Designated pursuant to section 1(a)(v) of E.O. 14024 for being a spouse or adult child of Suleiman Abusaidovich Kerimov, a person whose property and interests in property are blocked pursuant to section 1(a)(iii) of E.O. 14024.

8. LENG, Holger, Tallinn, Estonia; Switzerland; DOB 12 Jun 1969; nationality Estonia; alt. nationality Switzerland; Gender Male (individual) [RUSSIA-EO14024] (Linked To: MILUR SA).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Milur SA, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

9. PASCHE, Jacques, Switzerland; DOB 1955; nationality Switzerland; Gender Male (individual) [RUSSIA-EO14024] (Linked To: MILUR SA).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Milur SA, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

10. PAVLYUK, Mikhail Ilyich (Cyrillic: ПАВЛЮК, Михаил Ильич), Armenia; Russia; DOB 16 Nov 1966; POB Ukraine; nationality Russia; Gender Male (individual) [RUSSIA-EO14024] (Linked To: MILUR ELECTRONICS LLC).

    Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Milur Electronics LLC, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

11. RETTICH, Inga, Switzerland; Cyprus; DOB 06 Jul 1978; nationality Switzerland; Gender Female (individual) [RUSSIA-EO14024] (Linked To: BONUM CAPITAL CYPRUS LTD).

    Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Bonum Capital Cyprus Ltd, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

12. STUDHALTER, Alexander-Walter (a.k.a. STUDHALTER, Alexander), Oberruti-Allee 14, Horw 6048, Switzerland; United Kingdom; Luxembourg; Spain; Germany; France; DOB 25 Jul 1968; POB Luzern, Switzerland; nationality Switzerland; Gender Male (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the management consulting sector of the Russian Federation economy.

13. STUDHALTER, Hugo Ange Christophe (a.k.a. ETOURNEAU, Hugo Ange Christophe; a.k.a. STUDHALTER, Hugo), Oberruti-Allee 14, Horw 6048, Switzerland; DOB 12 Jan 2000; nationality France; alt. nationality Switzerland; Gender Male (individual) [RUSSIA-EO14024] (Linked To: SWISS INTERNATIONAL ADVISORY GROUP AG).

Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Swiss International Advisory Group AG, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

14. STUDHALTER, Jeremy Eric Camille (a.k.a. BAROZZI, Jeremy Eric Camille; a.k.a. STUDHALTER, Jeremy), Oberruti-Allee 14, Horw 6048, Switzerland; DOB 31 Oct 1996; POB Nice, Alpes-Maritimes, France; nationality France; Gender Male (individual) [RUSSIA-EO14024] (Linked To: SWISS INTERNATIONAL ADVISORY GROUP AG).

    Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of Swiss International Advisory Group AG, an entity whose property and interests in property are blocked pursuant to E.O. 14024.

Entities:

1. ADORABELLA AG (a.k.a. ADORABELLA LIMITED; a.k.a. ADORABELLA LTD; a.k.a. ADORABELLA MKOOO (Cyrillic: АДОРАБЕЛЛА МКООО); a.k.a. ADORABELLA SA), Dammstrasse 19, Zug 6300, Switzerland; Floor Office 1 G 25, B-R Solnechny, 25, Kaliningrad 236006, Russia; Organization Established Date 02 Jul 2021; Tax ID No. 495081111 (Switzerland); Legal Entity Number 2138006K8AF4JD339S40; Registration Number CH-170.3.046.017-9 (Switzerland) [RUSSIA-EO14024] (Linked To: GURYEV, Andrey Grigoryevich).

    Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of Andrey Grigoryevich Guryev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

2. ALSTONE INVESTMENT AG (a.k.a. ALSTONE INVESTMENT LTD; a.k.a. ALSTONE INVESTMENT SA; f.k.a. SWIRU HOLDING AG; f.k.a. SWIRU TRUSTEE LTD), Zentralstrasse 44, Luzern 6003, Switzerland; Matthofstrand 8, Luzern 6005, Switzerland; 380 Avenue Mrs L'D'Beaumont, Antibes 06160, France; Organization Established Date 30 May 1996; Tax ID No. 103488986 (Switzerland); alt. Tax ID No. 893478818 (France); Legal Entity Number 5493009YJ817TFZ7IY48; Registration Number CH-150.3.002.065-2 (Switzerland) [RUSSIA-EO14024] (Linked To: KATZ, Laurin).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Laurin Katz, a person whose property and interests in property are blocked pursuant to E.O. 14024.

3. BONUM CAPITAL CYPRUS LTD (Cyrillic: БОНУМ КАПИТАЛ КИПР ЛТД) (a.k.a. BONUM KAPITAL KIPR LTD), Themis Court, Flat No: D3, Floor No: 4, Evagora Papachristoforou 4, Limassol 3030, Cyprus; Organization Established Date 12 Jun 2013; Organization Type: Activities of holding companies; Tax ID No. CY10322854N (Cyprus); alt. Tax ID No. 9909479852 (Russia); Legal Entity

Number 213800CACNBGHWMQHO54; Registration Number HE322854 (Cyprus) [RUSSIA-EO14024] (Linked To: ALIEV, Murat Magomedovich).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Murat Magomedovich Aliev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

4. BONUM CAPITAL INVESTORS CORP (Cyrillic: БОНУМ КАПИТАЛ ИНВЕСТОРС КОРП), Road Town, Tortola, Virgin Islands, British; Organization Established Date 2016; Organization Type: Activities of holding companies [RUSSIA-EO14024] (Linked To: ALIEV, Murat Magomedovich).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Murat Magomedovich Aliev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

5. CHLODWIG ENTERPRISES AG (a.k.a. CHLODWIG ENTERPRISES LIMITED; a.k.a. CHLODWIG ENTERPRISES LTD; a.k.a. CHLODWIG ENTERPRISES МКООО (Cyrillic: ХЛОДВИГ ЭНТЕРПРАЙЗЕС МКООО); a.k.a. CHLODWIG ENTERPRISES SA), Dammstrasse 19, Zug 6300, Switzerland; Floor Office 1 G 25, B-R Solnechny, 25, Kaliningrad 236006, Russia; Organization Established Date 02 Jul 2021; Tax ID No. 277019596 (Switzerland); Legal Entity Number 213800HY3Z8VE6A5MX68; Registration Number CH-170.3.046.014-2 (Switzerland) [RUSSIA-EO14024] (Linked To: GURYEV, Andrey Grigoryevich).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of Andrey Grigoryevich Guryev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

6. CONSTELLATION ADVISORS LTD (Arabic: كونستيلاشين ادفيزرز ليمتد), Unit S310, Level 3, Emirates Financial Towers, Dubai International Financial Centre, Dubai 506980, United Arab Emirates; Organization Established Date 17 Feb 2015; Organization Type: Activities of holding companies; Registration Number 114390063 (United Arab Emirates) [RUSSIA-EO14024] (Linked To: GADZHIEV, Nariman Gadzhievich).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Nariman Gadzhievich Gadzhiev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

7. EMPEROR AVIATION LTD (a.k.a. EMPEROR AVIEISHN LTD (Cyrillic: ЭМПЕРОР АВИЭЙШН ЛТД)), W Business Centre, Level 3, Triq Karmenu Pirotta, Birkirkara BKR 1114, Malta; Presnenskaya nab. 8/1, Moscow 123112, Russia; Organization Established Date 27 Nov 2013; Tax ID No. 21637116 (Malta); alt. Tax ID No. 9909425511 (Russia); Registration Number C 62836 (Malta) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

Designated pursuant to sections 1(a)(i) and 1(a)(vi)(B) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy and for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

8. EURIMO HOLDING SA, Rue Guillaume J. Kroll 12C, Luxembourg 1882, Luxembourg; Organization Established Date 28 Jul 2008; Organization Type: Activities of holding companies; Tax ID No. B 140.315 (Luxembourg); Legal Entity Number 549300536OAT4X4PNG53 [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

9. LIMITED LIABILITY COMPANY AVIAKOMPANIYA DALNEVOSTOCHNAYA KSM (a.k.a. AVIAKOMPANIYA DALNEVOSTOCHNAYA KSM OOO), ul. Pionerskaya d. 39, pomeshch. 1001, Komsomolsk-on-Amur 681000, Russia; Organization Established Date 08 Oct 2014; Organization Type: Freight air transport; Tax ID No. 2703080980 (Russia); Registration Number 1142703004014 (Russia) [RUSSIA-EO14024] (Linked To: ALIEV, Murat Magomedovich).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Murat Magomedovich Aliev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

10. LIMITED LIABILITY COMPANY BONUM CAPITAL (a.k.a. BONUM CAPITAL LLC; a.k.a. BONUM KEPITAL OOO), per. Staromonetnyi d. 37, str. 1, pom. I, floor 3, komn. 15, Moscow 119017, Russia; per. Romanov d. 4, et/pom/kom 4/I/32, Moscow 125009, Russia; Tsvetnoy b-r, 15, building 1, room 63, Moscow 127051, Russia; Organization Established Date 27 Sep 2011; Organization Type: Trusts, funds and similar financial entities; Tax ID No. 7722757160 (Russia); Legal Entity Number 253400XGWKKNWUCF4147; Registration Number 1117746760130 (Russia) [RUSSIA-EO14024] (Linked To: ALIEV, Murat Magomedovich).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Murat Magomedovich Aliev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

11. LIMITED LIABILITY COMPANY BONUM INVESTMENTS (a.k.a. BONUM INVESTMENTS OOO), per. Romanov d. 4, et/pom/kom 4/I/30, Moscow 125009, Russia; Organization Established Date 20 Feb 2015; Organization Type: Other financial service activities, except insurance and pension funding activities,

n.e.c.; Tax ID No. 7706417487 (Russia); Registration Number 1157746124656 (Russia) [RUSSIA-EO14024] (Linked To: ALIEV, Murat Magomedovich).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Murat Magomedovich Aliev, a person whose property and interests in property are blocked pursuant to E.O. 14024.

12. LIMITED LIABILITY COMPANY BONUM MANAGEMENT (a.k.a. BONUM MENEDZHMENT OOO), B-r Tsvetnoi d. 15, str. 1, pomeshch. 59, Moscow 127051, Russia; Organization Established Date 09 Dec 2016; Organization Type: Other financial service activities, except insurance and pension funding activities, n.e.c.; Tax ID No. 7706444723 (Russia); Registration Number 5167746424621 (Russia) [RUSSIA-EO14024] (Linked To: BONUM CAPITAL CYPRUS LTD).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Bonum Capital Cyprus Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024.

13. LIMITED LIABILITY COMPANY RB-ESTEIT (a.k.a. RB-ESTEIT OOO), ul. Akademika Zhukova d. 25A, et/pom/of 4/17/404, Dzerzhinskiy 140090, Russia; Organization Established Date 28 Dec 2018; Organization Type: Real estate activities with own or leased property; Tax ID No. 5027271906 (Russia); Registration Number 1185027032794 (Russia) [RUSSIA-EO14024] (Linked To: LIMITED LIABILITY COMPANY BONUM INVESTMENTS).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Limited Liability Company Bonum Investments, a person whose property and interests in property are blocked pursuant to E.O. 14024.

14. MG INTERNATIONAL AG (a.k.a. JSC MG INTERNATIONAL AG; a.k.a. MG INTERNESHNL AG PREDSTAVITELSTVO; f.k.a. MILLENNIUM GROUP AG; a.k.a. PRED AO MG INTERNESHNL AG; a.k.a. PREDSTAVITELSTVO AKTSIONERNOGO OBSHCHESTVA MG INTERNESHNL AG SHVEITSARIYA G MOSCOW), Matthofstrand 8, Luzern 6005, Switzerland; per. Staromonetnyi d. 37, korp. 1, Moscow 119017, Russia; Organization Established Date 27 Sep 2006; Organization Type: Management consultancy activities; Tax ID No. 113176962 (Switzerland); alt. Tax ID No. 9909260877 (Russia); Legal Entity Number 549300YR513TAPXJGM21; Registration Number CH-100.3.786.838-5 (Switzerland) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the management consulting sector of the Russian Federation economy.

15. MILUR ELECTRONICS LLC (Armenian: ՄԻԼՈՐ ԷԼԵՔԹՐՈՆԻՔՍ ՍՊԸ), Raffi Str. #111, Malatia-Sebastia, Yerevan, Armenia; Organization Established Date 13 May 2022; Organization Type: Wholesale of electronic and telecommunications equipment and parts; Tax ID No. 01322889 (Armenia);

Registration Number 290.110.1237526 (Armenia) [RUSSIA-EO14024] (Linked To: JSC PKK MILANDR).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JSC PKK Milandr, a person whose property and interests in property are blocked pursuant to E.O. 14024.

16. MILUR SA, Chemin Des Planches 42, Epalinges 1066, Switzerland; Avenue des Alpes 104, Montreux 1820, Switzerland; Organization Established Date 10 Feb 2012; Organization Type: Wholesale of electronic and telecommunications equipment and parts; alt. Organization Type: Wholesale of other machinery and equipment; Registration Number CH-1550.1.105.045-4 (Switzerland) [RUSSIA-EO14024] (Linked To: MILUR ELECTRONICS LLC).

    Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of Milur Electronics LLC, a person whose property and interests in property are blocked pursuant to E.O. 14024.

17. PAPA OSCAR VENTURES GMBH (f.k.a. DWNTOWN.LA GMBH; f.k.a. PAPA OSCAR FASHION GROUP GMBH), Mainzer Landstr. 33, Frankfurt am Main 60329, Germany; Organization Established Date 12 Jun 2017; Organization Type: Activities of holding companies; Tax ID No. DE 313145928 (Germany); Legal Entity Number 391200IDSLOEBYSU9N27; Registration Number HRB 109296 (Germany) [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

18. PAPA OSCAR VENTURES SE SL, Calle Girona 67 - P. 3 PTA. 2, Barcelona 08009, Spain; Organization Established Date 01 Oct 2021; Organization Type: Activities of holding companies; Tax ID No. B16961633 (Spain) [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

19. SCI AAA PROPERTIES, Domaine Antica Serena, 309 Avenue Jules Romains, Nice 06100, France; Organization Established Date 19 Sep 2013; Organization Type: Real estate activities with own or leased property; Tax ID No. 797404373 (France); Legal Entity Number 549300AO0ISQ6ILHUU63 [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or

indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

20. SERVICE IMMOBILIERE ANTIBES SAS, 200 Impasse Felix, Antibes 06160, France; Organization Established Date 18 Sep 2006; Organization Type: Real estate activities with own or leased property; alt. Organization Type: Real estate activities on a fee or contract basis; Tax ID No. 491975553 (France) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

21. SERVICE IMMOBILIERE ET GESTION SAS, 200 Impasse Felix, Antibes 06160, France; Organization Established Date 05 Feb 2013; Organization Type: Real estate activities on a fee or contract basis; Tax ID No. 791354566 (France) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

22. SHARP EDGE ENGINEERING INC. (Chinese Traditional: 銳元科技有限公司) (a.k.a. RUIYUAN KEJI YOUXIAN GONGSI), 8F-4, Alley 22, Lane 513, Ruigang Rd. No 5, Taipei City, Neihu Dist., Taiwan; Organization Established Date 13 Dec 2016; Organization Type: Wholesale of other machinery and equipment; Tax ID No. 52484961 (Taiwan) [RUSSIA-EO14024] (Linked To: JSC PKK MILANDR).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JSC PKK Milandr, a person whose property and interests in property are blocked pursuant to E.O. 14024.

23. STUDHALTER INTERNATIONAL GROUP AG (f.k.a. RUFIN FINANZ AG; a.k.a. STUDHALTER INTERNATIONAL GROUPE AG; f.k.a. STUURMAN HOLDING AG), Matthofstrand 8, Luzern 6005, Switzerland; Organization Established Date 24 Mar 1998; Organization Type: Other financial service activities, except insurance and pension funding activities, n.e.c.; Tax ID No. 100923804 (Switzerland); Legal Entity Number 529900J9I6AM3N2EI717; Registration Number CH-100.3.021.077-4 (Switzerland) [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

24. SWISS INTERNATIONAL ADVISORY GROUP AG (f.k.a. INTRACONT TREUHAND AG; f.k.a. STUDHALTER TREUHAND AG), Matthofstrand 8, Luzern 6005, Switzerland; Organization Established Date 04 Nov 1986; Organization Type: Accounting, bookkeeping and auditing activities; tax consultancy; Tax ID No. 103755348 (Switzerland); Legal Entity Number 5493005XWZ1Q6ED29G15; Registration Number CH-100.3.006.955-6 (Switzerland) [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

25. SWISS INTERNATIONAL REAL ESTATE PORTFOLIO AG (f.k.a. SWISS INTERNATIONAL REAL ESTATE AG; f.k.a. V. MICHEL IMMOBILIEN AG), Matthofstrand 8, Luzern 6005, Switzerland; Organization Established Date 23 Oct 1996; Organization Type: Real estate activities with own or leased property; Tax ID No. 103524234 (Switzerland); Legal Entity Number 549300GY21AQGXZ45018; Registration Number CH-100.3.019.281-6 (Switzerland) [RUSSIA-EO14024] (Linked To: STUDHALTER, Alexander-Walter).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Alexander-Walter Studhalter, a person whose property and interests in property are blocked pursuant to E.O. 14024.

26. VH ANTIBES SAS, 200 Impasse Felix, Antibes 06160, France; 19 Boulevard Malesherbes, Paris 75008, France; Organization Established Date 15 May 2008; Organization Type: Real estate activities with own or leased property; Registration Number 504317025 (France) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

27. VILLA LEXA ESTATES SAS, 19 Boulevard Malesherbes, Paris 75008, France; Organization Established Date 01 Dec 2010; Organization Type: Real estate activities with own or leased property; Tax ID No. 528873854 (France) [RUSSIA-EO14024] (Linked To: KERIMOVA, Gulnara Suleymanovna).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Gulnara Suleymanovna Kerimova, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Aircraft:

1. 9H-AMN; Aircraft Manufacture Date 2006; Aircraft Model BD-700-1A11; Aircraft Manufacturer's Serial Number (MSN) 9324; Aircraft Tail Number 9H-AMN (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

2. 9H-ARK; Aircraft Manufacture Date 2019; Aircraft Model BD-700-1A10; Aircraft Manufacturer's Serial Number (MSN) 60011; Aircraft Tail Number 9H-ARK (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

3. 9H-EAA; Aircraft Manufacture Date 2014; Aircraft Model Citation XLS+; Aircraft Manufacturer's Serial Number (MSN) 560-6170; Aircraft Tail Number 9H-EAA (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).
   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

4. 9H-MAO; Aircraft Manufacture Date 2006; Aircraft Model BD-700-1A10; Aircraft Manufacturer's Serial Number (MSN) 9223; Aircraft Tail Number 9H-MAO (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

5. 9H-OKO; Aircraft Manufacture Date 2018; Aircraft Model G650; Aircraft Manufacturer's Serial Number (MSN) 6356; Aircraft Tail Number 9H-OKO (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

6. 9H-SIS; Aircraft Manufacture Date 2015; Aircraft Model CL-600-2B16 (604 Variant); Aircraft Manufacturer's Serial Number (MSN) 6050; Aircraft Tail Number 9H-SIS (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

7. 9H-SSK; Aircraft Manufacture Date 2016; Aircraft Model G650; Aircraft Manufacturer's Serial Number (MSN) 6195; Aircraft Tail Number 9H-SSK (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

8. 9H-TIO; Aircraft Manufacture Date 2018; Aircraft Model BD-700-1A11; Aircraft Manufacturer's Serial Number (MSN) 9813; Aircraft Tail Number 9H-TIO (aircraft) [RUSSIA-EO14024] (Linked To: EMPEROR AVIATION LTD).

   Identified as property in which Emperor Aviation Ltd, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

B. On November 14, 2022, OFAC resolved one or more duplicate entries on OFAC's lists for the following person designated pursuant to the Sergei Magnitsky Rule of Law Accountability Act of 2012, Public Law 112-208, Title IV (the Magnitsky Act); Executive Order 13818 of December 20, 2017, "Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption," 82 FR 60839, 3 CFR, 2018 Comp., p. 399, (E.O. 13818); and E.O. 14024, and whose property and interests in property subject to U.S. jurisdiction continue to be blocked under the Magnitsky Act, E.O. 13818, and E.O. 14024. To resolve these duplicate entries, OFAC updated one entry on the SDN List and additionally removed one entry on the SDN List.

Updated Entry:

1. KADYROV, Ramzan Akhmatovich (a.k.a. KADYROV, Ramzan; a.k.a. KADYROW, Ramzan Achmatowisch), Russia; DOB 05 Oct 1976; POB Tsentoroi, Chechen Republic, Russia; nationality Russia; Gender Male (individual) [MAGNIT] [GLOMAG].

-to-

KADYROV, Ramzan Akhmatovich (Cyrillic: КАДЫРОВ, Рамзан Ахматович) (a.k.a. KADYROV, Ramzan Akhmadovitch), Republic of Chechnya, Russia; Palm Jumeirah, Dubai, United Arab Emirates; DOB 05 Oct 1976; POB Tsenteroi, Republic of Chechnya, Russia; nationality Russia; Gender Male (individual) [MAGNIT] [GLOMAG] [RUSSIA-EO14024].

Removed Entry:

1. KADYROV, Ramzan Akhmatovich (Cyrillic: КАДЫРОВ, Рамзан Ахматович) (a.k.a. KADYROV, Ramzan Akhmadovitch), Republic of Chechnya, Russia; Palm Jumeirah, Dubai, United Arab Emirates; DOB 05 Oct 1976; POB Tsenteroi, Republic of Chechnya, Russia; nationality Russia; Gender Male (individual) [MAGNIT] [GLOMAG] [RUSSIA-EO14024].

Dated: November 14, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25084 Filed 11–17–22; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.
Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules; Final and Interim Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 423, 424, 425, and 455

[CMS–1770–F, CMS–1751–F2, CMS–1744–F2, CMS–5531–IFC]

RINs 0938–AU81, 0938–AU95, 0938–AU31, 0938–AU32

Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule and interim final rules.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; updates to conditions of payment for DMEPOS suppliers; HCPCS Level II coding and payment for wound care management products; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act); updates to the Medicare Ground Ambulance Data Collection System; provisions under the Infrastructure Investment and Jobs Act; and finalizes the CY 2022 Methadone Payment Exception for Opioid Treatment Programs IFC. We are also finalizing, as implemented, a few provisions included in the COVID–19 interim final rules with comment period.

DATES: These regulations are effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

Sarah Leipnik, (410) 786–3933, and Anne Blackfield, (410) 786–8518, for issues related to the comment solicitation on strategies for improving global surgical package valuation.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Regina Walker-Wren, (410) 786–9160, for issues related to nurse practitioner and clinical nurse specialist certification by the Nurse Portfolio Credentialing Center (NPCC).

Lindsey Baldwin, (410) 786–1694, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to PFS payment for behavioral health services.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for evaluation and management services.

Geri Mondowney, (410) 786–1172, Morgan Kitzmiller, (410) 786–1623, Julie Rauch, (410) 786–8932, and Tamika Brock, (312) 886–7904, for issues related to malpractice RVUs and geographic practice cost indices (GPCIs).

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to non-face-to-face nonphysician services/remote therapeutic monitoring services (RTM).

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Pamela West, (410) 786–2302, for issues related to revisions to regulations to allow audiologists to furnish diagnostic tests, as appropriate without a physician order.

Emily Forrest, (410) 786–8011, Laura Ashbaugh, (410) 786–1113, Anne Blackfield, (410) 786–8518, and Erick Carrera, (410) 786–8949, for issues related to PFS payment for dental services.

Heidi Oumarou, (410) 786–7942, for issues related to the rebasing and revising of the Medicare Economic Index (MEI).

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, and Rachel Radzyner, (410) 786–8215, for issues related to requiring manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds with respect to discarded amounts.

Laura Ashbaugh, (410) 786–1113, and Rasheeda Arthur, (410) 786–3434, for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov*, for issues related to FQHCs.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, for issues related to RHCs.

Daniel Feller, (410) 786–6913, and Elizabeth Truong (410) 786–6005, for issues related to coverage of colorectal cancer screening.

Heather Hostetler, (410) 786–4515, for issues related to removal of selected national coverage determinations.

Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Aryanna Abouzari, (415) 744–3668, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program burden reduction proposal on OHCAs.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and financial methodology.

Lucy Bertocci, (410) 786–4008, or *SharedSavingsProgram@cms.hhs.gov*, for inquiries related to Shared Savings Program advance investment payments, participation options and burden reduction policies.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to vaccine administration services.

Katie Parker, (410) 786–0537, for issues related to medical necessity and documentation requirements for nonemergency, scheduled, repetitive ambulance services.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider

enrollment regulation updates (including for skilled nursing facilities), State options for implementing Medicaid provider enrollment affiliation provisions, and conditions of payment for DMEPOS suppliers.

Mei Zhang, (410) 786–7837, and Kimberly Go, (410)786–4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov*, for issues related to the Medicare Ground Ambulance Data Collection System and Ambulance Fee Schedule (AFS).

Sundus Ashar, *Sundus.ashar1@cms.hhs.gov*, for issues related to HCPCS Level II Coding for skin substitutes.

Renee O'Neill, (410) 786–8821, or Kati Moore, (410) 786–5471, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

Lindsey Baldwin, (410) 786–1694 for inquiries related to Opioid Treatment Programs: CY 2022 Methadone Payment Exception.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022), Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021), Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major final rule includes provisions regarding other Medicare payment policies described in sections III. and IV.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2023 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this final rule addresses:

- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Determination of Malpractice Relative Value Units (RVUs) (section II.H.)
- Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services (section II.I.)
- Payment for Skin Substitutes (section II.J.)
- Provision to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order (section II.K.)
- Provisions on Medicare Parts A and B Payment for Dental Services (section II.L.)
- Rebasing and Revising the Medicare Economic Index (MEI) (section II.M.)
- Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940) (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests (section III.C.)
- Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers (section III.D.)
- Removal of Selected National Coverage Determinations (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services (section III.I.)
- Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (section III.J.)
- State Options for Implementing Medicaid Provider Enrollment Affiliation Provision (section III.K.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.L.)
- Medicare Ground Ambulance Data Collection System (GADCS) (section III.M.)
- Revisions to HCPCS Level II Coding Procedures for Skin Substitutes Products (section III.N.)
- Updates to the Quality Payment Program (section IV.)
- Opioid Treatment Programs: CY 2022 Methadone Payment Exception and Origin and Destination Requirements Under the Ambulance Fee Schedule (section V.A.)
- Finalizing provisions from the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (CMS–1744–IFC) (Section V.B.)
- Finalizing provisions from the Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS–5531–IFC) (Section V.C.)
- Collection of Information Requirements (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic

impacts, see section VII., Regulatory Impact Analysis, of this final rule.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2023 PFS final rule PE/HR'' on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the

indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting

the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for CY 2023. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the major adverse impact on MP RVUs that result from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of several dozen low volume HCPCS codes with recommended expected specialty assignments.

Response: After reviewing the information provided by the commenters to determine that the submitted specialty assignments were appropriate for the service in question, we are finalizing the additions in Table 1 to the list of expected specialty assignments for low volume services.

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TABLE 1: New Additions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Expected Specialty Assignment
15650	Transfer skin pedicle flap	Plastic and Reconstructive Surgery
15787	Abrasion lesions add-on	Internal Medicine
20705	Rmvl i-artic rx delivery dev	Orthopedic Surgery
21070	Remove coronoid process	Otolaryngology
21336	Open tx septal fx w/wo stabj	Otolaryngology
21440	Treat dental ridge fracture	Maxillofacial Surgery
23031	Drain shoulder bursa	Orthopedic Surgery
24160	Remove elbow joint implant	Orthopedic Surgery
24620	Treat elbow fracture	Orthopedic Surgery
26685	Treat hand dislocation	Hand Surgery
26705*	Treat knuckle dislocation	Orthopedic Surgery
26706	Pin knuckle dislocation	Hand Surgery
27448	Incision of thigh	Orthopedic Surgery
28405	Treatment of heel fracture	Orthopedic Surgery
31090	Exploration of sinuses	Otolaryngology
31643	Diag bronchoscope/catheter	Pulmonary Disease
31661	Bronch thermoplsty 2/> lobes	Pulmonary Disease
31830	Revise windpipe scar	Otolaryngology
33370*	Tcat plmt&rmvl cepd perq	Cardiology
33406	Replacement aortic valve opn	Thoracic Surgery
33894*	Evasc st rpr thrc/aa acrs br	Cardiology
33895*	Evasc st rpr thrc/aa x crsg	Cardiology
33897*	Perq trluml angp nt/recr coa	Cardiology
33997*	Rmvl perq right heart vad	Cardiology
34702	Evasc rpr a-ao ndgft rpt	Vascular Surgery
35587	Vein byp pop-tibl peroneal	Vascular Surgery
41114	Excision of tongue lesion	Otolaryngology
41153	Tongue mouth neck surgery	Otolaryngology
43112	Esphg tot w/thrcm	Thoracic Surgery
43770	Lap place gastr adj device	General Surgery
43880	Repair stomach-bowel fistula	General Surgery
45392	Colonoscopy w/endoscopic fnb	Gastroenterology
52327	Cystoscopy inject material	Urology
52400	Cystouretero w/congen repr	Urology
53665	Dilation of urethra	Urology
58140	Myomectomy abdom method	Obstetrics/Gynecology
58670	Laparoscopy tubal cautery	Obstetrics/Gynecology
59320	Revision of cervix	Obstetrics/Gynecology
61316	Implt cran bone flap to abdo	Neurosurgery
64583	Rev/rplct hpglsl nstm ary pg	Otolaryngology
64584	Rmvl hpglsl nstim ary pg	Otolaryngology
64834	Repair of hand or foot nerve	Hand Surgery
66720	Destruction ciliary body	Ophthalmology
67570	Decompress optic nerve	Ophthalmology
67902	Repair eyelid defect	Ophthalmology
68510	Biopsy of tear gland	Ophthalmology
69661	Revise middle ear bone	Otolaryngology
69716	Impltj oi implt skl tc esp	Otolaryngology
69719	Revj/rplcmt oi implt tc esp	Otolaryngology
69726	Rmvl oi implt skl perq esp	Otolaryngology
69727	Rmvl oi implt skl tc esp	Otolaryngology
77790	Radiation handling	Radiation Oncology
78660	Nuclear exam of tear flow	Nuclear Medicine
90956	Esrd srv 1 visit p mo 2-11	Nephrology
91113	Gi trc img intral colon i&r	Gastroenterology

HCPCS	Short Descriptor	Expected Specialty Assignment
92230	Eye exam with photos	Ophthalmology
93319	3d echo img cgen car anomal	Cardiology
94610	Surfactant admin thru tube	Pediatric Medicine
94625	Phy/qhp op pulm rhb w/o mntr	Pulmonary Disease
95958	Eeg monitoring/function test	Neurology
0446T	Insj impltbl glucose sensor	Endocrinology
0447T	Rmvl impltbl glucose sensor	Endocrinology
0448T	Remvl insj impltbl gluc sens	Endocrinology
G9488	Remote e/m est. pt 25mins	Internal Medicine

* Recommended specialty assignment crosswalked; see below.

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Comment: Commenters recommended an expected specialty assignment of interventional cardiology for CPT codes 33370, 33894, 33895, 33897, and 33997.

Response: We do not have PE/HR data for the interventional cardiology specialty as it was not part of the PPIS when it was conducted in 2007. We use the cardiology specialty for this specialty's PE/HR data, and therefore, we have crosswalked the CPT codes in question to the cardiology specialty on the list of expected specialty assignments for low volume services.

Comment: Commenters also recommended an expected specialty assignment of hand surgery for CPT code 26705.

Response: During our review of claims data for this code, we found that the most frequently reported specialty for CPT code 26705 was orthopedic surgery, reported more than twice as often as the hand surgery specialty. Therefore, we are finalizing orthopedic surgery and not hand surgery as the expected specialty assignment for CPT code 26705.

We also note for commenters that each HCPCS code that appears on the list of expected specialty assignments for low volume services remains on the list from year to year, even if the volume for the code in question rises to over 100 services for an individual calendar year. The HCPCS codes and expected specialty assignment remain on the list, and will be applied should the volume fall below 100 services in any calendar year; there is no need to ''reactivate'' individual codes as some commenters have suggested in past submissions.

After consideration of the public comments, we are finalizing the updates to the list of expected specialty assignments for low volume services as detailed above.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated

in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

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TABLE 2: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- Payment modifiers: Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.
usage = variable, see discussion below in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different

types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose and we are not finalizing any changes to the equipment interest rates for CY 2023.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

For CY 2023, as explained in detail in section II.M. of this final rule, we proposed to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. The MEI is an index that measures changes in the market price of the inputs used to furnish physician services. This index measure is authorized under section 1842(b)(3) of the Act, and is developed by the CMS Office of the Actuary. We believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, PE and malpractice. Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the MEI. In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs and the CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments to the RVUs to reflect changes in the MEI weights were made for the CY 2014 RVUs, when the MEI was last updated. In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the past when we have proposed a rebasing and/or revision of the MEI, as we discuss in section II.M. of this final rule, we typically have also proposed to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2014 PFS final rule. Instead, we proposed to delay the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the proposed rebased and revised MEI, which is being finalized for CY 2023, as discussed in section II.M. of this final rule. Because we proposed significant methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since

the last rebasing and revision of the MEI, we explained that we believe it is important to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporated the updated MEI into PFS ratesetting, and we believe this is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in section II.B. of this final rule, where we review our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. Similarly, we delayed the implementation of the proposed rebased and revised MEI for use in the PE geographic practice cost index (GPCI) and solicited comment on appropriate timing for implementation for potential future rulemaking, discussed in detail in section II.G. and section VI. of this final rule.

In light of the proposed delay in using the proposed update to the MEI to make the adjustments to the PE pools in steps 3 and 10 and the relativity adjustment in step 18, we solicited comment on when and how to best incorporate the proposed rebased and revised MEI discussed in section II.M. of the proposed rule into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. In section VI. of this final rule, we present the impacts of implementing the proposed rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period. Given the significance of the impacts that result from a full implementation and the interaction with other CY 2023 proposals, we did not consider proposing to fully implement a rebased and revised MEI in PFS ratesetting for CY 2023. We solicited comment on other implementation strategies for potential future rulemaking that are not outlined in section VI. of this final rule.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposed delayed implementation of the rebased and revised MEI in PFS ratesetting until the public had an opportunity to comment on the proposed changes to the MEI, as discussed in section II.M. of this final rule.

Response: We thank the commenters for their support.

Comment: Many commenters expressed concerns with the redistributive impacts discussed in section VI. of the proposed rule, where we discussed the alternative considered to implement the proposed rebased and revised MEI in PFS ratesetting through a 4-year transition for CY 2023. Many of the commenters cited other proposals and their confluence with the proposed rebased and revised MEI as a source of their concerns regarding the implementation of the MEI in PFS ratesetting. Most commenters noted that the AMA has said it intends to collect practice cost data from physician practices in the near future and urged CMS to pause consideration of other sources for the MEI until the AMA's efforts have concluded. A few commenters urged CMS to implement the MEI for PFS ratesetting when appropriate using a 4-year transition to minimize shifts and maintain stability in PFS payments.

Response: We appreciate commenters' feedback, specifically as it relates to updating PFS ratesetting, and will consider this information in future rulemaking. We note that we discuss comments relating to the proposed rebased and revised MEI in section II.M. of this final rule.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2023 direct PE input public use files, which are available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes

with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2023, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2023, we proposed to update the price of eight supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2022 PFS final rule. The eight supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 19, CY 2023 Invoices Received for Existing Direct PE Inputs.

We received the following comments on our proposal to update the price of eight supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2022 PFS final rule:

Comment: Several commenters submitted comments to clarify that the invoice they included in their submission that was identified as the Lysing Reagent (SL089) supply was intended for a different supply item, the Lysing Solution (SL039). The commenters stated that our proposed reduction of the price for the SL089 supply appeared to be based on the invoice they had as misidentified as being for the SL089 supply, when it was intended for the SL039 supply. The commenters asked CMS to disregard the earlier mistaken submission and submitted additional invoices with updated pricing for the SL089 supply for consideration to correct the oversight in their original submission.

Response: We appreciate the clarification from the commenters and the updated invoices with pricing information for the SL089 supply. We are finalizing an increase in the price of the Lysing Reagent (SL089) supply to $5.53 based on the average of the ten submitted invoices from the commenter. (Note: the separate discussion of the SL039 supply below is based on a different invoice submitted by a different interested party unconnected to the SL089 supply. We believe it is appropriate to consider and revise the price for the SL089 supply based on the clarification and new invoices submitted by commenters for that supply. However, given that the invoice for SL039 submitted by these commenters was not intended to be submitted for the SL039 supply, we did not consider the invoice for SL039 that was mistakenly submitted by these commenters.)

Comment: Several commenters stated their support for the proposed pricing changes to the EP014 and EP088 equipment items and the SA117, SK082, SL024, SL030, SL061, and SL469 supply items. The commenters urged CMS to finalize them as proposed in the final rule.

Response: We appreciate the support for our proposed pricing from the commenters.

In the proposed rule, we did not propose to update the price of another eight supplies and two equipment items which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- *Acetic acid 5% (SH001):* We received an invoice submission that would suggest an increase in price from 3 cents per ml to 9.5 cents per ml for the SH001 supply. However, the invoice stated that this price was for an ''Alcian Blue 1% in 3% Acetic Acid pH 2.5'' supply and it is not clear that this represents the same supply as the ''Acetic acid 5%'' described by the SH001 supply item. We also do not believe that the typical price for this supply has increased 200 percent in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SH001 supply from 1.2 cents in CY 2019 to its current price of 3 cents for CY 2022.
- *Cytology, lysing soln (CytoLyt) (SL039):* We received an invoice submission that would suggest an increase in price from 6 cents per ml to 80 cents per ml for the SL039 supply. We do not believe that the typical price for this supply has increased 1200% in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SL039 supply from 3.4 cents in CY 2019 to its current price of 6 cents for CY 2022.
- *Fixative (for tissue specimen) (SL068):* We received an invoice submission that would suggest an increase in price from 1.3 cents per ml to $4.87 for the SL068 supply. We believe that this was the result of confusion on the part of the interested party regarding the unit quantity for the SL068 supply. This item is paid on a per ml basis and not a per unit basis; there was not enough information on the submitted invoice to determine the price for the SL068 supply on a per ml basis.
- *Ethanol, 100% (SL189):* We received an invoice submission that would suggest an increase in price from 0.33 cents per ml to 1.2 cents per ml for the SL189 supply. However, we noted that the invoice was based on the price for a single gallon of 100% ethanol which is typically sold in much larger quantities than a single gallon. We found that 100% ethanol was readily available for sale online in larger unit sizes and the current price of 0.33 cents per ml (based on the past StrategyGen market research) appears to be accurate based on online bulk pricing. We also found that the submitted invoices for the ethanol, 70% (SL190), ethanol, 95% (SL248), and stain, PAP OG–6 (SL491) supplies were also based on pricing for a single gallon. Each of these supply items was also available for purchase in larger unit quantities which indicated that the current pricing remained typical for these supplies. Therefore, we did not propose to update the prices for the SL189, SL190, SL248 or SL491 supply, as we do not believe that the higher prices paid for smaller quantities of these supplies would be typical.
- *Biohazard specimen transport bag (SM008):* We received an invoice submission that would suggest an increase in price from 8 cents to 45 cents for the SM008 supply. However, it is not clear that the item described on the invoice is the same item as the SM008 supply. The invoice states only that the price is for ''Supplied Case Red Bags'' which was not enough information to determine if this would be typical for the SM008 supply. We also do not believe that the typical price for this supply has increased 460 percent in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SM008 supply from 3.5 cents in CY 2019 to its current price of 8 cents for CY 2022.
- *International Normalized Ratio (INR) analysis and reporting system w-software (EQ312):* We did not receive an invoice for this equipment item, only a letter stating that the cost of the EQ312 equipment should be increased from the current price of $19,325 to $1,600,000. We previously finalized a policy in the CY 2011 PFS final rule (75 FR 73205) to update supply and equipment prices through an invoice submission process. We require pricing data indicative of the typical market price of the supply or equipment item in question to update the price. It is not sufficient to state a different price without providing information to support a change in pricing. Since we did not receive an invoice to support the higher costs asserted in the letter, we did not propose a new price for the EQ312 equipment item. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*. We also noted that in order to be considered a direct PE input, an equipment item must be individually allocable to a particular patient for a particular service. Costs associated with the implementation, maintenance, and upgrade of equipment that is not individually allocable to a particular patient for a particular service, or other costs associated with running a practice, would typically be classified as forms of indirect PE under our methodology.

Prior to the publication of the proposed rule, the same interested parties that addressed the pricing of the EQ312 equipment item questioned the assignment of the General Practice specialty crosswalk for indirect PE for home Prothrombin Time (PT)/INR monitoring services. These individuals stated that the predominant code used for PT/INR monitoring (HCPCS code G0249) will be significantly and negatively impacted by the continuing implementation over a 4-year period of changes in the clinical labor rates

finalized in the CY 2022 PFS final rule (86 FR 65024). The individuals requested that CMS change the crosswalk for home PT/INR monitoring services to All Physicians or Pathology which would partially offset the reduction that HCPCS code G0249 is facing due to changes in the clinical labor rates.

We noted for these interested parties in the CY 2021 PFS final rule (85 FR 84477 and 84478)that we finalized a crosswalk to the General Practice specialty for home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250). The data submitted by the commenters at the time indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We disagreed, as we did in response to comments in the CY 2021 PFS final rule, that these home PT/INR monitoring services should be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment for the services that result from an unrelated policy proposal (the clinical labor pricing update). We also noted that we had not received any new information about PT/INR monitoring services since CY 2021 to indicate that Pathology would be more accurate choices for use in indirect PE allocation but are open to receiving new relevant information that CMS could consider in future rulemaking. As such, we did not propose to change the assigned specialty for PT/INR services; we direct interested parties to the previous discussion of this topic in the CY 2021 PFS final rule (85 FR 84477 and 84478) and again in the CY 2022 PFS final rule (86 FR 65000). Interested parties are encouraged to submit new information to support the most accurate specialty choice to use in indirect PE allocation for PT/INR monitoring services distinct from what has previously been reviewed during the last two rule cycles.

Comment: A commenter submitted additional direct and indirect cost data associated with pricing the INR analysis and reporting system w-software (EQ312) equipment. The commenter stated that they arrived at this amount based upon detailed review of all of the software system and related expenses involved with furnishing home INR monitoring services, including up front equipment and software purchases that comprise direct equipment practice expenses, up front maintenance and support services that comprise indirect practice expenses, and recurring support and telecommunications services that also comprise indirect practice expenses. The commenter submitted invoices detailing a one-time direct cost of $69,621, a one-time indirect cost of $84,126.31, and recurring annual costs of $963,638.52 associated with the EQ312 equipment.

Response: We agree with the commenter that the invoices support an increase in the purchase price of the equipment from the current $19,325 to the price of $69,621 listed on the invoices. However, we disagree that the one-time indirect cost of $84,126.31 or recurring annual costs of $963,638.52 listed on the invoices would constitute forms of direct PE which would be included in the equipment's price. The indirect costs on the submitted invoices are for project management and service order costs while the recurring annual costs comprise monthly maintenance and telecommunications expenses. We agree that these are real costs associated with the software, however they are classified as forms of indirect PE under our current methodology. The equipment cost formula that we use already incorporates maintenance and interest rates costs into the per-minute pricing calculation; if we were to include these expenses in the equipment cost as a form of direct PE, we would be making duplicative payment for the same expenses. We are therefore finalizing an increase in the price of the EQ312 equipment to $69,621 but not including the indirect and recurring annual costs in the equipment price as they are classified as forms of indirect PE.

Comment: The same commenter reiterated their previous request made in PFS rulemaking for CY 2021 for CMS to change the crosswalk for home PT/INR monitoring services from the previously finalized General Practice specialty to the All Physicians or Pathology specialty. The commenter stated that the code used to report ongoing home PT/INR monitoring (HCPCS code G0249) will again be significantly and negatively impacted in CY 2023 as a result of changes in the clinical labor rates with the corresponding budget neutrality adjustment and the drop in the conversion factor. The commenter stated that the Pathology specialty provides a better reflection of the indirect to direct costs associated with home PT/INR monitoring and also reflects a more appropriate indirect practice cost index (IPCI) for a service with very high indirect costs, such as home PT/IN monitoring. The commenter stated their belief that the indirect cost data captured in their submitted invoices supports a crosswalk to the Pathology specialty given the higher indirect costs of furnishing these services, including the on-going software costs that are not captured in the direct PE input; and that this specialty crosswalk change would help offset the cuts in the proposed rate for HCPCS code G0249.

Response: We continue to believe that assignment of the Pathology specialty for home PT/INR monitoring services as requested by the commenters would not be appropriate. As we stated in the proposed rule, we continue to disagree that these home PT/INR monitoring services should be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment that result from an unrelated policy proposal (the clinical labor pricing update). The commenter stated that home PT/INR monitoring services have high indirect expenses and suggested that this supported assignment of a specialty with a higher direct-to-indirect expense ratio than General Practice (which has a 31 to 69 percent ratio), such as Pathology (which has a 26 to 74 percent ratio). However, this is a misunderstanding of the direct-to-indirect ratio for each specialty, which is a ratio based on data from the Physician Practice Expense Information Survey (PPIS) conducted back in 2007. The direct-to-indirect ratio is merely a ratio, and not indicative of a specialty having higher or lower indirect expenses in absolute terms. Higher indirect expenses for a specialty are not correlated with a higher percentage of indirects as compared with directs in that ratio; in fact, the Independent Diagnostic Testing Facility specialty has both the highest indirect expenses of any specialty, as well as a low direct to indirect ratio (50 to 50%) precisely because IDTFs also have very high direct expenses as well. Similarly, the Pathology specialty had lower indirect expenses on the PPIS than the General Practice specialty; this contradicts the commenter's contention that the high indirect costs for home PT/INR monitoring services would justify a change to the Pathology specialty. We continue to believe that the data submitted by the commenters in the CY 2021 PFS final rule (85 FR 84477 and 84478) indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are not reflective of the Pathology specialty.

We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. However, we are cognizant that approach may not work

in all cases, particularly for newer services with costs that are not well accounted for in our PE methodology, or services with cost structures that do not necessarily reflect the specialties furnishing them. Although we have previously assigned the General Practice specialty to these codes, interested parties have provided additional information about these services suggesting assignment to a different specialty for purposes of allocating indirect cost. We believe that, as we work to identify ways to update the PE methodology and our data sources to better reflect costs for all services and changes in medical practice, it is best to apply a consistent approach in setting rates that does not over-allocate cost, which could result in significant increases in payments for these services. Considering our concerns, we will switch the specialty assignment for these services to the All Physician specialty, consistent with how we have treated other new services that do not quite fit our PE methodology in recent rulemaking (see for example the discussion of HCPCS codes G2082 and G2083 in the CY 2022 PFS final rule (86 FR 65014 and 65015) and again in this rule). We believe this will allow for improved stability in payments, and preserve access to this care for beneficiaries, while we work to identify longer term solutions.

- *Remote musculoskeletal therapy system (EQ402):* We received an invoice submission for a price of $1,000 for the EQ402 equipment item. Since this equipment already has a price of $1,000 we did not propose to make any changes in the pricing; we thank the interested party for their invoice submission confirming the current price.

The following are additional comments that we received associated with supply and equipment pricing:

Comment: Several commenters requested the creation of a new supply code to describe an alternate form of a basic injection pack. Commenters stated that for many services the use of Chloraprep (chlorhexidine) for intact skin preparation has become more typical than Betadine (povidone-iodine solution) and that the current basic injection pack described by supply code SA041 no longer accurately reflects typical resource use. Commenters requested that CMS create an alternative pack which instead includes Chloraprep (chlorhexidine) so that specialties can select the injection pack with the most appropriate antiseptic. Commenters requested that the new pack should mirror the SA041 basic injection pack with the addition of the patient prep swab, 1.5 ml chloraprep (SJ081) supply and removal of the Betadine povidone soln (SJ041) and sponge tipped applicator (SG009) supplies.

Response: We appreciate the feedback from the commenters on the changing nature of what supplies are typically included in basic injection packs, and as a result, we are creating an alternate injection pack with the new supply code SA135 which will be priced at $14.12 as detailed in Table 5.

TABLE 5: Alternate Injection Pack Supplies (SA135)

SA135	Pack, alternate injection	Number	Pack	14.116
	bandage, strip 0.75in x 3in	1	item	0.410
	underpad 2ftx3ft (Chux)	1	item	0.320
	gauze, sterile 4in x 4in	2	item	0.190
	gloves, sterile	2	pair	0.910
	gown, staff, impervious	1	item	1.186
	mask, surgical	1	item	0.430
	drape, sterile, for Mayo stand	1	item	1.070
	needle, 18-27g	2	item	0.040
	drape, sterile barrier 16in x 29in	1	item	0.510
	gown, surgical, sterile	1	item	5.130
	cap, surgical	1	item	1.140
	syringe 3ml	1	item	0.250
	lidocaine 1%-2% inj (Xylocaine)	5	ml	0.060
Added	**swab, patient prep, 1.5 ml (chloraprep)**	**1**	**item**	**1.090**

After consideration of the public comments, we are finalizing the creation of the SA135 alternate injection pack. We note that this supply is not currently included in any CPT or HCPCS codes but has been added to our direct PE database for future use in services.

Comment: A commenter expressed concern that the prices for the injectable fluorescein (SH033) and lidocaine (SH049) supplies were too low. The commenter submitted invoices for both supply items and requested that they be used to update their respective prices.

Response: After reviewing the invoices, we are updating the price of the fluorescein injectable (5ml uou) (SH033) supply from $38.02 to $49.13 based on an average of prices from five submitted invoices. We did not include the sixth invoice for the SH033 supply (with a listed price of $64.80) in this average as it described a different type of injectable fluorescein from the other five invoices (it described 2 mL of a 25% solution as opposed to 5 mL of a 10% solution on the other five invoices).

We are not updating the price of the lidocaine 2% w-epidural injectable (Xylocaine w-epi) (SH049) supply as the two submitted invoices were not usable for pricing. One of the invoices detailed a 3.5% type of lidocaine while the SH049 supply code specifies that it is for 2% lidocaine. The other submitted invoice specifically noted that it was a ''preservative free'' version of lidocaine which was more expensive than the typical item; we do not agree that this invoice would be accurate for establishing a new national price for the SH049 supply. We remain interested in additional information regarding updated pricing information for the SH049 and other supply/equipment codes; as noted below, interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking

process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

We did not make any proposals associated with HCPCS codes G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) or G0465 (*Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an FDA-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)*) in the CY 2023 PFS proposed rule. In the CY 2021 PFS final rule, we established contractor pricing for HCPCS code G0460 for CY 2021 (85 FR84497–84498). In the CY 2022 PFS final rule, we finalized a policy to maintain contractor pricing for HCPCS code G0460 as we did not have sufficient information to establish national pricing, and we did not receive public comments on either the proposal or comment solicitation to support establishing a national payment rate (86 FR 65019–65020). It remains unclear to us what the typical supply inputs would be for HCPCS code G0460 and whether they would include the use of the new 3C patch system.

Comment: Following the publication of the CY 2023 PFS proposed rule, we received two comments on the pricing of HCPCS codes G0460 and G0465, and the 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. One commenter submitted invoices associated with the pricing of the 3C patch system (SD343) supply for which we established a price of $625.00 in the CY 2021 PFS final rule (85 FR 84498). The commenter requested that CMS update its supply database based on invoices submitted for SD343 to reflect an updated price of $750.00 per unit. The commenter also requested national pricing for HCPCS codes G0460 and G0465, expressing concern that insufficient payment disproportionately impacts vulnerable populations. The commenter requested a payment rate of $1,408.90 for HCPCS G0465 in the office setting, stating that this rate would appropriately account for the purchase of the 3C patch, as well as the other related costs and supply inputs required for point of care creation and administration.

Another commenter requested the establishment of new codes to allow for quantity-specific payment when multiple patches are needed to treat wounds of various surface sizes. Both commenters stated that many months have passed since CMS updated NCD 270.3 in April 2021 (for Blood-Derived Products for Chronic, Non-Healing Wounds), however, the 3C patch remains nearly inaccessible in the office and facility settings because of insufficient payment by MACs. Both commenters suggested that, to date, just one MAC has assigned a payment rate for HCPCS code G0465, which the commenters believe is too low to cover the cost to purchase and administer the patch. One commenter expressed support for the professional fee to administer the patch in the facility setting determined by this MAC, First Coast ($135.97), with the appropriate geographic adjustments, and urged CMS either to apply this rate nationally or to require MACs to set a carrier price in a timely and transparent manner. Both commenters stated that health care providers in the remaining MAC jurisdictions have faced denials even when they follow the coverage guidelines specified by our NCD 270.3. One commenter contended that, as of 2019, 27.5 percent of the traditional Medicare beneficiaries had a diabetes diagnosis. Both commenters highlighted that, within this population, the prevalence of diabetes is significantly higher among Medicare FFS beneficiaries who identify as Native American or Black/African American relative to their white counterparts, and furthermore, these historically underserved populations are also more likely to develop foot ulcers and infections that require amputation. The commenters stated that the 3C Patch has the potential to help cure these concerning health disparities and requested that we make the 3C Patch accessible by establishing national pricing for HCPCS codes G0460 and G0465.

Response: We do not have enough information to establish national pricing at this time. We will consider the commenters' feedback for future rulemaking while maintaining contractor pricing for CY 2023, which will allow for more flexibility for contractors to establish appropriate pricing using available information. We appreciate the invoice submission with additional pricing information for the SD343 supply and will update our supply database for supply code SD343 at a price of $678.57 based on an average of the submitted invoices.

(1) Invoice Submission

We remind readers that we routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor

pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 6.

TABLE 6: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Update Proposals

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032). The proposed pricing increase for these three clinical labor types is included in Table 7; the CY 2023 pricing for all other clinical labor types would remain unchanged from the pricing finalized in the CY 2022 PFS final rule.

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TABLE 7: Proposed CY 2023 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.380	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.440	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.360	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.473	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.405	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.565	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.430	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.450	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.455	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.500	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.517	62%
L041A*	Angio Technician	L035A	0.41	0.60	0.503	45%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.520	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.520	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A	Mammography Technologist	BLS 29-2034	0.43	0.63	0.530	47%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.670	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.575	56%
L046A	CT Technologist	BLS 29-2035	0.46	0.76	0.610	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.615	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.585	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.585	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.713	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.695	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
L051C	RN/CORF	L051A	0.51	0.76	0.635	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.665	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.660	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.725	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.685	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.800	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.709	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.770	44%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.298	41%
L152A	Medical Physicist	AAPM Data	1.52	2.14	1.832	41%

* Updated for CY 2023

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Comment: Several commenters noted that there was an error in the proposed clinical labor pricing table in the CY 2023 PFS proposed rule (87 FR 45874) where the final rate per minute for the L041A Angio Technician clinical labor type was incorrectly listed at 0.58 rather than the correct 0.60 as specified in the preamble text.

Response: We agree that the incorrect rate per minute for the L041A clinical labor type was reflected in Table 5 of the proposed rule, and have corrected this error in Table 7 of this final rule. We apologize for any confusion that may have been caused by this mistake.

As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 PFS final rule in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for the proposed pricing updates to the Histotechnologist (L037B) and the Lab Tech/Histotechnologist (L035A) clinical labor types and urged CMS to finalize the updated pricing.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters requested that CMS update the clinical labor description of the Angio Technician (L041A) clinical labor type to ''Vascular Interventional Technologist.'' The commenters stated that this updated title for the L041A clinical labor type would better align with industry recognition of the advanced certification required to assist physicians with minimally invasive, image-guided vascular procedures.

Response: We appreciate the feedback and are finalizing a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist'' as requested by the commenter.

Comment: Several commenters disagreed with the proposed pricing for several different technologist clinical labor types. The commenters stated that basic certification is required for a radiologic technologist and that there are additional advanced modality certifications, such as for Computed Tomography (CT), Magnetic Resonance (MR), and Vascular Intervention (VI), which require additional educational programs and training for these advanced modalities/disciplines. The commenters stated that the proposed pricing for the Vascular Interventional Technologist (L041A), the Mammography Technologist (L043A), the CT Technologist (L046A), and the MRI Technologist (L047A) clinical labor types did not reflect the training and certification required for these occupations. The commenters submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey and requested that the pricing for these four clinical labor types be updated to reflect the wage data from the submitted survey.

Response: When we initiated the clinical labor pricing update last year, we lacked specific wage data for the Vascular Interventional Technologist (L041A), the Mammography Technologist (L043A), and the CT Technologist (L046A) clinical labor types; and relied on crosswalks for their pricing. Based on the information contained in the 2022 Radiologic Technologist Wage and Salary Survey, we now have specific wage data which will allow us to no longer rely on crosswalks for pricing for these clinical labor types. Therefore, we are finalizing an update in the pricing of these three clinical labor types: from 0.60 to 0.84 for the Vascular Interventional Technologist (L041A), from 0.63 to 0.79 for the Mammography Technologist (L043A), and from 0.76 to 0.78 for the CT Technologist (L046A). For the MRI Technologist (L047A), we were able to make use of direct BLS wage data for the occupation. In addition, since we continue to believe that the BLS is the most accurate source of information for wage data, we are not finalizing an increase in the pricing of the L047A clinical labor type. As a reminder, CY 2023 is the second year of the four-year transition to the updated clinical labor pricing, and we will continue to transition the prices established for these three clinical labor types over the next two years of the update.

Comment: A commenter thanked CMS for the agency's recent work in updating clinical labor pricing and stated that nurses and other nonphysician providers have been drastically undervalued for many years which could help to alleviate staffing shortages. The commenter stated that the table of clinical labor types in the proposed rule listed registered nurses (RNs) as their own category for labor pricing under the L051A clinical labor code, but then also included RNs in eight other categories of clinical labor with other practitioners. The commenter requested having RNs identified uniquely and removing the RN option from the other clinical labor categories, as the commenter stated that leaving RNs in other categories would only make the clinical labor update more confusing and could end up disadvantaging RNs in the long term which could exacerbate the current staffing shortage and worsen patient care.

Response: We do not agree that RNs should be removed from the other eight clinical labor types currently listed in our direct PE database. There is a long history of using these ''blended'' clinical labor categories under the PFS, and together these eight clinical labor types make up the overwhelming majority of all clinical labor (especially the RN/LPN/MTA blend described by the L037D clinical labor code). In the absence of alternative pricing information to value these blended clinical labor types, we continue to believe that the proposed prices are the most accurate valuations. We also note for the commenter that the pricing for the RN (L051A) clinical labor type is drawn directly from BLS wage data and the inclusion of RNs in other ''blended'' clinical labor types has no effect on the pricing of the L051A category itself.

Comment: A commenter stated that the current RN/LPN (L042A) clinical labor type assigned to CPT code 36516 did not accurately reflect the costs associated with this procedure. The

commenter stated that CPT code 36516 is a complex extracorporeal blood therapy procedure, conducted over a 5–1/2 to 6-hour period, that requires extensively trained and experienced nurse operators known as apheresis nurses. The commenter stated that the current assignment of the RN/LPN (L042A) clinical labor type for CPT code 36516 seriously undervalues the critical nurse labor cost component of this nearly six-hour procedure and requested that CMS establish a new ''Apheresis Nurse'' clinical labor type with a valuation of approximately $1.14 per minute. The commenter also stated that there are additional supply items not currently captured in the direct PE inputs for CPT code 36516 including a 4-liter accessory waste bag, several types of fluids, and biohazard waste costs.

Response: We remind the commenter that we did not propose the creation of any new clinical labor types nor did we propose any changes in the direct PE inputs for CPT code 36516. If the commenter has reason to believe that the RN/LPN (L042A) clinical labor type is not capturing the typical labor costs associated with CPT code 36516 or that there are additional supply costs not being captured in its direct PE inputs, we encourage them to nominate CPT code 35616 as potentially misvalued for additional review.

Comment: Several commenters stated that, to promote predictability and stability in physician payments and mitigate the financial impacts of significant fluctuations in physician payments that might accompany the clinical labor pricing update, CMS should consider using a threshold to limit the level of reductions in payments for specific services that would occur in a single year. Several commenters noted that in the CY 2023 Inpatient Prospective Payment System final rule, CMS implemented a permanent 5 percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year; the commenters suggested applying a similar cap of 5 percent, 10 percent, or 15 percent for the Physician Fee Schedule.

Response: We agree with the commenters on the importance of avoiding potentially disruptive changes in payment for affected interested parties and the need to promote payment stability from year-to-year. This is why we finalized the use of a multi-year transition for the clinical labor update in last year's CY 2022 PFS final rule to help smooth out the changes in payment resulting from the updated data (86 FR 65024). We also note for the commenters that section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929). Given the mechanisms already in place to smooth payment changes and promote stability, and considering the need to establish appropriate resource-based valuations, we do not believe the limitation suggested by commenters is warranted.

Comment: Several commenters stated that CMS should prioritize stability and predictability over ongoing updates and temporarily freeze the implementation of further policy updates. These commenters requested that CMS pause the ongoing clinical labor pricing update to avoid significant payment redistributions associated with the pricing update.

Response: We finalized the implementation of the clinical labor pricing update through the use of a 4-year transition in the CY 2022 PFS final rule (86 FR 65024). As we stated at the time, although we recognize that payment for some services will be reduced as a result of the pricing update due to the budget neutrality requirements of the PFS, we do not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs over time. The PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs; continuing to use clinical labor cost data that are nearly two decades old would maintain distortions in relativity that undervalue many services which involve a higher proportion of clinical labor. As noted above, we also finalized the implementation of the pricing update through a 4-year transition to help address the concerns of the commenters about stabilizing RVUs and reducing large fluctuations in year-to-year payments.

After consideration of the comments, we are finalizing the clinical labor prices as shown in Table 8.

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TABLE 8: Finalized CY 2023 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.380	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.440	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.360	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.473	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.405	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.565	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.430	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.450	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.455	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.500	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.517	62%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.624	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.520	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.520	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.611	84%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.670	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.575	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	0.622	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.615	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.585	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.585	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.713	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.695	78%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
L051C	RN/CORF	L051A	0.51	0.76	0.635	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.665	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.660	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.725	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.685	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.800	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.709	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.770	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.298	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.832	41%

* Updated for CY 2023

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the remaining course of the 4-year transition period. We welcome additional feedback on clinical labor pricing from commenters in next year's rulemaking cycle, especially any data that will continue to improve the accuracy of our finalized pricing.

d. Technical Corrections to Direct PE Input Database and Supporting Files

We did not propose any technical corrections to the direct PE input database or supporting files in the proposed rule. However, commenters identified the following issues after we issued the CY 2023 PFS proposed rule:

Comment: Several commenters requested that the SD332 bubble contrast supply, an ultrasound-specific contrast agent, should be removed from the direct PE inputs for CPT codes 76978 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion*) and 76979 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection*). Commenters stated that this supply item does not need to be included in the direct PE inputs for these two CPT codes because contrast agents are reported separately using existing HCPCS Level II supply codes, such as Q9950 (*Injection, sulfur hexafluoride lipid microspheres, per ml*).

Response: We appreciate the additional information from the commenters indicating that the SD332 supply is duplicative for CPT codes 76978 and 76979 since the supply is separately reported using HCPCS Level II supply codes. Therefore, we are finalizing the removal of the SD332 supply from these two CPT codes.

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020, on an interim final basis for the provision of self-administered esketamine. In the CY 2021 PFS final rule, we finalized a proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that summed the values associated with several codes (85 FR 84641 through 84642). Following the publication of the CY 2021 PFS final rule, interested parties expressed concerns that the finalized PE RVU had decreased for HCPCS codes G2082 and G2083 as compared to the proposed valuation and as compared to the previous CY 2020 interim final valuation. Interested parties questioned whether there had been an error in the PE allocation since CMS had finalized increases in the direct PE inputs for the services.

We reviewed the indirect PE allocation for HCPCS codes G2082 and G2083 in response to the interested party inquiry and discovered a technical change that was applied in error. Specifically, we inadvertently assigned a different physician specialty than we intended (''All Physicians'') to HCPCS codes G2082 and G2083 for indirect PE allocation in our ratesetting process during valuation of these codes in the CY 2020 PFS final rule, and continued that assignment into the CY 2021 PFS proposed rule. This specialty assignment caused the PE value for these services to be higher than anticipated for CY 2020. We intended to revise the assigned physician specialty for these codes to ''General Practice'' in the CY 2021 PFS final rule; however, we neglected to discuss this change in the course of PFS rulemaking for CY 2021. Since we initially applied this technical change in the CY 2021 PFS final rule without providing an explanation, we issued a correction notice (86 FR 14690) to remove this change from the CY 2021 PFS final rule, and to instead maintain the All Physicians specialty assignment through CY 2021. We apologize for any confusion this may have caused.

For CY 2022, we finalized our proposal to maintain the currently assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083 to maintain payment consistency with the rates published in the CY 2020 PFS final rule and the CY 2021 PFS proposed rule. Although we had previously intended to assign the General Practice specialty to these codes, interested parties have provided additional information about these services suggesting that maintaining the All Physicians specialty assignment for these codes will help maintain payment stability and preserve access to this care for beneficiaries. We solicited public comments to help us discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. For example, we do not believe

it would be appropriate to assign the Psychiatry specialty for these services given that HCPCS codes G2082 and G2083 include the high direct costs associated with esketamine supplies. The Psychiatry specialty is an outlier compared to most other specialties, allocating indirect costs at a 15:1 ratio based on direct costs because psychiatry services typically have very low direct costs. Assignment of most other specialties would result in allocation of direct costs at roughly a 3:1 ratio. We requested that commenters explain in their comments how the indirect PE allocation would affect the payment for these services. Specifically, to ensure appropriate payment for HCPCS codes G2082 and G2083, we wanted to get a better understanding of the indirect costs associated with these services, relative to other services furnished by the suggested specialty.

As we noted in the CY 2021 PFS final rule (85 FR 84498 through 84499) and CY 2022 PFS final rule (86 FR 65042), the RAND Corporation was studying potential improvements to our PE allocation methodology and the data that underlie it. We were interested in exploring ways that the PE methodology can be updated, which could include improvements to the indirect PE methodology to address newer services similar to those described by G2082 and G2083 which have a direct to indirect ratio that does not match their most commonly billed specialties. In CY 2022, we agreed with the commenters who supported the proposal to maintain the currently assigned physician specialty (All Physicians) for indirect PE allocation for these codes. After consideration of the public comments, we finalized our proposal to maintain the All Physicians specialty for indirect PE allocation for HCPCS codes G2082 and G2083 for CY 2022.

For CY 2023, we did not make any proposals regarding the assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083; however, we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to adopt a clear and recurring process to update, on an annual basis, supply costs for codes G2082 and G2083 with the most recently available wholesale acquisition cost (WAC) data and to include the ''Psychiatry'' specialty type in the allocation of the indirect PE for G2082 and G083. The commenter believed these recommended actions directly support the following two priority CMS initiatives: the CMS Behavioral Health Strategy and an approach to improve the PE methodology within the PFS. The commenter stated that the technical correction for CY 2021 to assign these HCPCS codes to the ''All Physician'' specialty preserved Medicare beneficiary access and was an improvement over the original CMS intent to assign them to the ''General Practice'' specialty but ''demonstrated the sensitive and intricate dependency of Medicare beneficiary access on reimbursement.''

The commenter urged CMS to provide additional insight behind its specialty designation of ''All Physicians'' for HCPCS codes G2082 and G2083, and argued that CMS deviated from its normal practice of using the specialty mix contained in the claims data for these codes. The commenter stated that, while CMS has cited concerns in applying the actual specialty mix, CMS has not provided sufficient information or data to suggest that the rates produced when the ''Psychiatry'' specialty is included produces an inaccurate payment. The commenter also requested that CMS consider the implementation of policies that allow for the construction of specialty blends in unique cases, such as HCPCS codes G2082 and G2083, in which the agency has concerns about applying a service's actual specialty mix. The commenter stated that, based on utilization data published with the CY 2023 PFS proposed rule, over 70 percent of practitioners administering esketamine are psychiatrists. Considering that it is primarily psychiatrists administering esketamine and CMS recognizes the imperative to improve the indirect PE and PFS rate setting methodology for behavioral health services, the commenter recommended a transition of specialty designation for HCPCS codes G2082 and G2083 to its actual specialty mix through a three-year phased-in approach. The commenter recognized CMS' concerns about assigning the Psychiatry specialty for HCPCS codes G2082 and G2083 given the higher supply costs for these services, but recommended that CMS adopt a specialty blend of three-fourths ''Psychiatry'' specialty type and one-fourth ''All Physician'' specialty type. The commenter believed that this specialty blend would result in appropriate reimbursement and acknowledge the role of psychiatrists while also addressing our concerns.

The commenter also stated that in CY 2021, CMS updated the price for the esketamine supply item for these codes using wholesale acquisition cost (WAC) data from the most recent available quarter, but did not again update the price using the latest WAC data in the CY 2022 PFS final rule, or propose to update the price in the CY 2023 PFS proposed rule. The commenter stated that, based on WAC data on submitted invoices for the most recently available quarter, the supply input that describes 56 mg (supply code SH109) for HCPCS code G2082 should be priced at $683.67, and the supply input describing 84 mg of esketamine (supply code SH110) for HCPCS code G2083 should be priced at $1025.50. The commenter urged CMS to align with its prior action and stated intention to address input price updates in future rulemaking by updating the supply pricing for SH109 and SH110 using WAC data annually, and to make clear the additional data or processes interested parties should follow to support annual updates for the esketamine supply items for these codes.

Response: We continue to believe that the All Physicians specialty most accurately captures the indirect PE allocation associated with HCPCS codes G2082 and G2083. We do not assign a blended combination of specialties for any other services and the commenters did not provide new data to support a change in specialty assignment aside from noting that many practitioners who report HCPCS codes G2082 and G2083 are in the Psychiatry specialty. We continue to believe that it would not be accurate to assign the Psychiatry specialty for HCPCS codes G2082 and G2083 due to its outlier status among specialties, whereby Psychiatry allocates indirect costs at a 15:1 ratio based on direct costs as compared to most other specialties having approximately a 3:1 ratio. We do not believe that Psychiatry would be an accurate specialty designation for HCPCS codes G2082 and G2083 given the high direct costs associated with esketamine (which would translate into disproportionately high indirect PE allocation at the 15:1 ratio). We also disagree that these services should be reassigned to a different specialty to offset reductions in payment that result from an unrelated policy proposal (the clinical labor pricing update).

However, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we agree with the commenters that we should update supply costs to reflect the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we are finalizing an updated price of $683.67 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we are finalizing an

updated price of $1025.50 for the supply input describing 84 mg of esketamine (supply code SH110) based on the submitted invoices.

After consideration of the public comments, we continue to believe that the All Physician specialty is the most accurate specialty assignment for HCPCS codes G2082 and G2083, and we are not finalizing any changes to the specialty assignment. However, as noted above we are finalizing an increase in the price of the SH109 supply to $683.67 and an increase in the price of the SH110 supply to $1025.50 to reflect the updated market-based prices associated with esketamine. We also received comments on other policies relating to these services that were not addressed in the CY 2023 PFS proposed rule, and which we are not addressing in this final rule. We appreciate the feedback from the commenters and will take it into consideration for possible future rulemaking.

5. Soliciting Public Comment on Strategies for Updates To Practice Expense Data Collection and Methodology

The PE inputs used in setting PFS rates, including both the development of PE RVUs and, historically, the relative shares among work, PE, and malpractice RVUs across the PFS, are central in developing accurate rates and maintaining appropriate relativity among PFS services and overall payment among the professionals and suppliers paid under the PFS. Consequently, the underlying PE data inputs are a consistent point of interest among interested parties. However, unlike other payment systems with cost reporting systems, PFS data inputs are primarily based on exogenous proprietary data that become available as the data are collected. Specifically, we rely on historical survey data (almost all of which is over a decade old), some publicly available data collected for other purposes (for example, Bureau of Labor Statistics (BLS) wage data), recommendations from the American Medical Association and other provider groups, and annual Medicare claims data.

a. History of Updates to PE Inputs

Each year we continue to improve accuracy, predictability, and sustainability of updates to the PE valuation methodology to reduce the risks of possible misvaluation and other unintended outcomes. We have continued to develop policies geared toward providing more consistent updates to the direct PE inputs used in PFS ratesetting, including supply/equipment pricing and clinical labor rates. These efforts to develop these policies should contribute to improved standardization and transparency for all PE inputs used to update the PFS. As we continue our work to improve the information we use in our PE methodology, we issued a general comment solicitation to better understand how we might improve the collection of PE data inputs and refine the PE methodology.

In recent years, we have refined specific PE data inputs using a combination of market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Last year, we implemented a final transition year for supply and equipment pricing updates and started the first year of a 4-year phase-in update to the clinical labor rates. However, the indirect PE data inputs remain tied to legacy information that is well over a decade old. To build on much needed progress, we now believe indirect PE would also benefit from a refresh that implements similar standard and routine updates. We believe that a data refresh, and use of data sources that receive routine refreshes, would reduce the likelihood of unpredictable shifts in payment, especially when such shifts could be driven by the age of data available rather than comprehensive information about changes in actual costs.

b. Data Collection, Analysis and Findings

In light of feedback from interested parties, CMS has prioritized stability and predictability over ongoing updates, and has taken a measured approach to updating PE data inputs. We have worked with interested parties and CMS contractors over a period of years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear, but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology. Thus, we must balance the various interests of the public, and any path forward should allow for ongoing and routine cycles of PE updates.

Of the various PE data inputs, we believe that indirect PE data inputs, which reflected costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability into our methodology to update PE data inputs. The primary source for indirect PE information is the Physician Practice Information Survey (PPIS), fielded by the AMA. The survey was most recently conducted in 2007 and 2008 (reflecting 2006 data). The survey respondents were self-employed physicians and selected nonphysician practitioners.

In general, interested parties have expressed the following concerns regarding CMS's approach to indirect PE allocation:

- CMS seems to rely on increasingly out-of-date data sources, and there is a dearth of mechanisms to update empirical inputs.
- The approach exacerbates payment differentials that possibly create inappropriate variation of reimbursement across ambulatory places of service (for example, significantly higher payments for the same service provided in a hospital outpatient department versus a physician office).
- CMS's method of indirect PE allocation may not accurately reflected variation in PE across different types of services, different practice characteristics, or evolving business models. Beyond these issues, we have also explored other concerns with our indirect PE allocation method in depth in previous rulemaking. For example, refer to our previous comment solicitation and discussion of resource costs for services involving the use of innovative technologies in our CY 2022 PFS proposed rule (86 FR 39125). PE data inputs, and the methodological and evidence-based principles that shape use of such information in the context of reimbursement, are discussed in depth in a RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html*.[1]

Various interested parties have taken issue with the use of certain costs in our current PE allocation methodology that they do not believe are associated with increased indirect PE. Some interested parties argue that the costs of disposable supplies, especially expensive supplies, and equipment are not relevant to allocating indirect PE; or that similarly, work in the facility setting (for example, work RVUs for surgical procedures) is not relevant to allocating indirect PE,

[1] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

though they agree that work in the office setting may be relevant to allocating indirect PE.[2] However, we do not believe that there is sufficient, if any, data or peer-reviewed evidence available to definitively show that shifting indirect PE allocations based on the setting of care, or based on specialty, would result in improved allocations of PE that reflect true costs. Further, varying indirect PE allocations based on setting of care or based on specialty might create unintended consequences such as reduced access to care for beneficiaries, or reduced competition and autonomy of small group practices or individual clinicians whose revenue is based in part on services furnished under contract in the facility setting.

We believe it is necessary to establish a roadmap toward more routine PE updates, especially because potentially improper or outdated allocation of PE across services may affect access to certain services, which could exacerbate disparities in care and outcomes. Establishing payments that better reflect current practice costs would mitigate possible unintended consequences, such as labor market distortions due to indirect cost allocations that do not reflect the current evolution of health care practice.[3] Interested parties have reiterated their desire for CMS to move away from the current PE allocation approach and continued to raise concerns with CMS's methodology and the underlying PE data inputs. In response to these and other concerns, we continue to review the methodology we use to establish the PE RVUs and to identify refinements. As part of this effort, we have contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.[4]

In this final rule, we are signaling our intent to move to a standardized and routine approach to valuation of indirect PE and we solicited feedback from interested parties on what this may entail, given our discussion above. We would propose the new approach to valuation of indirect PE in future rulemaking.

We solicited comment on the following topics related to identification of the appropriate instrument, methods, and timing for updating specialty-specific PE data:

- Potential approaches to design, revision, and fielding of a PE survey that foster transparency (for example, transparency in terms of the methods of survey design, the content of the survey instrument, and access to raw results for informing PFS ratesetting); and
- Mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations.

We also solicited comment on any alternatives to the above that would result in more predictable results, increased efficiencies, or reduced burdens. For example:

- Use of statistical clustering or other methods that would facilitate a shift away from specialty-specific inputs to inputs that relate to homogenous groups of specialties without a large change in valuation relative to the current PE allocations.
- Avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences.
- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE.
- A standardized mechanism and publicly available means to track and submit structured data and supporting documentation that informs pricing of supplies or equipment.
- Sound methodological approaches to offset circularity distortions, where variable costs are higher than necessary costs for practices with higher revenue.

We also solicited comment on the cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment). We requested that commenters address the following:

- Whether CMS should stagger updates year-to-year for each update, or establish ''milestone'' years at regular intervals during which all direct PE inputs would be updated in the same year.
- The optimal method of phasing in the aggregate effect of adjustments, such that the impacts of updates gradually ramp up to a full 100 percent over the course of a few years (for example, 25 percent of the aggregate adjustment in Year 1, then 50 percent of the aggregate adjustment in Year 2, etc.).
- How often CMS should repeat the cycle to ensure that direct PE inputs are based on the most up-to-date information, considering the burden of data collection on both respondents and researchers fielding instruments or maintaining datasets that generate data.

We received public comments on data collection, analysis and findings. The following is a summary of the comments we received and our responses.

Comment: Most commenters that responded to this RFI recommended that CMS delay any change to update the indirect PE survey inputs. Many commenters urged CMS to wait for AMA data collection efforts prior to implementing changes. In responding to our RFI, the AMA RUC underscored that CMS wrote in this year's proposed rule that the AMA PPIS continues to be the best available source of data necessary for the purpose of calculating indirect PE. AMA also points to the fact that CMS has relied on AMA physician cost data for 50 years in updating the MEI and 30 years updating the RBRVS. Additionally, the RUC urged that CMS continue to work with the AMA and various specialty societies involved in the previous data collection effort, and wait for an updated set of data to become available for use. The AMA indicated that it has continued work on updates and would likely be ready by early CY 2024 with refreshed data. One commenter submitted a jointly-signed letter that did not support the AMA RUC approaches, and described a different means of data collection and analysis for updating the PE methodology. In addition to emphasizing some of the same themes noted in findings from RAND's review of the PE landscape, the letter recommended that CMS form an expert advisory group, multidisciplinary in composition, and backed with a dedicated research and development team of CMS staff, to support CMS' strategic plans to update PFS ratesetting. In this letter, the commenter also posited that indirect allocations would eventually be unnecessary, as the methodology could be evolved toward an entirely different means to capture actual costs of services. Overall, we received few direct responses to many

[2] Kazungu, Jacob S., Edwine W. Barasa, Melvin Obadha, and Jane Chuma. ''What Characteristics of Provider Payment Mechanisms Influence Health Care Providers' Behaviour? A Literature Review.'' *The International Journal of Health Planning and Management* 33, no. 4 (October 2018): e892–905. *https://doi.org/10.1002/hpm.2565*.

[3] Laugesen, Miriam J. ''Regarding 'Committee Representation and Medicare Reimbursements: An Examination of the Resource-Based Relative Value Scale.' '' *Health Services Research* 53, no. 6 (December 2018): 4123–31. *https://doi.org/10.1111/1475-6773.13084*.

[4] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html*.

of the specific prompts included in our request for information.

Response: We reiterate that we continue to believe that the current AMA PPIS data does represent the best available source of information at this time. However, as we continue to engage with a broad range of perspectives from interested parties who frequently ask for CMS policy to better reflect rapidly changing health care costs, we acknowledge, in consideration of these perspectives and our work to analyze these issues, that these concerns may be addressed by consistent and transparent data refreshes.

We remain interested in possible alternatives to use of a sole source of data. We believe that transparency and repeatability should be key principles for examining future work to update indirect PE inputs. We have clear agreement among interested parties that the economic and medical landscapes have changed, and rapidly. Our intent remains to seek data that capture such changes on a more frequent basis, and allow for others to explore and study how best to assess and account for changes with more rapid feedback loops. Conversely, we understand that the competitive marketplace may create a dynamic whereby some market participants receive revenue for the licensing and sharing of proprietary information itself. We believe it remains important to avoid interference with this type of business arrangement between vendors and their customers, yet, we also believe that there is a strong public interest to support open, transparent, and low-cost means to conduct research on these topics. For example, we are not aware of any independent, third-party, peer-reviewed research focused on the characteristics of the health care labor market in light of advancements in automation (for example, empirical analysis of how software implementation may have a causal link to changes in the health care labor market). Simply put, there are no available studies that adequately answer the question, with sufficient predictive power and adequate empirical data, of how much clinical labor is saved, or replaced, by use of automation, in the context of furnishing practitioner services. Further, many, if not all examinations of automation and its effects on labor take a far broader focus than health care workforce only, and mainly use anecdotal information, with conclusions or hypotheses that focus on job gains/losses. We note that many commenters highlighted themes this year focusing on labor shortages, rather than labor surplusage. The comments that noted refreshed survey data alone would address the need for more precise, and up-to-date, allocations of indirect expenses seem discordant with other comments we received about updating our PE methodology to account for current advancements in automation, and associated software costs. Therefore, there are a number of competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

For these reasons, it is possible that CMS would look to using verifiable, more objective data sets in the future to supplement or augment survey data alone. Such action would be similar to how certain specialty data are used in current indirect PE calculations, and sourced from specialty societies themselves, as required by statute, in some cases as PPIS data were not available. Alternatively, we may explore the use of data already in the public domain. We believe that fast-moving changes to the distribution of costs and use of evolving technology, and more generally the innovations in how vendors support practices, reshape indirect expenses in ways that would require flexible but standardized methods to account for these on a more frequent basis in our ratesetting methodology.

We reiterate our needs described in our initial discussion for this RFI. We note that this interest to develop a roadmap for updates to our PE methodology is underpinned by a need to have better understanding of repeatability and reproducibility of results, as we move toward more consistent and frequent data collection. Some commenters expressed concerns over bias and validity. We believe some of those concerns may be alleviated by having means to refresh data and make transparent with more accuracy and precision how the information affects valuations for services payable under the PFS.

Further, we note that it is possible that with the current timing for AMA's planned updates, we would be unable to refresh data for several years. This would result in CMS using data nearly 20 years old to form indirect PE inputs used to set rates for services on the PFS. As these survey data are static inputs, and leverage only the responses gathered at the time of collection, which are applied using a methodology without any dynamic variables, this is quite distinct from each of the MEI and various other inputs in PE methodology.

We believe both the somewhat stale and static aspects of the PPIS, along with expected timing for updates is significantly at tension with the feedback we receive on a regular basis. Consistently, a broad range of perspectives across various interested parties frequently ask for CMS to better reflect costs in what has been a rapidly changing health care payment landscape. The medical community and others continue to point to shortcomings in our ratesetting methodology, which may be improved by consistent and transparent data refreshes.

Additionally, we acknowledge that some hold disparate points of view about the above process of updating our PE methodology. We note that part of the public comment process aims to encourage thinking and build consensus, or identifies a lack of consensus. We appreciate the dialogue, multiple perspectives, and encourage that the broader national community of health policy thought leaders, health economists, and health systems researchers, all continue to have such conversations with one another and with CMS. A diversity of perspectives is important to foster a more robust set of options for the best available path forward.

We again thank commenters for submitting feedback on our RFI. We reiterate that our RFI does not contain any specific proposals for CY 2023. We will consider possible proposals in future rulemaking.

c. Changes to Health Care Delivery and Practice Ownership Structures, and Business Relationships Among Clinicians and Health Care Organizations

Market consolidation, and shifts in workforce alignment, as well as an evolution in the type of business entities predominant in health care markets, all suggest significant transformation in the composition and proportions of practice expenses required to furnish care. These evolving conditions collectively highlight the need for a comprehensive update to PE data inputs, and possibly the PE methodology as a whole.[5] Ideally, more comprehensive PE data inputs and a different PE calculation methodology would better account for indirect/overhead costs, current trends in the delivery of health care, the use of machine learning technology, and EHRs, and the cost differentials in

[5] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

independent versus facility-based practices.

We solicited comment on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. We are interested in learning whether any PE data inputs may be obsolete, unnecessary, or misrepresentative of the actual costs involved in operating a medical practice.

We received public comments on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. The following is a summary of the comments we received and our responses.

Comment: A few commenters responding to our prompt to explore avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences, suggested that indirect PE inputs should not be part of payment for the facility rate of payment.

Commenters explained that because the facility bears the indirect costs for provision of services at the facility, and the physician or practitioner would receive indirect PE allocations for any in-office services, the indirect PE portion of the facility fee for a physician service is unwarranted.

Response: We note that the face value of a change that would reduce the indirect PE portions of our current facility fees for physicians' services to zero may have merit. We have open questions about this feedback, which we will explore further in our ongoing research. We believe, and related feedback from interested parties suggests, there are two considerable shifts in today's healthcare business models. First, many physicians and NPP's have become employed staff, versus independent practitioners. Second, the landscape includes far more variation in the ways that organizations interact and contract for clinical staff and auxiliary personnel, and structure their compensation. We would aim to better understand whether potentially reducing to zero any indirect PE portion that is part of the facility fee for physician services may or may not reduce competition, or have the unintended effect of favoring certain forms of arrangements over others.

Further, before proposing any policy, we would need to understand whether the policy could address related open questions. Our work with RAND to explore the relationship between different types of indirect costs and direct cost inputs remains one of few empirical efforts to examine the issue in-depth. In this year, and in previous years, when we have requested similar information from the public, we continue to receive anecdotal, if any evidence, when feedback from commenters aims to take issue with findings in the RAND studies.

d. Unintended Consequences and Missing Information

We solicited comment on additional information that we may have not considered or discussed above about updating and maintaining PE data inputs, as well as any unintended impacts (or positive outcomes) that could result from changes to the overall strategy. We are especially interested in public comment on any concerns about beneficiaries' access to care, possible consolidation of group practices, or burden on small group or solo practitioners. We are also interested in public comments on any collateral program integrity or quality issues that could arise from potential updates. We requested that any respondents who provide feedback ensure that the response includes discussion of any possible health equity impacts.

We received public comments on unintended consequences and missing information. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern that topics of AI, a related evolution of software and technology used to support provision of services, and ties to health equity are not well-suited for the process of updates to our annual rulemaking cycle. Commenters expressed concerns that the public comment process alone is not sufficient to provide information, and requested a separate RFI. We received a similar response from many interested parties that question how CMS has in the past, and will in the future, address definition of topics and terms that shape our PE inputs.

Response: We encourage interested parties to continue to provide feedback and suggestions to CMS that in general, give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Submissions should discuss the feasibility and burden associated with implementation of any suggested adjustments, and should highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments. In the interim, we will continue to consider ways that we may engage in dialogue with interested parties to better understand how to address possible long-term policies and methods for PFS ratesetting.

6. Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

In preparation for future rulemaking, we solicited public comment on strategies to improve the accuracy of payment for the global surgical packages (herein referred to as ''global packages') under the PFS. Currently, there are over 4,000 physicians' services paid as global packages under the PFS. Global packages generally include the surgical procedure and any services typically provided during the pre- and postoperative periods (including evaluation and management (E/M) services and hospital discharge services). There are three types of global packages:

- The 0-day global package, which includes the procedure and the preoperative and postoperative physicians' services on the day of the procedure.
- The 10-day global package, which includes services on the day of, and 10 days after, the procedure.
- The 90-day global package, which includes services furnished one day prior to the procedure, and on the day of, and 90 days immediately following the day of the procedure.

More detail about how global packages are billed and what activities are included may be found in Chapter 12, Section 40, of the Medicare Claims Processing Manual (Pub. 100–04).

We have applied the concept of global payment for some procedures since the inception of the PFS on January 1, 1992 (54 FR 59502). However, in the past decade we have engaged with interested parties regarding numerous concerns about the accuracy and validity of the valuation of global packages, with particular attention paid to the E/M visits included in the services. We have made previous requests for public feedback on global packages, including solicitations for information or data that could be used to help support more accurate valuations. We now wish to expand on our conversations with the public, considering the current status of a multi-year data collection and analysis project, as well as ongoing changes we have made to payments for other types of patient care that may impact the global packages.

a. History of Global Valuation Discussion

In the CY 2013 PFS proposed rule (77 FR 44737 through 44738), we discussed two reports released by the HHS Office of the Inspector General in 2005 and

2012 with findings that practitioners were performing fewer E/M postoperative visits than had been included in the valuation for these global packages, suggesting that Medicare was paying for care that was not being delivered. In response to the concerns raised by the OIG reports, we solicited public feedback on methods of obtaining accurate and current data on E/M services furnished as part of a global package. We summarized public comment in the CY 2013 PFS final rule (77 FR 68911 through 68913).

In the CY 2015 PFS proposed rule (79 FR 40341), we delved into barriers to accurate valuation of global packages, especially as compared to other forms of bundled payments made under the inpatient or outpatient prospective payment systems. In addition to the ongoing concerns about whether E/M visits presumed to be furnished in connection with global packages were actually being performed by the physician receiving the global package payment, we noted issues such as:

- E/M services in the global period that occur post-discharge are valued with PE values associated with follow-up visits in the physician's office. Many of these follow-up visits may occur in a hospital outpatient department where the physician may not incur many PE costs.
- The direct PE inputs often differ slightly between an E/M service furnished in a global period and a stand-alone E/M service. For example, follow-up visits for certain surgeries may include specialized clinical labor such as an RN rather than a general nurse blend.
- The types of physicians furnishing a specific service dictate the direct and indirect percentages, as well as the indirect practice cost index, in the PE methodology. Most surgical specialties have a lower direct percentage mix, resulting in higher indirect costs that extend to the E/M visits in the global periods.
- Because the E/M visits embedded in the global package are not reported separately and do not appear in claims data, it is difficult to quantify the number and level of E/M services furnished in connection with global packages under the fee-for-service system.
- In some cases we have limited billing of the 10- and 90-day global packages in conjunction with some of the payment policies intended to encourage coordination of care through payments for non-face-to-face services, such as transitional care management and chronic care management, because of presumed overlap between these services.

To address these concerns, we solicited comment and finalized a policy in the CY 2015 PFS final rule (79 FR 67586) intended to, over a period of several years, transition all services with 10-day and 90-day global periods to 0-day global periods. As stated in the CY 2015 PFS final rule, we believed it would be more accurate to value the surgical procedure-day services separately from postop E/M visits, and would avoid potentially duplicative or unwarranted payments. For our full discussion and rationale, refer to 79 FR 67586 through 67591. Implementation of this policy, however, was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 110–14). Section 523(a) of the MACRA amended section 1848(c)(8) of the Act to prohibit the Secretary from implementing the transition policy finalized in the CY 2015 PFS final rule. The amendments to section 1848(c)(8) of the Act also require CMS to collect additional data on how best to value global packages and to reassess every 4 years the continued need for this data collection. Section 1848(c)(8) of the Act directs CMS to use the information collected to improve the accuracy of valuation of these services under the PFS starting in CY 2019. (Refer to the CY 2016 PFS final rule at 80 FR 70915 for additional discussion of these requirements.)

In response to the statutory requirements as added by section 523(a) of the MACRA, we engaged in multiple discussions with interested parties about methods of data collection and analysis, including through public comment solicitation in the CY 2016 PFS proposed rule (80 FR 41707) and CY 2017 PFS proposed rule (81 FR 46191), a national listening session, and a town hall meeting. (Materials for the January 20, 2016 listening session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-01-20-MCRA-Presentation.pdf*. The transcript of the town hall meeting held August 25, 2016 is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2017-PFS-FR-Townhall.pdf*.) In the CY 2017 PFS final rule (81 FR 80209 through 80213), we finalized a claims-based process to collect data from practitioners on both the number and level of postoperative visits furnished as part of the 10- and 90-day global packages. We also contracted with RAND to support this data collection and analysis.

b. Data Collection, Analysis, and Findings

In 2019, RAND issued two reports based on its analysis of the data collected through the data collection process we established. The reports examined, using claims-based and survey-based data, the number of postoperative visits furnished during the 10- and 90-day global periods for certain high-volume procedures and the level of visits furnished for certain procedures. (Complete details about the data collected are discussed in the CY 2017 PFS final rule starting at 81 FR 80212, the CY 2020 PFS final rule at 84 FR 62857, and in the reports themselves, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*.) Notably, RAND's analysis found that, according to claims-based data, the reported number of E/M visits matched the expected number (included for purposes of PFS valuation) for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. Based on these analyses, RAND released a third report that analyzed the current valuation of global packages based on the difference between the number of postoperative E/M visits observed via the claims-based data collection process and the expected number of such E/M visits. The report modeled how valuation for global packages would change by adjusting the work RVUs, physician time, and direct PE inputs to reflect the observed number of E/M visits. The report provided hypothetical valuations for the global packages based on these adjustments. These three RAND reports were made available to the public and are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection*.

The RAND reports were shared with the public, and we received public comment about these reports in the CY 2020 PFS final rule (84 FR 62866). Public commenters raised concerns about the findings in the reports, including questions as to whether the E/M visit data were collected from a true representative sample of practitioners, and various other challenges to the validity of the RAND methodology. Other members of the public, however, were supportive of our overall efforts to collect and analyze the data, and supplied additional data similarly suggesting that the 10- and 90-day global packages are overvalued. In 2021, RAND responded to the CY 2020 public comments that were critical of

the methodologies used in the three earlier reports in a separate report entitled, ''Responses to Comments on RAND Global Services Reports,'' which is available at *https://www.rand.org/content/dam/rand/pubs/research_reports/RR4300/RR4314-1/RAND_RR4314-1.pdf/*.

While some interested parties have challenged the methodology or conclusions of the RAND reports, we have not yet received data suggesting that postoperative E/M visits are being performed more frequently than indicated by the data collected and analyzed in the RAND reports. We continue to be concerned that our current valuations of the global packages reflect certain E/M visits that are not typically furnished in the global period, and thus, are not occurring. We also believe that RAND has adequately responded to critiques of its methodologies and findings. However, as part of our ongoing assessment of our data collection process, we continue to welcome any comments from the public on ideas for other sources of data that would help us to assess global package valuation (including the typical number and level of E/M services), as well as our data collection methodology and the RAND report findings. We received some public comments in our request for comments on possible additional data sources and on our data collection methodology. These comments are summarized as follows:

Comment: Some commenters supported the findings and methodology of the RAND reports. Several commenters stated that the RAND's findings regarding E/M visit performance aligned with their own anecdotal observations and experiences. However, other commenters expressed skepticism of the RAND report findings and methodology, and many urged us to continue to rely on RUC valuations of global packages (including the number of embedded E/M visits included in the RUC surveys.) Several commenters observed that getting truly accurate information from claims data may be difficult; one commenter pointed out that since work done by NPPs or clinical staff is often not reported separately, it is difficult to get a complete picture of postoperative work. As in previous public discussions, commenters urged CMS to continue to examine claims data and electronic health records, or obtain postoperative E/M information through direct surveys of practitioners. Several commenters noted that we have spent many years performing data collection in response to the MACRA requirements, and one commenter requested that we cease our data collection efforts to avoid any additional burden on practitioner. Many commenters urged us to continue to work in collaboration with practitioners and other impacted parties to identify sources of postoperative E/M data and to maintain transparency about any additional collection efforts.

Response: We found that the comments we received, particularly those critical of the RAND reports and methodology, echo the feedback we received several years ago when we shared the RAND reports for public comment. Please see the discussion of the RAND reports and findings in the CY 2020 PFS final rule (84 FR 62866) and RAND's responses to the CY 2020 public comments in the RAND report entitled, ''Responses to Comments on RAND Global Services Reports,'' which is available at *https://www.rand.org/content/dam/rand/pubs/research_reports/RR4300/RR4314-1/RAND_RR4314-1.pdf/*. We note that we did not receive new data that might either affirm or contradict RAND's overall findings regarding E/M performance. We agree with commenters' observations that we have spent many years collecting and analyzing data regarding E/M performance in response to the MACRA requirements and other public concerns about the valuation of globals. While we will continue to evaluate potential sources of data regarding E/M performance, we agree with commenters who suggest that the overall lack of transparency within global packages can make identifying the nature of postoperative care provision difficult and continues to call into question the accuracy of globals that have been valued through standard valuation processes.

c. Changes to Health Care Delivery and Payment for E/M Services

Since the inception of the PFS 30 years ago, there have been significant changes in health care, including improvements in medical and information technology, new models of health care delivery and coordination between multiple clinicians furnishing care to a single patient, and an expanding beneficiary population. (For information on Medicare service utilization, beneficiary demographics, provider characteristics, and payment models, please visit the resources at *data.cms.gov*.) We asked to hear from the public on whether the postoperative health care landscape has changed in ways that impact the relevance of the global packages.

We believe that changes to health care delivery may impact proper valuation of global services. We solicited comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past 3 decades, as well as during the recent PHE, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care. We have formed hypotheses that some beneficiaries are not receiving the number of postoperative visits that were contemplated when valuing the global surgical packages or are not receiving any follow-up E/M visits at all during global periods either because the physician who performed the surgical procedure has determined they are unnecessary (perhaps due to improvements in medical technology or evolution in standards of care) or as the result of more comprehensive discharge planning. It has also been suggested by some interested parties that physicians are, in fact, performing the number of postoperative visits that were contemplated when valuing the global surgical packages, but the visits may, for various reasons, be scheduled outside the global period. Others have suggested that physicians are, without formally transferring follow-up care to another clinician, instructing patients to follow up with another physician or NPP (such as the patient's primary care physician or other practitioner), and that the other clinician then furnishes and bills for E/M services furnished for postoperative care (whether the care is performed during or after the global period). We appreciate comments on these ideas, and on other factors not mentioned here that could affect the ways that postoperative E/M care is provided.

We also solicited comment on whether, or how, recent changes in the coding and valuation of separately billable E/M services may have impacted global packages. One change is the expansion of payment for non-face-to-face care management services. Historically, an advantage of global packages was that they compensated physicians for non-face-to-face work related to the patient's transition from the hospital to the community, or management of other health care needs following a procedure or serious illness. Over the years, we have implemented payment for many care management services to better reflect non-face-to-face time spent by physicians and clinical staff on behalf of patients with complex health care needs, including transitional care management services in CY 2013 (77 FR 68978); chronic care

management in CY 2015 (78 FR 74414) and CY 2019 (83 FR 58577); complex chronic care management in CY 2017 (81 FR 80244); and principal care management in CY 2020 (84 FR 62962). We solicit comment on whether global packages, and especially those with 10- and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately not only for the postoperative E/M visits they furnish, but also for aspects of postoperative care management they furnish for some patients. We also would like to hear generally what, if any, components of preoperative or postoperative care are currently only compensated as part of payment for global packages.

We have also heard from some interested parties who believe that recent changes to the coding and valuation of standalone office and outpatient E/M visits finalized in the CY 2021 PFS final rule have skewed the relativity between these visits and the E/M visits included in the current global package valuations (which were not modified in response to the coding and valuation changes). In the CY 2020 PFS final rule (84 FR 62851 through 84 FR 62854), we finalized new—and generally increased, RVUs for the CPT-revised office and outpatient E/M code set. Some commenters encouraged us to increase the value of the E/M visits included in the global surgical packages commensurate with the increased RVUs for the standalone E/M visits. However, we declined to do so, noting that at the time that it was unclear whether it would be appropriate to treat the E/M visits reflected in global packages as discrete components of the package (in other words, to use a building-block approach to calculating the value of the service, versus valuing the services using the more holistic magnitude estimation, or possibly another approach.) Furthermore, we cited the uncertainty as to whether the E/M services included in valuing the global packages are typically furnished as part of global surgery services, reasoning that if the number and level of E/M services for global packages is not appropriate, adopting increases in the value of E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues. (Refer to the CY 2020 PFS final rule at 84 FR 62856 through 62860 for a complete summary of comments and our responses on the topic of increasing the value of E/M visits included in the global packages.) We welcomed additional comments on the perceived misalignment between the E/M visits included in global packages and separately billable E/M services, including thoughts on how this current tension reflects on global payment valuation and the appropriate methodology for determining appropriate values for global packages.

We received some public comments on whether changes to health care delivery and payment for E/M services may impact the performance of E/M visits or overall relevance of E/M visits. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted that while patients in general seem in greater need of critical care, there is also (from various commenters' perspective) either increasing opportunity or mounting pressure on practitioners to discharge patients from hospitals and arrange at-home care after surgeries. Many commenters stated that postoperative care provided by the proceduralists should still be considered a best practice. However, a few commenters agreed with some of our hypotheses—namely that for clinical reasons patients may not need to return for in-person postoperative care within the global period, or that scheduling conflicts may make timely return difficult. A few commenters also agreed that patients may, for reasons of convenience, receive some postoperative care from community practitioners rather than returning to the hospital where the surgical procedure was performed. Some commenters also suggested that there may be clinical reasons why it is better for a patient to receive postoperative care from a practitioner or NPP other than the proceduralist, such as in circumstances when the patient needs long-term or specialized postoperative care outside the expertise of the proceduralist. Overall, commenters expressed ambivalence about the impact the PHE and use of telehealth has had on postoperative care. A few commenters noted that some aspects of postoperative care—including sharing of test results or consultations—can be done via telehealth, while others described types of postoperative care that can only be done in-person. Commenters also expressed doubt about the impact of expanded payments for non-face-to-face services, noting that payments for care management or other non-face-to-face services do not include all post-surgical conditions and do not address in-person care.

Regarding our questions about the overall relevance of global packages, some commenters stated that paying for postoperative care as standalone visits would ensure that Medicare was only paying for the care that was being delivered. A few commenters suggested that postoperative care should be not only paid for separately, but paid at a higher rate. Other commenters stated that global packages continue to be necessary because they reduce administrative burden on practitioners and ensure payment of care provided by NPPs and clinical staff.

Response: While we did not receive a great deal of feedback on our specific request for information as to whether global packages are still relevant, we believe the information we received demonstrates that there may be variations in patients' individual postoperative care needs. While we agree with commenters that in-person visits with the proceduralist is the standard of care on which global packages were based, we will continue to examine whether this specific model of postoperative care is still necessary or relevant for all procedures.

Comment: Many commenters provided input on the valuation of the E/M visits embedded in global packages as compared to standalone E/M visits. Although commenters did not provide feedback on whether the misalignment reflects on the relevance of surgical packages, many commenters suggested that we should increase the value of global packages to reflect the increase in standalone E/M visits (both the office/outpatient increases finalized in CY 2020 at 84 FR 62851 through 84 FR 62854, and increases to certain hospital inpatient E/M visits proposed in CY 2023 at 87 FR 45993.) Some commenters suggested that the data collection requirement in the MACRA amendments to the statute does not preclude CMS from applying such increases to all global packages. Other commenters, however, agreed with our decision not to increase the global packages pending our inquiry into the performance of postoperative E/M visits.

Response: We direct commenters to the CY 2020 PFS final rule (84 FR 62851 through 84 FR 62854), where we discussed similar concerns. We continue to disagree with commenters' interpretation of the MACRA amendments. We note that section 1848(c)(8) of the Act, as amended by section 523(a) of the MACRA (Pub. L. 110–14), directs CMS to use the information collected to improve the accuracy of valuation of these services specifically requires that we use the data we obtain through data collection to revalue the global packages. Our data currently suggests that at least some global packages are inaccurately, revalued, and until we identify data that demonstrates otherwise, we do not believe it would be appropriate to apply

an across-the-board adjustment to the packages that is not supported by data. Additionally, we are also working to reconcile public recommendations that we revalue global packages on a holistic or case-by-case basis (discussed in greater detail in section II.B.6.d. of this final rule) with recommendations that we apply across-the-board increases to all global packages.

d. Strategies To Address Global Package Valuation

Consistent with the discussion above, we continue to believe that: (1) there is strong evidence suggesting that the current RVUs for global packages are inaccurate; (2) many interested parties agree that the current values for global packages should be reconsidered, whether they believe the values are too low or too high; and (3) it is necessary to take action to improve the valuation of the services currently valued and paid under the PFS as global surgical packages.

We would like to re-engage with the public about whether the global packages are indeed misvalued, and if so, what would be an appropriate approach to valuation. We have previously sought assistance from the public on possible methods of revaluation, such as in the CY 2015 PFS final rule (79 FR 67586).

As noted in the ''Data Collection, Analysis, and Findings'' section above (section II.B.6.b.), RAND has provided a comprehensive roadmap for a possible revaluation strategy. (See specifically the RAND report, ''Using Claims-Based Estimates of Postoperative Visits to Revalue Procedures with 10- and 90-Day Global Periods,'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*. We solicited additional input on the RAND methodology, including advantages and drawbacks of applying the RAND methodology to revaluation (in addition to previous feedback that was provided by the public in the CY 2020 PFS final rule at 84 FR 62867). We also requested input on specific alternatives, including: (1) requesting the RUC to make recommendations on new values; or (2) another method proposed by the public.

We solicited feedback from the public on possible strategies for a revaluation process for global services. We believe that the available information provided in the RAND reports (discussed in section II.B.6.b. of this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*) indicates that there is a mismatch between the value of the global package and work being performed. In particular, it appears that for some services, the number of postoperative visits typically furnished by the billing physician is much lower than what was reflected in the global package value, and thus we believe it may be necessary to revalue those services. (As noted in section II.B.6.b. of this final rule, RAND's analysis found that the reported number of E/M visits matched the expected E/M visits for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. We referred specifically to the RAND report, ''Claims-Based Reporting of Postoperative Visits for Procedures with 10- or 90-Day; Global Periods—Updated Results Using Calendar Year 2019 Data'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*). Because there are a large number and volume of services paid as global packages, we must consider the resources needed to revalue even a subset of the global packages, as well as the impacts across the PFS and healthcare delivery system in general if we were to change the values of a significant number of services at one time. We considered various approaches we could pursue, such as: (1) revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates); (2) revaluing only the 10-day global packages (because these appear to have the lowest rate of postoperative visit performance, per RAND's analysis of claims data); (3) revaluing 10-day global packages and some 90-day global packages (such as those with demonstrated low postoperative visit performance rates as identified in RAND's analysis of these services); or (4) relying on the Potentially Misvalued Code process to identify and revalue misvalued global packages over the course of many years. (We noted that regardless of whether we review particular global packages as part of a specific revaluation strategy, the public may always nominate any global packages to be reviewed through the Potentially Misvalued Code process; refer to the description of the Potentially Misvalued Code process in section II.C. of this final rule.) We solicited comment on any of the strategies identified in this paragraph, as well as any additional ideas members of the public may have that would address the concerns described above about valuation of global packages. We also solicited comment on ancillary considerations including timing considerations for implementation of any future strategy (such as whether to have staggered effective dates for new valuations and what criteria to use if assigning staggered effective dates.)

We also solicited comment on additional considerations affecting valuation of global services that may not have been thoroughly explored in previous public comment opportunities. For instance, we are aware that some interested parties are concerned that not enough attention has been paid to the value of preservice work bundled into the global payment, which could affect accurate valuation of 10- and 90-day global packages, as well as the value of the service if it is transitioned to a 0-day global. We solicited additional information about this concern, as well as any other concerns about valuation not otherwise mentioned here.

We received public comments on strategies to address global package valuation. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed that global surgical packages are misvalued and encouraged CMS to revalue the packages in order to reduce the impacts of improper valuation on the relative value scale. A few commenters agreed that packages were misvalued, but suggested we continue to work with impacted parties to find a method for revaluation. Other commenters stated that they do not believe that global packages were misvalued or, if they are misvalued, they should be revalued on a holistic and case-by-case basis using the RUC process or the Potentially Misvalued Code process. A few commenters suggested that CMS and the RUC collaborate on a specific method to revalue global packages. Commenters also noted that revaluing through the RUC process could take a number of years and may present resource challenges.

We received diverse comments on approaches for revaluing the codes, including revaluing all 10- and 90-day packages, revaluing some 10- and 90-day packages, or focusing just on the 10-day packages. Commenters who recommended focusing on the 10-day packages suggested that this would address services with lower demonstrated postoperative E/M visit rates, and would provide us with insight about revaluation that could then be applied to the 90-day packages as needed. Other commenters made suggestions including phasing out global packages by not valuing new CPT codes as globals, or changing the length

of global periods. While one commenter was in favor of revaluing all packages at one time, many commenters suggested revaluing over a number of years to avoid too much disruption to the relative value scale. One commenter suggested we wait until after the conclusion of the PHE to revalue any packages.

Response: We believe that the spectrum of comments demonstrates that there is not, at this time, clear public consensus on this issue or the preferred strategy for valuing globals. We will consider the specific strategies proposed by the commenters and the concerns regarding impact on the relative value scale and the resources that would be required to revalue these codes.

e. Other Payment Structure Changes, Unintended Consequences, and Missing Information

We solicited public comment on any other aspects of the global payment structure (aside from the valuation of services) that commenters believe are noteworthy. Much of the discussion over the years has focused on whether global surgical packages are properly valued and whether they are needed at all. We encourage commenters to point out ways in which global surgical packages may continue to have a positive impact on health care delivery (such as their potential to support innovation). We also solicited suggestions on other ways that global surgical package payments could be modified (aside from changing their valuation) that could help improve accurate valuation or help address other concerns about the payments (such as the lack of transparency about what care is being provided as part of the package).

We also requested comment on additional information that we may not have considered or discussed above about proper valuation of the global packages, as well as any unintended impacts (or positive outcomes) that could result from changes to how we value global services. We are especially interested in public comment on any concerns about beneficiaries' access to care, continuity of care, cost sharing, or program integrity.

We received limited public comments on other payment structure changes, unintended consequences, and missing information. The following is a summary of the comments we received and our responses.

Comment: A few commenters opined on the consequences of unbundling global payments. A few of these commenters raised concerns that unbundling the packages would reduce payments to physicians or NPPs. A few expressed concerns that beneficiaries might not want to pay the coinsurance for standalone E/M visits (should global packages be unbundled) and might decline postoperative care.

Response: We agree that the payments to practitioners might change in circumstances where globals are revalued, although we do not believe there is yet enough information to determine the financial impact should proceduralists bill separately for postoperative care for some procedures. We will continue to consider the potential impact of coinsurance for globals and postoperative care for beneficiaries.

After consideration of the comments, we wish to thank the commenters for their input. As outlined in the proposed rule, this discussion has spanned over a decade, with participation from specialty societies, advocacy groups, program integrity agencies, and Congress. We had hoped through this comment solicitation to nudge discussion into new or under-explored lanes of inquiry that would help us better understand how global packages fit into the current health care landscape. We appreciate the engagement we did receive with our requests for information regarding current health care practices. Additionally, numerous interested parties, those who have been engaged with the discussion for many years, as well as some new voices, provided comment that reinforced or reiterated concerns that have emerged in prior discussions.

In this year's comment solicitation, we received a spectrum of perspectives on: whether the globals are misvalued; if misvalued, whether they are undervalued or overvalued; whether we should continue to value them through our current processes or develop a new methodology that better addresses the unique challenges posed by bundled payments; and whether globals should be revalued individually, in batches, or in their entirety. Looking at the totality of the comments and keeping in mind discussion from prior years, we have identified a few common themes on which many seem to agree. The matter of global valuation is complex. Global packages comprise a large number of codes, and their valuation has a significant impact on the PFS relative value scale. Accurately valuing the work and other inputs of the globals is critically important to ensure not only that the practitioners providing those services are paid accurately for the work performed, but that there is no inequitable impact on practitioners paid outside of 10- and 90-day global packages. The diversity of procedures paid under global packages may mean that blanket approaches to valuation or revaluation may not achieve the desired degree of accuracy. And, finally, while universally agreed-upon data strategies may prove elusive, good data analysis is a critical foundation on which to base any method for valuing these packages. We appreciate the public's engagement on this issue, and continue to welcome additional insights from interested parties as we consider appropriate next steps.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the

results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also considered information provided by other interested parties. We conducted a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/Fee-for-Service-Payment/Physician default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior

reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897) we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2023 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative.

An interested party nominated the home-based physician visit codes: CPT code 99344 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family*), CPT code 99345 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family*), CPT code 99349 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family*), and CPT code 99350 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting*

problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family) as potentially misvalued.

In their submission, the nominator expressed concern that there is no payment for transportation costs incurred when it is medically necessary for a physician to drive to the home of the patient for a face-to-face in-home E/M Visit, and that they are not compensated for opportunity loss they incur by seeing fewer patients because they spend time commuting to patients' homes, versus seeing more patients that come to their offices. The nominator also argued that Medicare does not compensate physicians for the work and time associated with assessing a patient's home environment, which provides insight into a patient's overall health and living conditions. The nominator collectively called these non-medical factors that can affect a patient's overall health the ''Social Determinants of Health'' (SDoH). The nominator requested that we increase the overall RVUs for CPT codes 99344, 99345, 99349, and 99350, by including the resources associated with: (1) the physician's transportation costs to patients' homes; (2) lost income opportunity for home versus in-office visits; and (3) in-home SDoH assessment work. The nominator estimated that the adjustments to RVUs to reflect transportation costs and opportunity costs would result in a Medicare payment that is 67 percent higher than the current Home-based E/M Visits payment rates, and that adjustments to account for the physician's SDoH assessment would add an additional 55 percent increase to the payment rates for Home-based E/M Visits. In total, the nominator suggests that if these resources were taken into account, the payment rates for Home-based E/M CPT codes would increase by what the nominator estimates as a 222 percent increase from their current amounts.

The nominator included references as evidence to support their claim that the home-based E/M CPT codes are potentially misvalued, such as the CMS ''Medicaid Non-Emergency Medical Transportation Booklet for Providers'' (April 2016) [6] [7] and a press release from the Better Medicare Alliance entitled, ''Report Shows Dramatic Increase in Medicare Advantage Activity to Address Social Determinants of Health, But Barriers Remain''.[8]

We noted that the nominator did not nominate the entire family of home-based E/M visit codes (please see Table 9 for a list of home-based E/M codes).

TABLE 9: Home-Based E/M CPT Codes for CY 2023

CPT	CPT Descriptor
Nominated Home Visits Codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Home Visits Codes Not Nominated:	
99341	New patient home visit, typically 20 minutes
99342	New patient home visit, typically 30 minutes
99343	New patient home visit, typically 45 minutes
99347	Established patient home visit, typically 15 minutes
99348	Established patient home visit, typically 25 minutes

When we establish values for codes or consider whether codes are potentially misvalued under the PFS, we take into account the resources involved in furnishing the specific service as described by the CPT code. As such, historically, we do not take into account: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in one setting versus another; or (3) the physician or other practitioner's work and time expended in performing activities that are outside the scope of the specific service as described by the CPT code. These are not considered to be resources involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Act, and, as such, do not provide justification for potential misvaluation of those payments. That said, in February 2021, the AMA CPT Editorial Panel deleted the family of domiciliary codes, CPT codes 99324 to 99340, and merged the services described by those codes into the existing family of home-based E/M visits, CPT codes 99341 to 99350 (a range of codes that includes CPT codes 99344, 99345, 99349, and 99350). In addition, the AMA RUC made recommendations regarding the values for these home-based E/M codes as discussed in section II.F. of the CY 2023 PFS proposed rule (87 FR 45999) and in section II.F. of this final rule. Since CMS had already received AMA RUC recommendations for these home-based E/M visit codes, we considered those recommendations and solicited additional public comments, recommendations, and independent analysis as supporting evidence from all interested parties regarding the valuations for the home-based E/M visits, including CPT codes 99344, 99345, 99349, and 99350. Because we discussed and solicited public comment on the valuation of these codes in the proposed rule, we stated that we were not considering these home-based E/M

[6] *https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nemt-booklet.pdf.*

[7] *https://storage.aanp.org/www/documents/NP-Infographic.pdf.*

[8] *https://bettermedicarealliance.org/news/report-shows-dramatic-increase-in-medicare-advantage-activity-to-address-social-determinants-of-health-but-barriers-remain/#:~:text=Social%20determinants%20of%20health%20are,to%20the%20World%20Health%20Organization.*

visits as potentially misvalued for CY 2023.

An interested party has nominated the following cataract surgery codes, CPT codes 65820 (*Goniotomy—Incision to improve eye fluid flow*), 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*), 66982 (*Complex Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*), 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*)), 66989 (*Complex Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more),* and 66991 (*Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more),* as well as the following retinal procedure codes, CPT codes 67015 (*Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy)),* 67036 (*Vitrectomy, mechanical, pars plana approach),* 67039 (*Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation),* 67040 (*Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation*), 67041 (*Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (e.g., macular pucker)*), 67042 (*Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (e.g., for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil)*), 67043 (*Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (e.g., choroidal neovascularization), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil) and laser photocoagulation*), 67108 (*Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*), and 67113 (*Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens*), as potentially misvalued because there is currently no established non-facility payment rate for these global 090-day surgical procedures. These codes are complex surgical eye procedures, and they require dedicated spaces, similar to facility-based spaces that are not typically found in an ophthalmologist's office—such as a well-lighted and sterile surgical theater; specific eye surgery equipment; and, possibly, clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery, including anesthesia services. In the past, with concerns for patient safety and given the intricate and delicate nature of these surgeries, we understood that these procedures would only be performed in a well-equipped and fully staffed medical facility. For Medicare Part B, payment for these services is only made for procedures furnished in the facility settings, but this nominator suggests that these cataract and retinal procedures can be properly performed in the non-facility office, safely, effectively, and perhaps more conveniently for patients and physicians; and thus requests that we should establish non-facility RVUs under the PFS to recognize the additional resources that would be expended in the non-facility setting.

The nominator has included a list of practice expense (PE) items involved in furnishing these services in the non-facility setting to help us to consider establishing non-facility values for these codes. They include the possible number and types of clinical staff and their work time in minutes as well as a list of various equipment and supplies typically needed to furnish the services described by the nominated codes.

The nominator also noted that there is projected backlog for these cataract and retinal services that may have been building up due to the COVID–19 restrictions from the past 2 years. We solicited comment on the merits of continuing to value these codes only in the facility setting, as opposed to also establishing non-facility values for these cataract and retinal surgery codes. We also solicited comment on any appropriate safety considerations for these codes in the non-facility setting, and whether these codes are potentially misvalued. We noted that in last year's CY 2022 PFS final rule with comment (86 FR 65096 through 65097), we did review CPT codes 66982, 66984, 66987, 66988, 66989, 66991, and 0671T (Cataract Removal *with* Drainage Device Insertion) and did not establish non-facility values for those services, but we did note a potential rank order anomaly when considering minimally invasive glaucoma surgeries (MIGS) and cataract surgeries together, and suggested that the AMA RUC should consider re-surveying all of the codes in this family.

An interested party nominated add-on CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*) as a potentially misvalued service with respect to the physician's labor for spinal surgeries involving the use of biomechanical synthetic cage devices versus the use of structural allograft bone as it relates to a set of CPT codes related to anterior cervical discectomy and fusion (ACDF). Ordinarily, interested parties nominate a primary service code as potentially misvalued, or a primary service code and its related add-on codes, but not an add-on code alone. The valuation of an add-on code is typically developed with reference to some portion of the work (or other resource inputs) involved in furnishing the primary service code. For example, the AMA CPT 2022 Professional Edition, page 147, states ''Use code 20931 in conjunction with codes 22319, 22532–22533, 22548–22558, 22590–22612, 22630, 22633, 22634, 22800–22812''. The primary spinal surgery codes and the add-on CPT code 20931 have not been recently reconsidered or reviewed by the AMA RUC or CMS, and no new or additional information has been included with this nomination to persuade CMS that CPT code 20931 is individually potentially misvalued. This nomination of an add-on code as potentially misvalued is similar to the nomination we discussed in the CY 2022 PFS proposed rule (86 FR 65044) of CPT code 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2*) and the accompanying add-on codes.

The nominator refers to two different methods of vertebral fusion: one using biomechanical synthetic cage devices, the other using structural allograft bone; and describes a typical vertebral fusion case that uses three units of one of these products. Both of these methods of vertebral fusion are described by CPT

code 22551 (includes a 90-day global period), which has a work RVU of 25.00. Both methods of vertebral fusion also involve two units of CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*), which have a total work RVU of 13.00 (6.50 × 2), and 1 unit of CPT code 22846 (*Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)*), which has a work RVU of 12.40. The vertebral fusion method employing three synthetic cage devices with plate would involve three units of CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*) for a total work RVU of 12.75 (4.25 × 3), and one unit of CPT code 20930 (*Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)*) with a work RVU of 0.00 (because Medicare considers this code to be bundled into codes for other services). The nominator states that the typical vertebral fusion employing three synthetic cage devices with plate would total to 63.15 work RVUs.

In contrast, the nominator asserts that the vertebral fusion method employing structural allograft bones with plate involves the same set of services and codes (that is, one unit of CPT code 22551, two units of CPT code 22552, and one unit of CPT code 22846), but the structural allograft bone method includes CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*), with a work RVU of 1.81, instead of CPT codes 22853 and 20930, for a total work RVU of 52.21. The nominator suggests that this difference in total work RVUs for the two methods of vertebral fusion, 63.15 versus 52.21, is evidence that add-on CPT code 20931 is potentially misvalued; however, we do not agree with this nominator's method of aggregating and comparing sums of work RVUs for groups of services that may be furnished together as being potentially misvalued, nor consider CPT code 20931 as the source of misvaluation within this grouping.

We understand that the nominator believes there should be an equivalent total sum payment for all services involved in vertebral fusion surgeries using either method, and that there should not be a potential incentive for physicians to prefer the method that uses synthetic cage devices because of the higher available payment amount. The nominator asserts that the total sum payment for this kind of spinal surgery using the structural allograft bone method is undervalued as compared to the total sum payment for this kind of spinal surgery using the synthetic cage method.

We note that CPT code 22853, which the commenter associates with the synthetic cage device method of vertebral fusion, is a 45-minute ZZZ-code (indicating an add-on code) with an IWPUT (intra-service work (RVU) per unit of time) of 0.0944, whereas CPT code 20931, which the commenter associates with the allograph method of vertebral fusion, is a 20-minute ZZZ-code with an IWPUT of 0.0905. Given the much longer intra-service time and greater IWPUT for CPT code 22853 than for CPT code 20931, the allograph method of vertebral fusion would be expected to have a lower total sum of work RVUs.

The nominator's description of why and how each vertebral fusion method is potentially misvalued when compared to the other does not present a situation that fits within our process for identifying individual services that are potentially misvalued using certain criteria, as described in the beginning of this section. Our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to individual codes, or with the inter-code relativity between the RVUs assigned to several individual codes found within a family of codes with hierarchical relationships. We generally do not examine the summed differences in total RVUs (as is the case presented here), based on billing patterns for a combination of codes representing differing physician work for different methods of performing a service, and then comparing the total RVUs of each method as evidence of the potential misvaluation of codes. We do not believe that the nominator has provided sufficient evidence to demonstrate that CPT code 20931 itself is misvalued, and therefore, we are not inclined to propose this code as potentially misvalued; however, we solicited additional comment and any independent analysis and studies (see the supporting documentation options listed above under ''CY 2023 Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service) as supporting evidence from commenters in agreement or disagreement with this nomination.

See Table 10 for the listing of nominated potentially misvalued codes.

TABLE 10: Interested Parties' Nominations of CPT Codes as Potentially Misvalued for CY 2023

CPT	CPT Descriptor
Home Visits codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Cataract Surgery codes:	
65820	Relieve inner eye pressure
66174	Translum dil eye canal
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66989	Xcpsl ctrc rmvl cplx insj 1+
66991	Xcapsl ctrc rmvl insj 1+
Retinal Procedure codes:	
67015	Release of eye fluid
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67108	Repair detached retina
67113	Repair retinal detach cplx
Spinal Surgery code:	
20931	Allograft, structural, for spine surgery only (add-on code)

We received public comments on our discussion of public nominations for potentially misvalued codes and decision not to propose them as potentially misvalued. The following is a summary of the comments we received and our responses.

We received a number of public comments on the nominated home-based E/M visit CPT codes 99344, 99345, 99349, and 99350.

Comment: Commenters were disappointed, stating that CMS did not take into account the inclusion of the nominator's request for consideration for: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in the patient's home versus in the office or at a facility; or (3) the physician or other practitioner's work and time expended assessing a patient's home environment and/or ''Social Determinants of Health'' (SDoH) assessments. Commenters explained that the typical home-bound patient, who requires a physician home visit, is comparatively more frail, with multiple chronic conditions. Some commenters suggested add-on codes, similar to the codes for at-home COVID–19 Vaccinations, for physician transportation costs to the patient's home.

Response: We appreciate the feedback from commenters and encourage further discussion as we gain more experience with the new codes. As discussed in our proposed rule, the costs identified by commenters are not considered to be specific work, practice expense, or malpractice expense resource inputs that are taken into account in valuation of individual services under the PFS, so they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Act. As such, these costs do not provide justification for potential misvaluation of the identified codes. We also noted in the CY 2023 PFS proposed rule (87 FR 45883) that the AMA RUC made recommendations regarding the values for these home-based E/M visit codes. Since CMS had already received AMA RUC recommendations for these home-based E/M visit codes for this year's proposed rule, we referred readers to the discussion and solicitation of public comments on those recommendations in the proposed rule. We solicited additional public comments, recommendations, and independent analysis as supporting evidence from all interested parties regarding the valuations for the home-based E/M visits, including CPT codes 99344, 99345, 99349, and 99350. We refer readers to section II.F. of this final rule for a summary and our responses to those comments. With regard to the comments requesting additional coding, we appreciate commenters' suggestions, and, as we gain information from utilization of the newly-reviewed codes and receive additional feedback from interested parties, we may consider changes in future rulemaking.

Comment: One commenter stated that his Home Visit PEs are not lower than those of an office practice, but did not offer any code-level details to support this statement.

Response: We appreciate the perspective of interested parties, but we would need code-level PE details to evaluate potential code valuation issues.

We received numerous comments on the Cataract and Retinal Surgery codes which were nominated as potentially misvalued with a request to establish nonfacility payment rates for these complicated 090-day global surgical procedures.

Comment: Several commenters requested that CMS revise the current work RVU for CPT code 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*) and instead use the

higher AMA RUC-recommended work RVU value or, short of that, transition the valuation we established in the CY 2022 PFS final rule over 3 years.

Response: We thank commenters for this comment. CPT code 66174 was reviewed and finalized in last year's rule (85 FR 65095), and we will not consider this code as potentially misvalued for CY 2023. We did not identify or propose CPT code 66174 as potentially misvalued in the proposed rule. As such, this comment is outside the scope of the proposed rule.

Comment: Many commenters recounted the evolution of these Cataract and Retinal Surgery codes—once exclusively performed in hospital operating theaters, then performed in ASCs, and now perhaps maturing into the next phase of eye care and Office-Based Surgeries (OBS). Commenters were mainly in favor of establishing payment amounts for these services in the non-facility office setting, which would recognize the additional PE resources involved in furnishing the services in those settings. Commenters also stated that there are significant advantages to be gained when these cataract and retinal surgery services are furnished in non-facility office settings. OBS may offer faster scheduling and coordinating with the surgeon, patient, and patient's family caretaker, since they bypass additional schedule coordination, and avoid potential staffing or availability issues with the hospital or ASC operating room. These commenters suggested that scheduling activities may be more efficient and flexible in the OBS setting, leading to fewer and shorter delays in delivering these Cataract and Retinal Surgeries to alleviate the patient's urgent eye problem (especially during recent COVID–19-related restrictions). The commenters also suggested that office-based surgical staff are also more likely to be familiar to the patient than a hospital operating room or ASC staff. One commenter offered that organizations, such as the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), may offer accreditation for practitioners interested in furnishing OBS for these services, to prove they can demonstrate they have adequate equipment, adequate sterility, adequate backup power and lights, adequate clinical surgery personnel, and adequate emergency personnel, should there be a need for them, compared to hospital operating rooms or ASCs, possibly maintaining certifications with periodic re-inspections.

Some Hospital/ASC-based commenters noted that, after decades of ophthalmologist experience with these Cataract and Retinal Surgery codes, they had a number of concerns about these services shifting toward office-based surgeries compared with Hospital/ASC settings and whether OBS can adequately address these concerns, including: (1) Sterility controls equal or better than a hospital operating room or a dedicated ASC operating theater; (2) Anesthesia for the OBS that is different in the office where valium oral sedation may be used and the patient being monitored by the physician eye surgeon, rather than in an O.R. with general sedation via IV administered and monitored by an anesthesiologist; (3) Equipment quality and maintenance is a concern and in the smaller typical office setting, there may not be the backups and redundancies that may be found in the larger facility settings, with automatic emergency power switchovers that may not be installed for the OBS; (4) Patient complications being detected in the pre-screening phase, possible complications occurring during the surgical procedure phase, and possible complications during the post-procedure phase, are concerns for the OBS, which may not have the full facility resources to address emergency situations arising from the office based surgery; (5) Staff for OBS are likely to be well familiar with eye surgeries and the patients themselves, but a general O.R. or ASC staff might be more experienced in responding to a wider range of surgical related complications; (6) The intricate, delicate, and complicated surgical procedures performed by varying experienced eye surgeons remains a concern when these procedures are performed outside of a full facility operating theater; (7) There is considered by some commenters to be a paucity of independent, high-quality, peer-reviewed clinical data supporting the safety or feasibility of retina surgery performed in an office setting, nor do they believe that there is any widespread demand by retina specialists or patients for this OBS option.

Response: We appreciate commenters' perspectives regarding their experience and concerns for Cataract and Retinal Surgeries being furnished as OBS. As we continue to consider how and where these services are furnished, and whether they are typically furnished in different settings, information such as the comments provided by these and other commenters are helpful. Based upon commenters' feedback, we have concerns about these services being furnished in non-facility settings. It is also unclear whether these services are routinely being furnished outside of facility settings. CMS will continue to evaluate whether these services are being furnished in non-facility settings and will consider establishing non-facility values for these services at that time.

Comment: The AMA RUC commented that it defers to the ophthalmology and retinal specialty societies to determine whether these services could be safely performed in the non-facility setting; the specialty societies recommend against CMS moving forward with making these services payable as OBS, citing many of the same commenters' concerns listed earlier in this section.

Response: We appreciate the AMA RUC's response to this issue, explaining that they defer to the specialty societies' position on this issue.

After consideration of public comments, we will continue to gather information concerning Cataract and Retinal Surgeries in the non-facility office settings and their implications to Medicare payment for future rulemaking.

We received a few public comments on the nominated CPT code 20931 (*Allograft, structural, for spine surgery only (add-on code)*) and other codes related to anterior cervical discectomy and fusion (ACDF).

Comment: One commenter agreed with the nominator that CPT code 20931 is misvalued when compared to CPT code 22853 (*Insertion of cage or mesh device to spine bone and disc space during spine fusion (add-on code)*) and other codes related to anterior cervical discectomy and fusion (ACDF), where the higher payment for CPT code 22853 inappropriately incentivizes surgeons to insert the synthetic cage spacer over the bone allograft. However, one commenter stated that there is no evidence that CPT code 20931 is misvalued, and that the valuation of CPT code 20931 should not be equivalent to CPT code 22853.

Response: We thank these commenters for their feedback. As this nomination is almost identical to a grouping of related codes for ACDF that had been presented in the CY 2022 PFS proposed rule (86 FR 65044), under CPT code 22551 as misvalued, and as it was discussed at that time and reviewed again in this rule, we do not believe that the nominator has provided sufficient evidence to demonstrate that CPT code 20931 is misvalued nor that this code's payment should be made equivalent to CPT code 22853. As stated earlier, our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to individual codes, or with the inter-code relativity between the

RVUs assigned to several individual codes found within a family of codes with hierarchical relationships. We generally do not examine the summed differences in total RVUs (as is the case presented here), based on billing patterns for a combination of codes representing differing physician work for different methods of performing a service, and then comparing the total RVUs of each method as evidence of the potential misvaluation of codes. We do not believe that the nominator or other interested parties have provided sufficient evidence to demonstrate that CPT code 20931 itself is misvalued, and therefore, we are not inclined to propose (or adopt) this code as potentially misvalued.

After consideration of public comments, we are finalizing our proposal not to adopt any of the nominated codes as potentially misvalued codes. We encourage commenters who wish to nominate codes as potentially misvalued to consider the types of supporting documentation listed in the beginning of this section, as that information is important for us to consider in our process for reviewing nominations of potentially misvalued codes.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (§ 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare Telehealth Services List to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic: Category 3. This new category describes services that were added to the Medicare Telehealth Services List during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio-video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criterion described above. We assessed codes that were temporarily available on the list for the duration of the PHE to determine their appropriateness for inclusion on the Medicare Telehealth Services List on a Category 3 basis. We have reassessed the services that are temporarily available via telehealth for the PHE, based on both information provided by interested parties and our own internal review. We have assessed whether or not these services can, outside of the circumstances of the PHE, be furnished using the full scope of service elements via two-way, audio-video communication technology, without jeopardizing patient safety or quality of care, and we now believe that there are additional services that would be appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis that we did not identify in the CY 2021 rulemaking. In the proposed rule, we proposed to add these additional services to the Medicare Telehealth Services List on a Category 3 basis, as further discussed below.

The Medicare Telehealth Services List, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2023, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2022. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare Telehealth Services List, including where to submit these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2023

Under our current policy, we add services to the Medicare Telehealth Services List on a Category 1 basis when we determine that they are similar to services on the existing Medicare Telehealth Services List for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criterion not only streamlines our review process for publicly requested services that fall into this category, but also expedites our ability to identify codes for the Medicare Telehealth Services List that resemble those services already on the Medicare Telehealth Services List. We add services on a Category 2 basis when the service does not fall within Category 1, and based upon our assessment of whether the services are accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. We add services on a temporary Category 3 basis when the services were temporarily included on the Medicare Telehealth Services List during the PHE, and we find that there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2023. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. We also assessed the appropriateness of adding these services to the Medicare Telehealth Services List on a Category 3 basis instead.

We did not propose changes to the length of time the services that we temporarily included on a Category 3 basis will remain on the Medicare Telehealth Services List; the services we temporarily included on the Medicare Telehealth Services List on a Category 3 basis will continue to be included through the end of CY 2023. In the CY 2023 PFS proposed rule, we noted that in the event that the PHE extends well into CY 2023, we may consider revising this policy.

We proposed to add some services to the Medicare Telehealth Services List on a Category 3 basis through the end of 2023, some of which we had not previously added to the Medicare Telehealth List during the PHE, but have been added on a subregulatory basis as provided in § 410.78(f) of our regulations. For some of these services, we received information from interested parties suggesting potential clinical benefit. For others, we continue to believe there is sufficient evidence of potential clinical benefit to warrant allowing additional time for interested parties to gather data to support their possible inclusion on the Medicare Telehealth Services List on a Category 1 or 2 basis. The Medicare Telehealth Services List requests for CY 2023 are listed in Table 11.

Additionally, the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) amended section 1834(m) of the Act to extend a number of flexibilities that are in place during the PHE for COVID–19 for 151 days after the end of the PHE. To align the availability of these services with those flexibilities extended under the Act, we proposed to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE.

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TABLE 11: Services Requested for Addition to the Medicare Telehealth Services List for CY 2023

HCPCS	Long Descriptor	Basis
	Code Family	
	Lactation classes	
S9443	Lactation classes, non-physician provider, per session	
	Telephone E/M	
99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	3
99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	3
99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	3
	Therapy	
90901	Biofeedback training by any modality	1
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	1
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	1
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	1
97150	Therapeutic procedure(s), group (2 or more individuals)	1
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.	1
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	1

HCPCS	Long Descriptor	Basis
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	1
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes	1
97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes	1
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes	1
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes	1
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes	1
98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	1
98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	1
98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	1
Gastrointestinal tract imaging		
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report	3
Ambulatory continuous glucose monitoring		
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report	N/A
Electronic analysis of implanted neurostimulator pulse generator/transmitter		
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	3
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	3
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	3
Adaptive behavior treatment and Behavior identification assessment		

HCPCS	Long Descriptor	Basis
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	2
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	2
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	2
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	2
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	2
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	2
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	2
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	2
0362T	Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2

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We remind interested parties that the criterion for adding services to the Medicare Telehealth Services List under Category 1 is that the requested services are similar to professional consultations, office visits, and/or office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services listed in Table 11 met the Category 1 or 2 criteria.

We received a request to permanently add CPT code S9443 (*Lactation classes, non-physician provider, per session*) to the Medicare Telehealth Services List. This service has a status code of ''I,'' which means that it is not valid for Medicare billing purposes. We understand that this is a temporary code established by a private payor for private payor use, and thus, it is not valid for nor payable by Medicare. As such, this code is not separately billable under the PFS. We generally do not add services to the Medicare Telehealth Services List unless they are separately billable under the PFS. Outside of the circumstances of the PHE, the Medicare Telehealth Services List only includes services that are covered if they are furnished without the use of telecommunication technology in-person. Because CPT code S9443 is not billable under the PFS when furnished in-person, we do not believe it would be appropriate to allow the service to be billed separately when furnished as a Medicare telehealth service. As noted in the CY 2018 PFS final rule (82 FR 53011), if a service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of the statute. We did not propose to add CPT code S9443 to the Medicare Telehealth Services List.

Comment: A commenter requested that this code (CPT code S9443) be added on a Category 3 basis, citing financial pressures and staff shortages, which are affecting labor and delivery units.

Response: We thank the commenter for this comment, but as noted in the proposed rule, this code is not separately billable under the PFS when furnished in-person, so we do not believe that it should be considered a telehealth service within the meaning of the statute. We continue to believe it would be inappropriate to allow CPT code S9443 to be billed separately when furnished as a Medicare telehealth service, and we are finalizing our proposal not to add CPT code S9443 to the Medicare Telehealth Services List.

(1) Therapy Services

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116, 97150, and 97530; Physical Therapy Evaluations: CPT codes 97161–97164; Therapy Personal Care services: CPT codes 97535, 97537, and 97542; and Therapy Tests and Measurements services: CPT codes 97750, 97755, and 97763, to the Medicare Telehealth Services List on a Category 1 basis.

In the CY 2022 PFS final rule (86 FR 65051), we determined that these services did not meet the Category 1 criteria for addition to the Medicare Telehealth Services List because they involve direct observation and/or physical contact between the practitioner and the patient and, in many instances, are therapeutic in

nature, and that they did not meet Category 2 criteria, because we thought that the request did not provide sufficient detail to determine whether all of the necessary elements of the service could be furnished remotely. We continue to believe this is the case. We still do not have sufficient information to determine whether these services meet the Category 2 criteria. However, we noted that some of these codes, including codes 97110, 97112, 97116, 97150, 97530, 97161–97164, 97535, 97542, 97750, and 97755 have been added to the list on a temporary basis for the duration of the PHE.

In assessing the evidence that was supplied by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely. Information regarding safety, appropriateness, and that indicates that all elements of a given CPT code can be furnished via telehealth is still needed to assess whether these services meet the Category 2 criteria. However, we also believe that the therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE (including CPT codes 97150, 97530, and 97542), but are not currently included on a Category 3 basis, may continue to be furnished safely via two-way, audio-video communication technology outside of the circumstances of the PHE.

Therefore, we proposed that CPT codes 97150, 97530, and 97542 (the set of therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE) be added to the Medicare Telehealth Services List through the end of CY 2023 on a temporary, Category 3 basis, to allow time to gather additional data that could support their possible inclusion on the list on a permanent basis. CPT codes 97110, 97112, 97116, 97161–97168, 97535, 97750, and 97755 will continue to be available on the Medicare Telehealth Services List on a Category 3 basis. We anticipate that keeping these services on the Medicare Telehealth Services List on a Category 3 basis, as proposed, through the end of CY 2023 would preserve access to care and promote health equity, and based on information provided by interested parties and internal review, we believe that they may safely be furnished as telehealth outside of the circumstances of the PHE through the end of CY 2023. However, we remind readers that the practitioners who primarily furnish these services, physical therapists, are not, outside the circumstances of the PHE (and the 151-day period following the expiration of the PHE), authorized to furnish Medicare telehealth services. We noted that, if the PHE and the 151-day period following the expiration of the PHE both end in CY 2023, the pre-PHE rules will take effect, and these services could no longer be furnished by therapists as Medicare telehealth services.

Certain other requested therapy services, namely CPT codes 97537, 97763, 90901, and 98960–98962 were not on the Medicare Telehealth Services List prior to June 16, 2022; however, we added these services to the Medicare Telehealth Services List on a temporary basis during the PHE, in accordance with § 410.78(f). As explained below in section II.D.1.d. of this final rule, services included on the Medicare Telehealth Services List on a temporary basis during the PHE that have not been added to the list on a Category 3 basis will remain on the list for 151 days following the end of the PHE. Furthermore, we proposed to add CPT codes 97537, 97763, 90901, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis through the end of CY 2023. Our clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology during the circumstances of the PHE, and information provided by requestors indicates that there may be clinical benefit; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. Including these services on the Medicare Telehealth Services List during the PHE and through CY 2023 will allow additional time for the development of evidence for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List on a Category 1 or 2 basis. We continue to encourage commenters to supply additional information in support of adding these services to the Medicare Telehealth Services List on a permanent basis, including information regarding the safety and appropriateness of furnishing these services via telehealth.

Comment: Several commenters supported our addition of the listed therapy services to the Medicare Telehealth Services List on a Category 3 basis. However, commenters stated that many of these codes should be added permanently; commenters specifically stated that therapy services, including CPT codes 97110, 97112, 97116, 97150, 97161–97164, 97530, 97535, 97537, 97542, 97750, 97755, 97763, 90901, 98960, 98961, and 98962 should be added permanently, stating that these codes have been used successfully to provide telehealth services throughout the PHE and have shown that the same quality of care can be given with equal or higher levels of patient satisfaction as in-person visits. According to these commenters, the PHE has given ample data to support that, when used appropriately, telehealth can have a positive effect on outcomes for patients who are restricted from a full course of in-person therapy visits, which they claim is at a lower cost of care, and the inclusion of these therapy service codes on the Medicare Telehealth Services List on a Category 1 or Category 2 basis would preserve access to these services beyond the temporary extension and ease administrative burden should Congress act in the future to make rehabilitation services delivered via telehealth permanent.

Response: We note that all of the above-mentioned therapy services are either currently on the Medicare Telehealth Services List on a Category 3 basis, or we have proposed to add them on a Category 3 basis for CY 2023, to continue to gather data with regard to likely clinical benefit when furnished via telehealth outside of the circumstances of the PHE. We continue to believe that the process as discussed in the CY 2021 PFS final rule (85 FR 84506 through 84509), whereby we created the Category 3 basis for adding to or deleting services from the Medicare Telehealth Services List is the appropriate means of potentially adding services permanently for those services that were temporarily added under the circumstances of the PHE, as this process allows for the collection and evaluation of data that could potentially support permanent inclusion following the 151-day period after the end of the PHE. We believe our proposal, consistent with the amendments made by provisions of the CAA, 2022, to extend the period that these services will be available on the Medicare Telehealth Services List temporarily for the PHE by 151 days following the end of the PHE will further enhance the opportunity for the collection of information on the experiences of clinicians who are furnishing telehealth services during the PHE for COVID–19. This will also help us to determine which services may ultimately be eligible for permanent addition under Category 1 or Category 2 criteria, and we encourage interested parties to use this

extended time period to gather data on use of services, that is more than statements of support and more than subjective attestations of clinical benefit, to support their potential addition in future rulemaking.

Comment: Commenters requested clarification on whether CPT codes for Occupational Therapy (97165, 97166, 97167, and 97168) and Speech Therapy (92522 and 92523) were included in the list of Category 3 codes for CY 2023, and should be added on a Category 3 basis.

Response: We clarify that these codes (CPT codes 97165–97168 and 92521–92524) are currently included on the Medicare Telehealth Services List available on a Category 3 basis.

After consideration of public comments, we are finalizing our proposed addition of CPT codes 90901, 97150, 97530, 97537, 97542, 97763, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis.

(2) Telephone E/M Services

We have also received requests to temporarily add Telephone E/M visit codes, CPT codes 99441, 99442, and 99443 to the Medicare Telehealth Services List on a Category 3 basis. In the March 31, 2020 interim final rule with comment period (IFC), we established separate payment for audio-only telephone E/M services (85 FR 19264 through 19266) for the duration of the PHE for the COVID–19 pandemic. Although these services were previously considered non-covered under the PFS, in the context of the PHE for COVID–19 and with the goal of reducing exposure risks associated with COVID–19 (especially in situations when two-way, audio and video technology is not available to furnish a Medicare telehealth service), we believed there were circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. In the May 8, 2020 COVID–19 IFC, we noted that interested parties had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not using video-enabled communication technology from their homes. In other words, there were many cases where practitioners who would ordinarily furnish audio-video telehealth or in-person visits to evaluate and manage patients' medical concerns were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE for COVID–19, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the PHE for COVID–19 was not accurately captured by the valuation of these services that we established in the March 31, 2020 IFC (85 FR 27590). This will be particularly true to the extent that these audio-only services are serving as a substitute for office/outpatient (O/O) Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology, which is contrary to the situation we anticipated when establishing separate payment for them in the March 31, 2020 IFC. In the May 8, 2020 COVID–19 IFC, we stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the O/O E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous O/O E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the O/O E/M codes. Specifically, we crosswalked the levels 2–4 O/O E/Ms for established patients, as described by CPT codes 99212, 99213, and 99214, to CPT codes 99441, 99442, and 99443, respectively. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for O/O E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare Telehealth Services List for the duration of the PHE for COVID–19 (85 FR 27590).

In the CY 2022 PFS final rule (86 FR 65055), in response to requests that these codes be added to the Medicare Telehealth Services List on a Category 3 basis, we stated that we were finalizing a change to the definition of ''telecommunications system'' to allow telehealth services for the diagnosis, evaluation, and treatment of mental health conditions to be furnished through audio-only technology in certain circumstances after the end of the PHE. For example, the O/O E/M codes are on the Medicare Telehealth Services List permanently and when used to describe care for mental health conditions, will be reportable when furnished via audio-only technology to patients in their homes. Since audio-only telecommunications technology can be used to furnish mental health telehealth services to patients in their homes, the addition of these codes to the Medicare Telehealth Services List is unnecessary for mental health telehealth services. For telehealth services other than mental health care, we stated that we believe that two-way, audio-video communications technology is the appropriate standard that will apply for telehealth services after the PHE ends. Further, we noted that section 1834(m)(2)(A) of the Act requires that payment to a distant site physician or practitioner that furnishes Medicare telehealth services to an eligible telehealth individual be equal to the amount that would have been paid under Medicare if such physician or practitioner had furnished the service without a telecommunications system. We believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. However, these audio-only telephone E/M services are inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications. Outside the circumstances of the PHE, the telephone E/M services would not be analogous to in-person care; nor would they be a substitute for a face-to-face encounter. Therefore, we do not believe it will be appropriate for these codes to remain on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE extension period. Accordingly, we did not propose to keep these telephone E/M services on the Medicare Telehealth Services List after that period on a Category 3 basis, because the codes describe services that can only be furnished using audio-only telecommunications technology, and outside of the circumstances of the PHE, they do not describe services that are a substitute for an in-person visit. While we acknowledge that audio-only technology can be used to furnish mental health telehealth services to patients in their homes under certain circumstances after the PHE ends, two-way, audio-video communications technology continues to be the appropriate standard that will apply for Medicare telehealth services after the PHE and the 151-day extension period. As we noted in the CY 2021 PFS final rule (85 FR 84535), we will assign these Telephone E/M visit codes (CPT codes 99441, 99442, and 99443) a ''bundled'' status after the end of the PHE and the 151-day extension period, and we will post the RUC-recommended RVUs for

these codes in accordance with our usual practice.

We received public comments on Telephone E/M Services. The following is a summary of the comments we received and our responses.

Comment: Many commenters urged us to continue to make payment for Telephone E/M visit codes following 151 days after the PHE. Some commenters stated that payment for these services should be made permanent while others request that they be added to the Medicare Telehealth Services List on a Category 3 basis. Commenters stated that experience during the PHE indicated that telehealth can provide a viable alternative to office visits. Commenters stated that, although patient-provider communication using both audio and visual modes is considered optimal for telehealth delivery, many patients are unable to use the video technology required due to lack of broadband or cellular data, technology that does not support video, or difficulty in using video technology. Commenters cited access concerns, particularly for patients who live in rural areas or who lack of broadband access, as well as disparities in access to technology and in digital literacy.

A commenter noted that, in the CY 2023 PFS proposed rule, CMS further stated that telephone E/M services are neither analogous to an in-person E/M visit nor can the telephone E/M substitute for an in-person E/M visit. However, as noted above, in the second IFC, CMS did believe telephone E/Ms were serving as a substitute for in-person E/M visits, and because of that, began to reimburse them the same rate as in-person E/M visits. Commenters noted that this would indicate they are analogous to an in-person service and would fit the criteria to be on the Medicare Telehealth Services List permanently.

Response: We reiterate that we believe these audio-only telephone E/M services are inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications. We continue to believe that, outside the circumstances of the PHE, these services will no longer serve as a substitute for in-person care that is ordinarily furnished in a face-to-face encounter. Section 1834(m)(1) of the Act requires that we make payment for telehealth services ''notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary.'' Section 1834(m)(2)(A) of the Act requires that we make payment to a physician or practitioner located at a distant site for a telehealth service at an amount equal to the amount that the physician or practitioner would have been paid if the service had instead been furnished without the use of a telecommunications system. Taken together, we believe that the statute requires that Medicare telehealth services be analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. We recognize that we added the telephone E/M services to the Medicare Telehealth Services List on a temporary basis during the PHE to address the associated extraordinary public health and safety, and healthcare access issues. However, outside of the circumstances of the PHE, we continue to believe that our longstanding regulatory interpretation of ''telecommunications system'' generally precludes the use of audio-only technology for purposes of Medicare telehealth services, with the exception under certain circumstances of telehealth services to diagnose, evaluate, or treat a mental health disorder (including treatment of a diagnosed SUD or co-occurring mental health disorder). That rule and the exception are specified in our regulation at § 410.78(a)(3). At the conclusion of the PHE and the 151-day extension period provided by the CAA, 2022, the only Medicare telehealth services that will be permitted to be furnished using audio-only technology will be the mental health telehealth services. When a practitioner furnishes such an E/M service using audio-only technology, they would bill for the same service they would bill if the service had been furnished in person. As such, there is not a need to add the telephone-only E/M codes to the Medicare Telehealth Services List for this purpose.

Comment: A commenter stated that, if CMS removes the telephone E/M CPT codes 99441–99443 from the Medicare Telehealth Services List on the 152nd day after the PHE ends, CMS should then create and establish particular values for a third and higher level of virtual check-in service that would be similar to the telephone E/M services that have been available during the PHE. The commenter is requesting that this third virtual check-in code would crosswalk to CPT code 99443, and should assign RVUs to HCPCS codes G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*), G2252 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*), and a third potential check-in code with crosswalks to CPT codes 99441–99443, respectively.

Response: We appreciate the comment and may consider potential coding revisions for future rulemaking. However, we believe that, in light of the fact that the virtual check-in codes are intended for practitioners to have a non-face-to-face discussion with a patient to determine the need for care, the necessity for a longer virtual check-in (for example, 21–30 minutes) is not clear. Moreover, if a patient requires evaluation and management (E/M) services that are sufficiently complicated to last longer than the 11–20 minutes considered in HCPCS code G2252, then there are many other E/M visit codes that are already available as Medicare telehealth.

After consideration of public comments, we are finalizing our proposal not to add these CPT codes 99441–99443 to the Medicare Telehealth Services List on a Category 3 basis; rather, we will retain CPT codes 99441–99443 on the Medicare Telehealth Services List through expiration of the 151-day period following the end of the PHE, at which point they will revert to bundled status.

(3) GI Tract Imaging and Continuous Glucose Monitoring

We received requests to add CPT codes describing GI Tract Imaging, CPT code 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) and Ambulatory Continuous Glucose Monitoring, CPT code 95251 (*Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report*), to the Medicare Telehealth Services List on a Category 3 basis. We believe these codes may describe services that are inherently non-face-to-face services, (the patient need not be

present in order for the service to be furnished in its entirety), and therefore, they do not describe services that are a substitute for an in-person visit. As stated earlier, we believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. For this and other reasons, we did not propose to add these services to the Medicare Telehealth Services List on a Category 3 basis; we do not believe these CPT codes describe services that are a substitute for an in-person visit, and we believe that services that are not inherently face-to-face services are not services that can be furnished as Medicare telehealth services. Even so, we are interested in information that would help us to understand whether these services would meet the criteria for inclusion on the Medicare Telehealth Services List either for the PHE, as Category 3 services, or permanently on a Category 1 or 2 basis, given our questions as to whether they are inherently non-face-to-face services, and therefore, may not fit within the scope of services that could be furnished as Medicare telehealth services. Therefore, we also solicited comment on whether these services would involve an in-person service when furnished without the use of a telecommunications system.

We received public comments on GI Tract Imaging and Continuous Glucose Monitoring. The following is a summary of the comments we received and our responses.

Comment: A commenter agreed that CPT code 91110 describes a service that is inherently a non-face-to-face service, as the patient is not present in order for the service to be furnished in its entirety. The commenter described the services as involving swallowing a capsule camera that captures images of the gastrointestinal tract, which are recorded on the capsule and subsequently reviewed by the clinician using special computer software. The commenter stated that the ingestion of the capsule is the only component of this service that requires direct observation by a health care provider. The commenter noted that less than 10 percent of the service time/work associated with CPT code 91110 involves any direct interaction with the patient, and the small amount of patient interaction can be done safely and effectively via a telehealth visit with video, per the FDA clearance.

According to one commenter, since the capsule service should only be offered to an established patient, an in-person interaction to administer the capsule is unnecessary and the patient can safely do so in the home setting.

Response: We appreciate this background information from the commenters. Given that this service describes collection, interpretation, and reporting, we believe this code describes services that are not inherently non-face-to-face, and therefore, they do not describe a service that is a substitute for an in-person visit. Additionally, the face-to-face portion of the service would require the patient to be physically present.

Comment: Some commenters agreed with CMS' assessment that Ambulatory Continuous Glucose Monitoring, CPT code 95251, is an inherently non-face-to-face service, and therefore, does not describe a service that is a substitute for an in-person visit. CPT code 95251 does not involve an in-person visit when furnished without the use of a telecommunications system.

One commenter opposed our proposal not to add CPT code 95251 to the Medicare Telehealth Services List on a Category 3 basis, citing the importance of this service in treating gestational diabetes, saying CMS should add CPT code 95251 to the list on a Category 3 basis when it is billed with CPT codes 99213 (*Established patient office or other outpatient visit, 20–29 minutes*) or 99214 (*Established patient office or other outpatient visit, 30–39 minutes*) and the appropriate modifier. Another commenter cited 2020 claims data that shows CPT code 95251 is billed 8.2 percent and 62.6 percent of the time with CPT codes 99213 and 99214, respectively, demonstrating that this service is typically performed face-to-face.

Response: We appreciate the comments. We continue to believe, and commenters have confirmed, that CPT code 95251 is not a substitute for an in-person visit, as this code describes physician analysis, interpretation, and reporting, which does not inherently describe a face-to-face encounter. Accordingly, this code does not describe a service that, when conducted via telehealth, is a substitute for a face-to-face service. As noted in the CY 2018 PFS final rule (82 FR 53011), if a service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of the statute.

After consideration of public comments, we are finalizing our proposal not to add CPT code 91110 or CPT code 95251 to the Medicare Telehealth Services List on a Category 3 basis.

(4) Neurostimulator Pulse Generator/ Transmitter

We received requests to add codes describing the electronic analysis of an implanted neurostimulator pulse generator/transmitter to the Medicare Telehealth Services List. These included a request to add CPT codes 95976 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) permanently on a Category 1 basis, as well as a request to add CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/ transmitter, without programming*), 95983 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/ transmitter programming, first 15*

minutes face-to-face time with physician or other qualified health care professional), and 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)*) to the Medicare Telehealth Services List on a temporary Category 3 basis.

The request to add CPT codes 95976 and 95977, which are codes that describe analysis of cranial nerve neurostimulation, indicated that the ability to fully furnish this service using two-way, audio-video communication technology was forthcoming, but is currently unavailable. Therefore, we did not propose to add CPT codes 95976 and 95977 to the Medicare Telehealth Services List, because the full scope of service elements described by these codes cannot currently be furnished via two-way, audio-video communication technology. However, we will consider additional evidence regarding the ability to furnish these services as telehealth services, such as information indicating that current technology has evolved, as it becomes available for future rulemaking. We also did not propose to add them on a Category 1 basis because they do not describe services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List.

With regard to CPT codes 95970, 95983, and 95984, which describe general brain nerve neurostimulation, we have some concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE, and Medicare claims data suggest that these services are being provided via telehealth. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. With that said, CPT codes 95970, 95983, and 95984 do meet the criteria for temporary inclusion on the Medicare Telehealth Services List on a Category 3 basis. Therefore, we proposed to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis, while we solicited comment on our concerns regarding patient safety and whether these services are appropriate for inclusion on the Medicare Telehealth Services List outside the circumstances of the PHE.

Comment: Commenters agreed with CMS that the full scope of service elements described by CPT codes 95976 and 95977 cannot currently be furnished via two-way, audio-video communication technology, and they state that the agency should reconsider these services for possible addition to the Medicare Telehealth Services List as evidence develops regarding the ability to furnish these services as telehealth services.

Response: We appreciate commenters' support for this proposal and are finalizing our proposal to not add these services to the Medicare Telehealth Services List.

Comment: Commenters supported our proposal to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis. Some commenters expressed disappointment that we did not propose to add them to the Medicate Telehealth Services List permanently. In response to our comment solicitation regarding patient safety concerns, a commenter noted that the technology includes safety features, including a prominent network status indicator that appears on both the clinician's programmer, as well as the patient's device, and the ''Protected Recovery Program'' (PRP) feature that ensures the patient is returned to a known state if a remote session is interrupted. According to one commenter, systems have been successfully in use for over a year and a half that allow for a stable, secure 2-way telehealth connection for brain stimulator pulse generator programming. Commenters stated that these systems route through a secure HIPAA-compliant server and allow the managing physician qualified health care professional (QHP) to remotely control all essential functions of the patient device while providing real time audio and video to allow for patient assessment and feedback. The commenter noted that CMS' concerns regarding patient safety if the programming is incorrect or if another problem occurred have been addressed in the development and deployment of existing remote brain neurostimulator programming systems. The commenter stated that these systems ensure that the patient controller has a ''safe'' program (set of stimulation parameters). In the event of an interruption in the remote connection, they noted that the device automatically reverts to this ''safe'' program, so that the patient is not left with a potentially problematic set of programming parameters.

The commenter also noted that all elements can be fully and effectively performed by a remotely located clinician using two-way, audio/video telecommunication technology including direct programming of implantable neurostimulator devices, and these services are critical to the successful therapy regimens and health outcomes of people with Parkinson's disease.

Response: We continue to believe that these services are most appropriately added to the Medicare Telehealth Services on a Category 3 basis. Adding them on a Category 3 basis will allow the continued collection of information through the experiences of clinicians who are furnishing these services via telehealth during the PHE for COVID–19, and help us to determine whether these services may ultimately be eligible for addition to the Medicare Telehealth Services List on a Category 1 or Category 2 basis. We encourage interested parties to use this extended time period to gather data on these services to support their potential addition to the Medicare Telehealth Services List on a Category 1 or Category 2 basis in the future.

After consideration of public comments, we are finalizing our proposals not to add CPT codes 95976 and 95977 to the Medicare Telehealth Services List, and to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis.

(5) Emotional/Behavior Assessment Services and Psychological or Neuropsychological Testing and Evaluation Services

We received requests to add a number of emotional/behavior assessment services and psychological, or neuropsychological testing and evaluation services, described by CPT codes 97151 (*Behavior identification assessment, administered by a*

physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan), 97152 (*Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes*), 97153 (*Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes*), 97154 (*Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes*), 97155 (*Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes*), 97156 (*Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes*), 97157 (*Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes*), 97158 (*Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes*), 0362T (*Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*), and 0373T (*Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*) to the Medicare Telehealth Services List permanently on a Category 2 basis. These services are currently on the Medicare Telehealth Services List temporarily for the duration of the PHE. We believe that, for these services, there is likely to be clinical benefit when furnished via telehealth, and therefore, they meet the criteria for temporary inclusion on a Category 3 basis. We did not identify these services during our initial assessment of services that should be temporarily available on the Medicare Telehealth Services List on a Category 3 basis in CY 2021 rulemaking; however, we proposed to include these services on the Medicare Telehealth Services List on a Category 3 basis, in light of information we received from the requestors describing the potential clinical benefit of these services when furnished via telehealth. However, we do have concerns regarding whether, outside the circumstances of the PHE, the full scope of service elements can occur in a manner that does not jeopardize quality of care, whether this patient population could be fully assessed via interactive audio-video technology, and whether these services could be conducted in a way that maintains the safety of the beneficiary. This patient population often includes patients with moderate to severe challenges in oral communication, and they may require close observation of their movements within all of their environmental cues, which include, for instance, smell, sound, and colors around the room. We are concerned that two-way, audio and video communications technology would not fully capture these behavioral nuances. We believe more time may be necessary to develop evidence that could support the decision to add these services to the Medicare Telehealth Services List permanently on a Category 1 or Category 2 basis. We solicited comment on our patient safety concerns.

We received public comments on emotional/behavior assessment and psychological or neuropsychological testing and evaluation services. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of these services on a Category 3 basis. Some commenters suggested that the services should be added permanently, rather than temporarily on a Category 3 basis.

One commenter urged us to permanently add CPT codes 97151, 97152, 97153, 97154, 97155, and 97156, but did not find sufficient evidence supporting safe, effective telehealth delivery of the services represented by codes 97157, 97158, 0362T, or 0373T; however, the commenter supported our proposal to add the latter four codes on a Category 3 basis.

A few commenters responded to our concerns regarding patient safety, quality of care, and whether the full scope of service elements can be met via two-way audio-video communication technology. In response to our questions about regarding whether this patient population can be assessed fully and safely via interactive audio-video technology and our concerns that patients with moderate to severe communication difficulties often require close observation of their responses to cues in their environments (for example, odors, sounds, colors) that could not be accomplished remotely via technology, a commenter acknowledged our concerns, but noted that the services represented by this code set are not specific to any patient population; rather, they noted that they are for any patient for whom they may be medically necessary. The commenter included emerging evidence of the efficacy of telehealth delivery of the services, including research articles relevant to each service. The commenter noted that no reports of significant adverse events or negative side effects were noted in research; however, the commenter indicated that when the assessment or treatment services targeted behaviors in patients with developmental disabilities that carried risk of harm, the supervising behavior analysts (QHPs) had the behavior technicians or caregivers who delivered the services take precautions to protect patients.

A commenter agreed there may be concern that some patients may not be able to be fully assessed via interactive audio-visual technology; however, they stated that the benefits of furnishing these services via telehealth outweigh the concerns. The commenter also noted that the decision as to the appropriateness of care should be determined by the provider, without financial disincentives between in-person and telehealth care. The commenter noted that there are significant benefits to being able to provide these services via telehealth. The commenter stated that patients with dementia or other cognitive or psychological impairments may require the assistance of additional parties

during a visit, and that providing these services remotely can allow for inclusion of other people, including family, significant others, and additional practitioners, who can provide substantial benefits. According to the commenter, this is not always the case for in-person visits, as caregivers and other family members may not be able to take time off from work or travel to the appointments, and virtual visits allow for the practitioner, the patient, and important family members to be in separate locations while still being able to participate in the visit. Additionally, the commenter noted that psychiatric patients often have social anxiety issues, leading to limitations on leaving safe places like their home, facility, or family, and remote visits are important ways to ensure these patients maintain access to care.

A commenter did not support these services remaining on the Medicare Telehealth Services List, stating such additions may pose beneficiary safety and quality-of-care issues. The commenter urged us to exercise extreme caution when adding additional mental-health-related services to the Medicare Telehealth Services List on a temporary basis, considering the unique challenges faced by persons living with mental health conditions, and the multiple, system-wide issues currently complicating the delivery of safe and effective mental health care.

Response: We note that CPT codes 90853 and 96121 are already permanently on the Medicare Telehealth Services List. Regarding CPT codes 96130–96133, 97151–97158, 0362T, and 0373T, we continue to believe our proposal to add these services on a Category 3 basis is appropriate and preferable. Adding these CPT codes to the Medicare Telehealth Services List on a Category 3 basis will allow for the collection and evaluation of data that could potentially support permanent inclusion on the Medicare Telehealth Services List, and we look forward to evaluating such data in the future.

After consideration of public comments, we are finalizing our proposal to retain CPT codes 97151–97158, 0362T, and 0373T on the Medicare Telehealth Services List on a Category 3 basis.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

As discussed above, there are services that are included on the Medicare Telehealth Services List temporarily during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition to the list under the Category 1 or Category 2 criteria. In addition to the services we proposed for addition to the Medicare Telehealth Services List on a Category 3 basis in response to requests, we also proposed to add a number of services to the Medicare Telehealth Services List on a Category 3 basis that are currently included on the Medicare Telehealth Services List temporarily during the PHE that were not specifically requested for permanent addition. These services would be included on the Medicare Telehealth Services List through 2023 to allow us time to evaluate data that may support their permanent addition to the list on a Category 1 or Category 2 basis.

The services we proposed for addition to the Medicare Telehealth Services List temporarily on a Category 3 basis include CPT codes 90875 (*Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes*), 92012 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*), 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*), 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*), 94005 (*Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more*), 96105 (*Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, e.g., by Boston Diagnostic Aphasia Examination*) with interpretation and report, per hour), 96110 (*Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument*), 96112 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour*), 96113 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)*), 96127 (*Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument), 96170 (Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)*), 97129 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes*), 97130 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)*), and 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*). Our analyses of these services indicate that there is some evidence of possible clinical benefit associated with these services when furnished via telehealth. We believe these services can safely be furnished via real-time, audio and visual interactive telecommunications under the circumstances of the PHE, but there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria.

Some audiology testing services are currently temporarily included on the Medicare Telehealth Services List for the duration of the PHE. These are CPT codes 92550 (*Tympanometry and reflex threshold measurements*), 92552 (*Pure tone audiometry (threshold); air only), 92553 (Pure tone audiometry (threshold); air and bone*), 92555 (*Speech audiometry threshold;*), 92556 (*Speech audiometry threshold; with speech recognition*), 92557 (*Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)*), 92563 (*Tone decay test), 92565 (Stenger test, pure tone*), 92567 (*Tympanometry (impedance testing)*), 92568 (*Acoustic reflex testing, threshold*), 92570 (*Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing*), 92587 (*Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3–6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report*), 92588 (*Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report*), 92601 (*Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming*), 92625 (*Assessment of tinnitus (includes pitch, loudness matching, and masking)*), 92626 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour*), 92627 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)*). We have received information that, during the PHE, certain practitioners have developed the capacity to perform these services using remote technology including specialized equipment inside an audiometric soundproof booth. We believe that, in circumstances in which such equipment is available at the originating site, these services can be furnished in a way in which all of the elements of the services are met and that there is likely to be a clinical benefit when these services are furnished via telehealth. Therefore, we proposed to add these services to the Medicare Telehealth Services List on a Category 3 basis, which will allow these services to be available via telehealth through the end of CY 2023. We solicited comments regarding how widespread the availability of this remote technology is, and whether interested parties believe these services can be furnished in a way that does not jeopardize patient safety or quality of care when these services are furnished remotely.

Additionally, as discussed in section II.F. of this final rule, we proposed to create HCPCS codes G0316 (listed as GXXX1 in our proposed rule)(*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report G0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report G0316 for any time unit less than 15 minutes)*), G0317 (listed as GXXX2 in our proposed rule) (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0,). (Do not report G0317 for any time unit less than 15 minutes)*), and G0318 (listed as GXXX3 in our proposed rule) (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report G0318 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report G0318 for any time unit less than 15 minutes)*) to describe prolonged services associated with certain types of E/M services. These codes will be replacing existing codes that describe prolonged services, specifically inpatient prolonged services CPT codes 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient or observation Evaluation and Management service)*) and 99357 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*). These services are similar to services currently on the Medicare Telehealth Services List, such as CPT codes 99356 and 99357, which were added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2016 rule (80 FR 71060–71062), as well as O/O prolonged service HCPCS code G2212 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*), which was added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2021 rule (85 FR 84506). Similarly, we believe that these proposed HCPCS G codes will be sufficiently similar to psychiatric diagnostic procedures or O/O visits currently on the Medicare Telehealth Services List to qualify for inclusion on the list on a Category 1 basis. Therefore, we proposed to add proposed HCPCS codes G0316, G0317, and G0318 to the Medicare Telehealth Services List on a Category 1 basis.

Table 12 lists the services that we are finalizing for addition to the Medicare Telehealth Services List on a Category 3 basis. Table 13 lists the services we are finalizing for permanent addition to the Medicare Telehealth Services List on a Category 1 basis.

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TABLE 12: Services Finalized for Addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of CY 2023

HCPCS	Short Descriptor
90875	Psychophysiological therapy
90901	Biofeedback train any meth
92012	Eye exam estab pat
92014	Eye exam & tx estab pt 1/>vst
92507	Speech/hearing therapy
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
94005	Home vent mgmt supervision
95970	Alys npgt w/o prgrmg
95983	Alys brn npgt prgrmg 15 min
95984	Alys brn npgt prgrmg addl 15
96105	Assessment of aphasia
96110	Developmental screen w/score
96112	Devel tst phys/qhp 1st hr
96113	Devel tst phys/qhp ea addl
96127	Brief emotional/behav assmt
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97150	Group therapeutic procedures
97151	Bhv id assmt by phys/qhp
97152	Bhv id suprt assmt by 1 tech
97153	Adaptive behavior tx by tech
97154	Grp adapt bhv tx by tech
97155	Adapt behavior tx phys/qhp
97156	Fam adapt bhv tx gdn phy/qhp
97157	Mult fam adapt bhv tx gdn
97158	Grp adapt bhv tx by phy/qhp
97530	Therapeutic activities
97537	Community/work reintegration
97542	Wheelchair mngment training
97763	Orthc/prostc mgmt sbsq enc
98960	Self-mgmt educ & train 1 pt
98961	Self-mgmt educ/train 2-4 pt
98962	Self-mgmt educ/train 5-8 pt
99473	Self-meas bp pt educaj/train
0362T	Bhv id suprt assmt ea 15 min
0373T	Adapt bhv tx ea 15 min

TABLE 13: Services Finalized for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS	Short Descriptor
G0316	Prolonged inpatient or observation services by physician or other QHP
G0317	Prolonged nursing facility services by physician or other QHP
G0318	Prolonged home or residence services by physician or other QHP
G3002	Chronic pain tx monthly b
G3003	Addition 15m pain mang

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We received public comments on these other services that we proposed for addition to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of many of these services on a Category 3 basis.

Response: We appreciate the support for our proposals.

Comment: One commenter stated that ophthalmologic services (92002, 92004, 92012 and 92014) are generally covered via telehealth by other insurance plans, including Medicare Advantage plans and the Veterans Health Administration, and should also be available to Medicare beneficiaries. Commenters supported the addition of CPT codes 92012 and 92014 on a Category 3 basis.

Response: We thank commenters for their support of our proposal, and we are finalizing as proposed the addition of CPT codes 92012 and 92014 to the Medicare Telehealth Services List on a Category 3 basis. We did not identify or propose CPT codes 92002 or 92004 as Medicare telehealth in the proposed rule. As such, discussion of these codes is outside the scope of this rule.

Comment: Regarding our comment solicitation related to patient safety for audiology services, a commenter stated that there is now strong evidence confirming that patients who receive therapy services via telehealth have similar, or even better outcomes, compared to patients who received traditional in-person therapy services (including citations of studies). This commenter cited this evidence in urging us to add these services permanently. A commenter stated that the Veteran's Administration has shown, for many years, that audiology services can be safely provided, via telehealth, without sacrificing patient outcomes or quality of care, and that the technology required to perform these procedures via telehealth, in many cases with the assistance of an audiology assistant or technician at a remote location, is readily available. Commenters requested that many audiology services that are not currently available on the Medicare Telehealth Services List be added on a Category 3 basis.

Response: We appreciate the information provided by commenters, and we may consider this information in future rulemaking. Given support of commenters, as well as information provided, we are finalizing the addition of audiology CPT codes 92550, 92552, 92553, 92555, 92556, 92557, 92563, 92565, 92567, 92568, 92570, 92587, 92588, 92601, 92625, 92626, and 92627 to the Medicare Telehealth Services List on a Category 3 basis, as proposed.

Comment: Commenters supported the addition of the proposed prolonged services HCPCS codes G0316–G0318 permanently on a Category 1 basis, stating that doing so is essential to maintaining consistency with the new coding and payment structure for inpatient E/M services.

Response: We appreciate commenters' support for this proposal. We are finalizing the addition of HCPCS codes G0316, G0317, and G0318 to the Medicare Telehealth Services List on a Category 1 basis, as proposed.

Comment: Numerous commenters requested that we add many services that are temporarily available for the PHE to the Medicare Telehealth Services List that are currently on the list on a temporary basis, but that we did not propose to continue on the list to be available as Medicare telehealth services be added on a Category 3 basis

Response: As discussed above, we identified the services we considered appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis by conducting an internal review to assess those services that may, outside of the circumstances of the PHE, be furnished using the full scope of service elements for their respective service/code via two-way, audio-video communication technology, as though the service were provided in-person. The commenters did not present new information indicating that our analysis was incomplete. Furthermore, because we did not propose to add the services requested by these commenters to the Medicare Telehealth Services List on a Category 3 basis, we found these comments to be outside the scope of the proposed rule.

As discussed in section II.E. of this final rule, we proposed to create two HCPCS G-codes to describe monthly Chronic Pain Management and Treatment services: HCPCS code G3002 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)*) and HCPCS code G3003 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for G3002). (When using G3003, 15 minutes must be met or exceeded.)*).

Comment: As discussed in section II.E.4.(33) in the CY 2023 PFS proposed rule, we solicited comment regarding how best the initial visit and subsequent visits should be conducted (for example, in-person, via telehealth, or the use of a telecommunications system, and any implications for additional or different coding). We also considered whether to add the CPM codes to the Medicare

Telehealth Services List. Many commenters asked us to add CPM services to the Medicare Telehealth Services List. One commenter stated that the CPM code(s) would be appropriate to add on a Category 1 basis, since chronic pain limits patient mobility and a ''silver lining'' of the COVID–19 pandemic is that telehealth flexibilities improved access to pain care. This commenter continued that it can be very burdensome for patients, especially those with ''high impact'' chronic pain, to physically get to doctor appointments, undergo the hardship of driving, walking distances, standing in line, and sitting for long periods in waiting rooms, all of which may exacerbate pain that has been ongoing for days to weeks. The commenter emphasized how important access to telehealth is for this particular group of Medicare patients and urged us to add it to the Medicare Telehealth Services List. One commenter stated that telehealth should be an option, because of geographic factors (rural dwellers are underserved) and life circumstances (child care, transportation), which can make repeated in-person appointments inaccessible. This commenter continued that people with chronic pain can experience challenging issues traveling to see a clinician, and often inquire about the availability of receiving integrative care through telehealth. For these reasons, this commenter recommended that we add the CPM services to the Medicare Telehealth Services List. One commenter stated they believed that telehealth increases self-efficacy in people living with pain. As a middle pathway, another commenter requested that we allow providers to use their discretion when determining if telehealth is appropriate for their patient. Another commenter added that telehealth visits should always be with the agreement of the patient as some people are more comfortable with face-to-face interactions. One commenter noted telehealth is appropriate once patients are established on their care plan, while another commenter suggested that at minimum, telehealth be allowed for all follow up visits.

Response: As discussed earlier in this section, we agree with the commenter's suggestion to add CPM services to the Medicare Telehealth Services List on a Category 1 basis. We believe that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the CPM services are sufficiently similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List for these services to be added on a Category 1 basis. By its nature, and because of the many treatment challenges described by these and other commenters in section II.E.4.(33), pain care is ideally suited to telehealth, and we believe appropriate to be furnished through interactive, real-time telecommunications technology. Like certain other non-face-to face PFS services, there are also components of HCPCS codes G3002 and G3003 describing care planning or care coordination with other health care professionals that are commonly furnished remotely using telecommunications technology, and do not require the patient to be present/in-person with the practitioner when they are furnished. As such, these components of HCPCS codes G3002 and G3003 are not considered telehealth services for purposes of Medicare, and we do not need to consider whether the non-face-to-face aspects of HCPCS codes G3002 and G3003 are similar to other telehealth services. We are finalizing in this rule that any of the CPM in-person components included in HCPCS codes G3002 and G3003 may be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries. However, we reiterate as provided in the code descriptor that the initial CPM services visit billed under HCPCS code G3002 must be furnished in-person without the use of telecommunications technology. (For further clarification about the initial in person visit requirements, please see section II.E.4.(33).)

Comment: One commenter asked that we enable the CPM codes, in addition to being rendered through telehealth, to be furnished through audio-only technology.

Response: We appreciate the comment. In the CY 2022 PFS final rule, we finalized a policy to revise the definition of ''telecommunications system'' at § 410.78(a)(3) to allow the use of audio-only technology for the diagnosis, evaluation, or treatment of mental health conditions under certain circumstances (described in detail at 86 FR 64996, 65056 through 65060) that allow visits and other services furnished via audio-only technology to be reported as Medicare telehealth services, with the appropriate modifier. We acknowledge that certain scope of service aspects of CPM may pertain to the diagnosis, evaluation, or treatment of mental health conditions. We expect clinicians will bill for the HCPCS code that most accurately describes the services furnished, including in instances where the service being furnished might determine the technological modality used to deliver the service.

After consideration of public comments, we are finalizing our proposal to add CPT codes 90875, 92012, 92014, 92507, 94005, 96105, 96110, 96112, 96113, 96127, 96170, 96171, 97129, 97130, and 99473 to the Medicare Telehealth Services List on a Category 3 basis, and finalizing our proposal to add HCPCS codes G0316, G0317, and G0318, G3002, and G3003 to the Medicare Telehealth Services List on a Category 1 basis.

d. Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE

As we noted in the CY 2022 PFS final rule (86 FR 65054), at the conclusion of the PHE for COVID–19, the associated waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through our regular notice-and-comment rulemaking process, through which we established and maintain the Medicare Telehealth Services List. Services that have been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of CY 2023. We have explained that under our current policy, all other services that were temporarily added to the Medicare Telehealth Services List on an interim basis during the PHE and have not been added to the Medicare Telehealth Services List on a Category 1, 2, or 3 basis will not remain on the list after the end of the PHE (85 FR 84506–84509). As explained in section II.D.1.e. of this final rule, Division P, Title III, Subsection A of the Consolidated Appropriations Act, 2022 (CAA, 2022), extends some of the flexibilities implemented during the PHE for COVID–19 for an additional 151 days after the end of the PHE, including section 301(a) of Division P, Title III, Subtitle A of the CAA, 2022, which specifies that, for services on the Medicare Telehealth Services List as of the date of enactment (March 15, 2022) furnished during 151 days after the end of the PHE, the originating site for the telehealth service can be any site in the United States at which the beneficiary is located when the service is furnished, including the beneficiary's home. To give full effect to this provision, we believe it is necessary to continue to include the services on the Medicare Telehealth Services List through the 151-day period after the end of the PHE that were temporarily added to the list

during the PHE but have not since been added on a Category 3 or other basis, and which are currently set to be removed from the list at the end of the PHE. As such, we proposed to continue to include on the Medicare Telehealth Services List the services that are currently set to be removed from the list when the PHE ends (that is, those not currently added to the list on a Category 1, 2, or 3 basis) for an additional 151 days after the PHE ends. Table 14 lists those services that are temporarily included on the list available for the PHE, which we proposed to retain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE. The services listed in Table 14 will no longer be available on the Medicare Telehealth Services List on the 152nd day after the end of the PHE. As previously explained, on the 152nd day after the end of the PHE, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, as aforementioned, and telehealth claims for these services furnished on or after the codes are removed from the list will be denied. We proposed to align the temporary availability of services available as Medicare telehealth services until the end of the PHE with the 151-day extensions of flexibilities enacted in the CAA, 2022 in order to simplify the process of ending the PHE-related flexibilities and to minimize possible errors.

Comment: A commenter noted that CPT code 94664 did not appear in Table 10 of the proposed rule despite being a code that was temporarily added for the PHE.

Response: We agree that CPT code 94664 was inadvertently omitted from Table 10 of the proposed rule. As a code that was temporarily added to the Medicare Telehealth Services List for the duration of the PHE, it should have been included among codes that we proposed will remain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE. We have corrected this error in Table 14, and we are finalizing that CPT code 94664 will remain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE.

Comment: Many commenters supported our proposal to align the period of availability for services that are temporarily available for the duration of the PHE with the 151-day extension of certain telehealth flexibilities associated with the CAA, 2022. Some commenters stated that we should eliminate the temporary designation for all services on the Medicare Telehealth Services List, making permanent all services currently available.

Response: We thank commenters for their support of our proposal to allow services that would be available for the duration of the PHE to remain on the Medicare Telehealth Services List through the 151-day period following the end of the PHE. We continue to believe that services, including those that we added on a temporary interim basis for the PHE for COVID–19, should be considered for permanent addition to the Medicare Telehealth Services List through the regular annual process we established as required by section 1834(m)(4)(F)(ii) of the Act. While we have included some services on the Medicare Telehealth Services List on a temporary Category 3 basis through the end of CY 2023, this was to allow for the continued development of data to support their potential future consideration for permanent addition to the list on a Category 1 or Category 2 basis; we review all items on the Medicare Telehealth Services List each year as per our established process. Interested parties may continue to use the annual submission process to request the addition of any services to or deletion of services from the Medicare Telehealth Services List, regardless of whether the service was added on a temporary Category 3 basis. We note that the services that are included on the Medicare Telehealth Services list on a Category 3 basis will remain on the list for an additional period beyond 151 days after the end of the PHE, which is currently through the end of 2023. We understand that, if the PHE is in effect for most of the year next year, the 151-day period after the PHE may end on a date that is beyond December 31, 2023. We clarify that in this instance, the Category 3 services would remain on the Medicare Telehealth Services List through December 31, 2023 or 151 days after the PHE, if later. We will consider whether any additional extensions are needed in the future.

TABLE 14: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following End of the PHE

HCPCS	Short Descriptor
77427	Radiation tx management x5
92002	Eye exam new patient
92004	Eye exam new patient
93750	Interrogation vad in person
94002	Vent mgmt inpat init day
94003	Vent mgmt inpat subq day
94004	Vent mgmt nf per day
94664	Evaluate pt use of inhaler
96125	Cognitive test by hc pro
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99324	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99325	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99326	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99327	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99328	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient (deleted from the PFS for CY 2023)
99344	Home visit new patient
99345	Home visit new patient
99441	Phone e/m phys/qhp 5-10 min
99442	Phone e/m phys/qhp 11-20 min
99443	Phone e/m phys/qhp 21-30 min
99468	Neonate crit care initial
99471	Ped critical care initial
99475	Ped crit care age 2-5 init
99477	Init day hosp neonate care

e. Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022

As discussed in the CY 2021 PFS final rule (85 FR 84506), legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We used these authorities to establish several flexibilities to accommodate changes in the delivery of care during the PHE. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. At the end of the PHE for COVID–19, these waivers and interim policies will expire, and payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act.

Section 1834(m)(7) of the Act (as added by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018)), removes the geographic restrictions under section 1834(m)(4)(C)(i) of the Act and authorizes the patient's home as a permissible originating site, for telehealth services furnished for purposes of treatment of a substance use disorder (SUD) or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. Section 123(a) of Division CC of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020) amended section 1834(m)(7)(A) of the

Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and for which the patient's home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID–19. Section 123(a) of the CAA, 2021 also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7), unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. For a full discussion of our implementation of section 123(a) of the CAA, 2021, refer to our CY 2022 PFS final rule (86 FR 64996).

In the proposed rule, we proposed to implement provisions of section 1834(m) of the Act (including the amendments made by the CAA, 2021) and provisions of the CAA, 2022 that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE.

Sections 301, 302, 303, 304, and 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that are on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). Specifically, section 301(a) of the CAA, 2022 amended section 1834(m)(4)(C) of the Act to add a new clause (iii), which temporarily expands the scope of telehealth originating sites for those services to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID–19. Section 301(a) also amended section 1834(m)(7)(A) of the Act to apply the expanded scope of telehealth originating site policy to include any location in the United States in new clause (iii) of section 1834(m)(4)(C) of the Act during the 151-day period for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and to individuals with a SUD diagnosis for purposes of treatment of the SUD or a co-occurring mental health disorder for this 151-day post-PHE extension period. In addition to this provision, section 301(b) of the CAA, 2022 amended section 1834(m)(2)(B) of the Act to add a new clause (iii) that allows payment of an originating site facility fee to an originating site with respect to those telehealth services furnished during the 151-day period only if the originating site is one that meets the geographic requirements in section 1834(m)(4)(C)(i) of the Act, and is a setting included on the enumerated list of originating sites under section 1834(m)(4)(C)(ii) of the Act (other than the patient's home).

Section 302 of the CAA, 2022 amended section 1834(m)(4)(E) of the Act to temporarily expand the definition of eligible telehealth practitioners for the 151-day period beginning on the first day after the end of the PHE for COVID–19 to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists.

Section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to temporarily continue payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE using the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which, in accordance with section 1834(m)(8)(B) of the Act, is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

Section 304(a) of the CAA, 2022 amended section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on the 152nd day after the PHE ends. In addition, section 304(b) and (c) of the CAA, 2022 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we proposed to revise the regulatory text at § 410.78(b)(3)(xiv) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19, to conform with the statute. See section II.B.3. of this final rule for our proposal to implement similar changes for RHC and FQHC mental health visits.

Finally, section 305 of the CAA, 2022 added a new paragraph (9) to section 1834(m) of the Act to require the Secretary to continue to provide for coverage and payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2022, date of enactment that are furnished via an audio-only telecommunications system during the 151-day period beginning on the first day after the end of the PHE for COVID–19. The new paragraph applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are designated to as eligible to be furnished via audio-only technology as of the date of enactment of the CAA, 2022 (that is, March 15, 2022). These are the services for which CMS waived the requirements of section 1834(m)(1) of the Act and the first sentence of § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, during the PHE. Under this waiver, CMS permitted the audio-only telephone E/M services and certain behavioral health counseling and educational services to be furnished via audio-only equipment during the PHE for COVID–19. We proposed to continue to make payment for services included on the Medicare Telehealth Services List as of March 15, 2022 that are furnished via an audio-only telecommunications system for the 151-day period beginning on the first day after the end of the PHE. We read section 305 of the CAA, 2022 to require that we continue to make payment for services furnished via audio-only telecommunications systems (each described by a HCPCS code, including their successor codes) for the 151-day period after the end of the PHE. These services include certain behavioral health, counseling, and educational services. (*https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf*, n.d.). A list of the services that involve audio-only interaction but are included on the Medicare Telehealth Services List for the duration of the PHE is available at the CMS website, *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*.

Section 309 of Division P, Title III, Subtitle A of the CAA, 2022 authorizes the Secretary to implement the amendments described above made by

sections 301 through 305 through program instruction or otherwise. Given that the end date of the PHE is not yet known and could occur before the rulemaking process for the CY 2023 PFS is complete, and that the changes made by these provisions are very specific and concise, we announced in the CY 2023 PFS proposed rule that we intended to issue program instructions or other subregulatory guidance to effectuate the changes described above, other than the proposed revisions to § 410.78. We intend to issue these instructions in the near future. We believe this approach will serve to ensure a smooth transition after the end of the PHE for COVID–19.

We received public comments on our proposals to implement section 304(a) of the CAA, 2022, which amended section 1834(m)(7)(B)(i) of the Act, regarding the requirement that an in-person visit with the physician or practitioner must occur within 6 months prior to the initial mental health telehealth service. The following is a summary of the comments we received and our responses.

In-Person Requirements

Comment: Many commenters expressed general support for our proposals to implement and effectuate changes via program instructions, and subregulatory guidance, based on the fact that the last day of the PHE remains uncertain, but varied in their level of concern about whether the post-PHE transition period, of 151 days, would allow enough flexibility. Commenters expressed concerns that a sudden shift in the in-person visit requirements, beginning 152 days after the end of the PHE, could create beneficiary access issues, additional strain on the existing health care workforce shortage, and significant confusion among clinical and administrative staff about how to align resources and inform beneficiaries. Some commenters noted that the public will receive only 60 days' notice before the last day of the PHE, which they believe would not allow adequate time to coordinate in-person care across many different settings of care and varied individual beneficiary needs. A few commenters suggested that CMS should take the narrowest interpretation of the intent of Congress for in-person visit requirements prior to the initial mental health telehealth service, on the basis that the Secretary has the authority to specify the requirements associated with the required interval for similar follow-up in-person visit requirements. Other commenters expressed confusion about how individual physicians or practitioners would ensure appropriate record keeping and overall compliance plans would be updated to provide a means of verifying that any individual service met the in-person visit requirements. Some commenters whose focus is on enabling and supporting telehealth care through various health IT solutions requested that CMS provide more specifics on timing and possible ways to standardize the means by which individual physicians or practitioners document compliance with in-person requirements.

We also received comments that outlined concerns or possible risks to patient safety when patients with certain mental health conditions were treated remotely. These commenters provided examples of high-risk circumstances, such as possible risks associated with treating complex, or atypical patients, via telehealth. Commenters discussed that care of certain patients, who may have a severe or rare diagnosis, may also be under a course of treatment, where that plan of care includes a medication regimen that requires close monitoring. Alternatively, one commenter mentioned that certain beneficiaries with significant complex needs may demonstrate possible outcomes that may be superior when delivered via telehealth versus in-person. We also received a broad range of comments suggesting varied ways that CMS could implement the in-person visit requirements for mental health telehealth services.

Response: We appreciate these commenters' feedback. We did not propose to modify our established policies to implement these in-person visit requirements (except as it pertains to the 151-day extension for the 6-month requirement for an in-person visit for mental health treatment). We recognize that the CAA, 2022 delays implementation of the in-person visit requirements for mental health telehealth services for a period of 151 days after the final day of the PHE. As explained above and in the proposed rule, we are implementing section 304(a) of the CAA, 2022. and further emphasize that the availability of furnishing these services via telehealth does not preclude practitioners from seeing patients in-person, when indicated. We will continue to gather information on these mental health telehealth services as they are utilized, and we will take this information into consideration in the future for possible rulemaking.

Comment: Several commenters suggested that no in-person requirement should be enforced at all.

Response: We appreciate commenters' feedback. The statute does require an in-person, non-telehealth visit within 6 months prior to the first mental health services furnished via Medicare telehealth. However, we clarify that we do not believe this requirement applies to beneficiaries who began receiving mental health telehealth services in their homes during the PHE. In other words, if a beneficiary began receiving mental health telehealth services during the PHE or during the 151-day period after the end of the PHE, then they would not be required to have an in-person visit within 6 months; rather, they will be considered established and will instead be required to have at least one in-person visit every 12 months (so long as any such subsequent telehealth service is furnished by the same individual physician or practitioner (or a practitioner of the same sub-specialty in the same practice) to the same beneficiary). This means that these services would be subject to the requirement that an in-person visit is furnished within 12 months of each mental health telehealth service for those services that are subject to in-person visit requirements (unless an exception is documented by their treating practitioner). For discussion of additional requirements for these services, please see the discussion in the CY 2022 PFS final rule.

f. Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID–19

Prior to CY 2017, Medicare telehealth services furnished via interactive audio and video telecommunications systems were reported using the GT modifier. In the CY 2017 PFS Final Rule, CMS finalized creation of a new Place of Service (POS) code for Medicare telehealth, POS ''02'' (81 FR 80199–80201). When a physician or practitioner submits a claim for their services, including claims for telehealth services, they include a place of service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate and the non-facility (or office) rate. The PFS non-facility rate is the single amount paid to a physician or other practitioner for services furnished in their office. The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care, like a hospital, where Medicare is making a separate payment to a facility entity in addition to the payment to the billing physician or practitioner. This separate payment, often referred to as a ''facility fee,'' reflects the facility's costs associated with the service (clinical staff, supplies,

and equipment) and is paid in addition to what is paid to the professional under the PFS. POS ''02'' indicates that the service was furnished via telehealth, and under the pre-PHE process, was then paid at the facility payment rate.

As discussed in the March 31, 2020 IFC, (refer to 85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID–19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in-person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for the COVID–19 pandemic, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which should be applied to claim lines that describe services furnished via telehealth and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth.

We further noted that we are maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for the COVID–19 pandemic.

We proposed that Medicare telehealth services furnished on or before the 151st day after the end of the PHE, in alignment with the extensions of telehealth-related flexibilities in the CAA, 2022, will continue to be processed for payment as Medicare telehealth claims when accompanied with the modifier ''95.'' We further proposed that physicians and practitioners can continue to report the place of service code that would have been reported had the service been furnished in-person during the 151-day period after the end of the PHE, as finalized on an interim basis in the March 31 IFC (85 FR 19233). We proposed that Medicare telehealth services performed with dates of service occurring on or after the 152nd day after the end of the PHE will revert to pre-PHE rules and will no longer require modifier ''95'' to be appended to the claim, but the appropriate place of service (POS) indicator will need to be included on the claim to be processed for payment as Medicare telehealth claims in order to properly identify the place where the service was furnished. We further proposed that, for Medicare telehealth services furnished on or after the 152nd day after the end of the PHE, the POS indicators for Medicare telehealth will be:

- POS ''02''—is redefined as Telehealth Provided Other than in Patient's Home (*Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology.*); and
- POS ''10''—Telehealth Provided in Patient's Home (*Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.*).

We remind readers that we defined ''home'' in our CY 2022 PFS final rule (86 FR 65059) to include, as: ''both in general and for this purpose, a beneficiary's home can include temporary lodging, such as hotels and homeless shelters. We also clarified that for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished 'in the home of an individual' for purposes of section 1834(m)(4)(C)(ii)(X) of the Act.''

In our proposed rule, we discussed that, once the flexibilities for the geographic restrictions and the site of service waivers for Medicare telehealth services expire (on the 152nd day after the end of the PHE, per the CAA, 2022), POS ''02'' would once again be required for all Medicare telehealth claims (with the exception of certain Medicare telehealth for mental health services). In the proposed rule, we noted that the exceptions include claims for Medicare telehealth mental health telehealth services, clinical assessments for patients with ESRD that are receiving home dialysis, and Medicare telehealth treatment of an SUD or mental health services that are co-occurring mental health disorder with substance use treatment that are furnished to with the patient in their home (that is, the originating site is in a private residence and not a hospital or other facility setting), in which case POS ''10'' could be used by the billing practitioner. In our proposed rule, we further discussed that, on or after the 152nd day after the PHE has expired, payment for Medicare telehealth services using either of the Medicare telehealth POS codes would be made at the PFS facility payment rate, in accordance with established PFS policy outside the circumstances of the PHE. We proposed to align payment for those telehealth services described as taking place in the beneficiary's home, using POS ''10'' for Medicare telehealth, and those services not provided in a patient's home, using POS ''02'' for Medicare telehealth, to be made at the same facility payment amount. We believe that the facility payment amount best reflects the practice expenses, both direct and indirect, involved in furnishing services via telehealth (please see section II.B. of this final rule for further discussion regarding practice expense).

We further proposed that, beginning January 1, 2023, a physician or other qualified health care practitioner billing for telehealth services furnished using audio-only communications technology shall append CPT modifier ''93'' (*Synchronous Telemedicine Service Rendered Via Telephone or Other Real-Time Interactive Audio-Only Telecommunications System: Synchronous telemedicine service is defined as a real-time interaction between a physician or other qualified health care professional and a patient who is located away at a distant site from the physician or other qualified health care professional. The totality of the communication of information exchanged between the physician or other qualified health care professional and the patient during the course of the synchronous telemedicine service must be of an amount and nature that is sufficient to meet the key components and/or requirements of the same service when rendered via a face-to-face interaction*) to Medicare telehealth claims (for those services for which the use of audio-only technology is permitted under § 410.78(a)(3)), to identify them as having been furnished using audio-only technology. We noted that we have also instructed all relevant providers, including RHCs, FQHCs, and OTPs to append Medicare modifier ''FQ'' (*Medicare telehealth service was furnished using audio-only*

communication technology) for allowable audio-only services furnished in those settings; however, consistent with our proposal for audio-only services furnished under the PFS, we also proposed to require all relevant providers, including RHCs, FQHCs, and OTPs to use modifier ''93'' when billing for eligible mental health services furnished via audio-only telecommunications technology. We believe that using modifier ''93'', which is a CPT modifier, will simplify billing, as this modifier is used by payers outside of Medicare. Currently, these modifiers can only be applied to Medicare telehealth mental health services and those telehealth services for the treatment of a SUD or a co-occurring mental health disorder when the originating site is the beneficiary's home.

Supervising practitioners continue to be required to append the ''FR'' modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

Comment: Some commenters expressed concern regarding our proposed approach to the use of modifiers for billing of Medicare telehealth services. One commenter noted that we had inadvertently overlooked the fact that after the transition period, facility-based providers would not be able to bill using the POS code fields, as the CMS–1450 (UB–04) institutional claim form does not permit use of POS code fields. The commenter noted that this may have been an oversight.

Response: We thank commenters for offering feedback on technical issues associated with our proposed policies for use of modifiers that allow claims processing and billing for professional services under Part B, which includes Medicare telehealth services. We reiterate that 151 days after the end of the PHE, Medicare telehealth services will once again be subject to the statutory requirements in section 1834(m) of the Act. As such, only physicians and the practitioners specified in section 1834(m)(4)(E) of the Act will be able to serve as distant site practitioners to furnish and bill for Medicare telehealth services, and those services would be billed on the professional, not the institutional, claim form. Thus, beginning on the 152nd day after the PHE ends, only certain types of practitioners will be permitted to furnish and bill for Medicare telehealth services, and none of those practitioners would be ''facility-based providers.''

Comment: Many commenters requested that we continue to allow for services that would have been furnished in a non-facility setting outside of the circumstances of the PHE to be billed at the non-facility rate for telehealth services following the end of the PHE. Commenters stated that they were concerned that reverting to the facility rate for telehealth services will lead practitioners to offer telehealth less frequently and inhibit access. According to these commenters, many patients in rural and underserved areas are now able to access mental health services, often for the first time. Many commenters emphasized their concerns that mental health services would be particularly impacted, as there is already high demand for these services and relatively low numbers of available practitioners.

One commenter requested that we maintain payment at the non-facility-based rate for telehealth services furnished in office settings through the end of 2023, stating that changing payment to the facility rate would result in a nearly 30 percent cut for some services, which they believed will harm access to telehealth services.

Some commenters, including MedPAC, expressed concern that payment at the facility rate will create the unintended effects of shifting beneficiaries toward both higher intensity and volume of virtual care modalities that would be inappropriate for beneficiaries. In MedPAC's comment, they offered their March 2022 MedPAC Report to Congress (*https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v2_SEC.pdf*), which noted that Medicare spending can be sensitive to shifts in the site of care, and that the negative impact of the pandemic on E/M services may have been more significant in 2020 were it not for Medicare telehealth.

Some commenters, including MedPAC, provided examples and explanations that raised questions about uncertainty of clinical benefit and possible overpayment for Medicare telehealth and offered evidence that many patients who used telehealth during the PHE would prefer in-person visits, once it is safe to do so.

Response: We acknowledge the commenters' concerns. We note that there are many nuances to this issue, and we seek to minimize confusion and practitioner burden during the period immediately following the PHE. We are concerned about issues raised by commenters related to payment stability in the post-PHE period, as care delivery will potentially be transitioning between virtual, hybrid, and in-person models. As such, we are finalizing that we will continue to allow for payment be made for Medicare telehealth services at the place of service for telehealth services that ordinarily would have been paid under the PFS, if the services were furnished in-person, through the latter of the end of the of CY 2023 or the end of the calendar year in which the PHE ends. For those services furnished in a facility as an originating site, POS 02 may be used, and the corresponding facility fee can be billed, per pre-PHE policy, beginning the 152nd day after the end of the PHE.

Comment: Some commenters expressed concern that our proposals to transition to the use of new modifiers would create confusion and administrative burden, without sufficient time to allow for the sufficient training education of clinical and administrative staff to implement new billing practices. Others supported immediate implementation.

Response: We appreciate commenters' feedback. We believe that the use of these modifiers following the end of the PHE, when implemented, will enable practitioners to better report (and allow CMS to better understand) how they practice and when certain services are furnished via telehealth. We do not agree that these modifiers/codes would cause confusion; rather, they will provide clarity. Moreover, education regarding these modifiers/codes will be made available, as necessary.

After consideration of public comments, we are finalizing our proposals, with some modifications regarding the use of telehealth modifiers/codes and the payment rates. Practitioners will continue to bill with modifier 95 along with the POS code corresponding to where the service would have been furnished in-person through the later of the end of the year in which the PHE ends or CY 2023. As stated earlier, for those services furnished in a facility as an originating site, POS 02 may be used, and the corresponding facility fee can be billed, per pre-PHE policy, beginning the 152nd day after the end of the PHE.

Additionally, effective on and after January 1, 2023, CPT modifier ''93'' can be appended to claim lines, as appropriate, for services furnished using audio-only communications technology in accordance with our regulation at § 410.78(a)(3). All providers, including RHCs, FQHCs, and OTPs must append Medicare modifier ''FQ'' (*Medicare telehealth service was furnished using audio-only communication technology*) for allowable audio-only services furnished in those settings. However,

consistent with our proposal for audio-only services furnished under the PFS, we are also finalizing to require all providers including RHCs, FQHCs, and OTPs to use modifier ''93'' when billing for eligible mental health services furnished via audio-only telecommunications technology. Providers have the option to use the ''FQ'' or the 93'' modifiers or both where appropriate and true, since they are identical in meaning.

Supervising practitioners continue to be required to append the ''FR'' modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

In response to the issues raised by commenters related to payment stability in the post-PHE period, we are reiterating that we are finalizing that, for Medicare telehealth services, we will continue to maintain payment at the POS had the service been furnished in-person, and this will allow payments to continue to be made at the non-facility-based rate for Medicare telehealth services through the latter of the end of CY 2023 or the end of the calendar year in which the PHE ends.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner.

For professional services furnished incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), direct supervision of a physician is required (see also § 410.27(a)(1)(iv)(D) for hospital outpatient services).Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners can only bill Medicare for telehealth services under Medicare telehealth waivers that are effective only during the PHE for COVID–19 (based on the emergency waiver authority established in section 1135(b)(8) of the Act), and for 151 days after the final day of the PHE for COVID–19, as specified by provisions of the CAA, 2022. We noted that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth services. Outside of the PHE and the 151-day period after the PHE ends, such clinicians include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We remind readers that after December 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception to allow immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their professional services, will no longer apply. As such, after the end of the calendar year in which the PHE ends, Medicare telehealth services can no longer be performed by clinical staff incident to the professional services of the billing physician or practitioner who directly supervises the service through their virtual presence.

While we did not propose to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, as with last year's rulemaking (86 FR 39149 through 50), we continue to solicit information on whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology should potentially be made permanent. We also solicited comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time, audio/video technology for only a subset of services, as we recognize that it may be inappropriate to allow direct supervision without physical presence for some services due to potential concerns over patient safety. As discussed in last year's final rule (86 FR 65063), and based on gaps in the currently available evidence, we are in need of more information as we consider whether to make permanent a temporary exception to our direct supervision policy.

We received public comments on expiration of PHE flexibilities for direct supervision requirements. The following is a summary of the comments we received and our responses.

Comment: Commenters offered a variety of perspectives and suggestions for possible ways that CMS could modify the direct supervision requirements. Many commenters that recommended a permanent change to direct supervision rules supported their feedback by raising issues such as health care workforce shortages and concern with clinician burnout that would possibly occur from implementing the pre-PHE direct supervision requirements. Others noted that certain NPPs, such as PAs, and advanced practice nurse practitioners are authorized under state law statutory requirements in many states to practice independently under virtual supervision of a physician. Still others based their recommendations that we establish a permanent virtual direct supervision on a specialty-level or service-level analysis. For example, commenters identified a certain specialty or family of codes that would be typically low-risk for patient safety issues, and indicated that those specialties or services would be appropriate candidates for a permanent virtual direct supervision policy. Some

commenters mentioned that virtual direct supervision may also reduce the burden and overhead costs associated with enrolling their practitioners through multiple MAC jurisdictions.

Response: We continue to gather information on this topic, and we appreciate the information provided by commenters. We remind readers that, as described earlier in this section, our current temporary policy to permit immediate availability for purposes of direct supervision through the virtual presence of the billing clinician was adopted to address the circumstances of the PHE for COVID–19. We believe allowing additional time to collect information and evidence for direct supervision through virtual presence will help us to better understand the potential circumstances in which this flexibility could be appropriate permanently, outside of the PHE for COVID–19. We realize that direct supervision through virtual presence is probably not something that we would have contemplated without our experience in implementing this policy during the PHE, and we hope to learn more about this in the near future. We also note that the Secretary renewed the PHE for the COVID–19 pandemic for a 90-day period beginning on October 13, 2022,[9] which means that the PHE would expire on January 11, 2023, absent any further action by the Secretary regarding the PHE for COVID–19. As such, we expect to continue to permit direct supervision through virtual presence through at least the end of CY 2023 under our previously finalized policy which, as specified in § 410.32(a)(3)(ii), continues through the end of the calendar year in which the PHE ends. With that said, CMS will consider the comments received from the proposed rule for potential future PFS rulemaking.

3. Telehealth Originating Site Facility Fee Update

Section 1834(m)(2)(B) of the Act established the initial Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00, and specifies that for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The final MEI increase for CY 2023 is 3.8 percent and is based on the most recent historical percentage increase of the 2017-based MEI for the second quarter of 2022.

Therefore, for CY 2023, the final payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $28.64. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period are shown in Table 15.

TABLE 15: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64

[9] *https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.*

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we solicit public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we consider and responded to public comments received on the interim final values, and typically make any appropriate adjustments and finalize those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing

particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. We also include a summary of interested party reactions to our approach when available. We noted in past rulemaking that many commenters and interested parties have expressed concerns over the years with our reviews of and updates to work RVUs based on changes in the best available information regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we use to update the RVUs is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the ''old time'' values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies to adjust for reductions in time, suggesting that our adjustments to the RUC-recommended work RVUs are inappropriate. Other interested parties have expressed general concerns with our refinements to RUC-recommended values. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding our approach to RUC-recommended work times and RVUs. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended

work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2023 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. Commenters recommended that CMS embrace the clinical input from practicing physicians when valid surveys were conducted and provide a clinical rationale when proposing crosswalks for valuation of services.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2023 PFS final rule, CPT codes 22632 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace*), 63035 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar*), 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia*), and 99285 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making*) all share the same intraservice and total work time of 60 minutes. However, these codes had very different proposed work RVUs of 5.22 and 3.86 and 5.50 and 4.00, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the

RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information).

With regard to the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters did not agree with CMS valuing codes based on work RVU increments. Commenters stated that this methodology for valuing codes inaccurately treats all components of the physician time as having identical intensity and would lead to incorrect work valuations. Commenters stated that CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC and other interested parties.

Response: We believe that using the incremental difference between the work RVUs of codes is a valid methodology for setting values, especially when valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently used an incremental methodology in which we value a code based upon the incremental work RVU difference between the code and another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between the work RVUs of codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other interested parties as part of our review process, although we remind readers again that we do not believe that it is necessary for codes to share the same site of service, patient population, or utilization level in order to serve as an appropriate crosswalk.

Comment: Several commenters stated that they were concerned about CMS' lack of consideration for compelling evidence that services have changed. Commenters stated that CMS appeared to dismiss the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. Commenters stated that CMS' failure to discuss compelling evidence does not reflect the long history of reviewing potentially misvalued codes, first through the statutorily mandated 5-year review processes and more recently from continuous annual reviews. Commenters stated that CMS has discussed compelling evidence in rulemaking since the inception of the RBRVS and has informed public commenters to consider compelling evidence to identify potentially misvalued codes. Commenters requested that CMS address the compelling evidence submitted with the RUC recommendations when the agency does not accept the RUC's recommended work RVUs.

Response: The concept of compelling evidence was developed by the RUC as part of its work RVU review process for individual codes. The RUC determines whether there is compelling evidence to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that the RUC developed the concept of compelling evidence for its own review process; an evaluation of ''compelling evidence,'' at least as conceptualized by the RUC, is not part of our review process, as our focus is the time and intensity of services, in accordance with the statute. With that said, we do consider changes in technology, patient population, and other compelling evidence criteria, as such evidence may affect the time and intensity of a service under review. For example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. We instead focus on evaluating and addressing the time and intensity of services when reviewing potentially misvalued codes because section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service.

Comment: Several commenters raised the issue of the refinement panel which was last reformed in CY 2016. Commenters stated that the refinement panel was not obsolete and was not mutually exclusive with the change to include all proposed valuations in each year's proposed rule. Commenters stated that for 2 decades, the refinement panel process was considered by interested parties to be an appeals process and its elimination discontinued CMS' reliance on outside interested parties to provide accountability through a transparent appeals process. Commenters requested that CMS consider these issues and create an objective, transparent and consistently applied formal appeals process that would be open to any commenting organization.

Response: We did not propose any changes to the refinement panel for CY 2023. As we stated in the CY 2016 PFS final rule (80 FR 70917 and 70918), the refinement panel was established to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in balancing the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. When developing the CY 2016 proposed rule, and continuing to the present, we did not believe that the refinement panel had generally served as the kind of ''appeals'' or reconsideration process that some interested parties envisioned in their comments. We also believe that the refinement panel was not achieving its intended purpose. Rather than providing us with additional information, balanced across specialty interests, to assist us in establishing work RVUs, the refinement panel

process generally served to rehash the issues raised and information already discussed at the RUC meetings and considered by CMS. In contrast to the prior process of establishing interim final values and using a refinement panel process that generally was not observed by members of the public, we continue to believe that the current process of proposing the majority of code values in a proposed rule, giving the public the opportunity to comment on those proposed values, and then finalizing those values in a final rule offers greater transparency and accountability.

We also note that we did not finalize our proposal to eliminate the refinement panel completely in CY 2016. We retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. We also remind interested parties that we have established an annual process for the public nomination of potentially misvalued codes. This process, described in the CY 2012 PFS final rule (76 FR 73058), provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 16 contains a list of codes and descriptors for which we proposed work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2022. The finalized work RVUs, work time and other payment information for all CY 2023 payable codes are available on the CMS website under downloads for the CY 2023 PFS final rule at (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 18 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of PE RVUs, we address certain proposed refinements that would be common across codes. We also address the refinements to particular codes that we are finalizing in section II.B. of this rule. We note that for each refinement of the RUC-recommended direct PE inputs that we are finalizing, we indicate the potential impact on direct costs for that service. We also note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also noted that many of the refinements listed in Table 17 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the final direct PE inputs for CY 2023 are displayed in the CY 2023 direct PE input files, available on the CMS website under the downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the final CY 2023 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general

guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of PE RVUs, for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2023, we received invoices for several new supply and equipment items. Tables 19 and 20 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 19 and 20 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2023 are available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The technical component (TC) (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for hospital outpatient (HOPD) services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by the section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography. For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2023, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined above for purposes of this cap. Beginning for CY 2023, we proposed to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0493T (*Contact near-infrared spectroscopy studies of lower extremity wounds (e.g., for oxyhemoglobin measurement)*), 0640T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound*), 0641T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound*), 0642T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound*), 0651T (*Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report*), 0658T (*Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score*), 0689T (*Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure)*), 0690T (*Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)*), 0694T (*3-dimensional volumetric imaging and reconstruction of breast or axillary lymph node tissue, each excised specimen, 3-dimensional automatic specimen reorientation, interpretation and report, real-time intraoperative*), 0700T (*Molecular fluorescent imaging of suspicious nevus; first lesion*), 0701T (*Molecular fluorescent imaging of suspicious nevus; each additional lesion (List separately in addition to code for primary procedure)*), and 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*). As CPT codes 0493T, 0642T, 0651T, 0658T, and 76883 are not within the statutory scope of services to which the OPPS cap applies, as they cannot be split into professional and technical components, or they only describe the professional component (PC), we thus proposed to add these codes to the OPPS DRA caps list in error. Therefore, we are not finalizing our proposal to add them to the list of services to which the OPPS cap applies. We believe that the remaining codes, CPT codes 0640T, 0641T, 0689T, 0690T, 0694T, 0700T, and 0701T, meet the definition of imaging services under section 1848(b)(4)(B of the Act, and thus, should be subject to the OPPS cap. Therefore, we are finalizing our proposal to add CPT codes 0640T, 0641T, 0689T, 0690T, 0694T, 0700T, and 0701T to the list of services to which the OPPS cap applies, and we are not finalizing our proposal to add CPT codes 0493T, 0642T, 0651T, 0658T, and 76883 to the OPPS cap list.

4. Valuation of Specific Codes for CY 2023

(1) Anterior Abdominal Hernia Repair (CPT Codes 15778, 49591, 49592, 49593, 49594, 49595, 49596, 49613, 49614, 49615, 49616, 49617, 49618, 49621, 49622, and 49623)

In April 2021, the RUC reviewed an existing code that describes hernia repair, CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*). CPT code 49565 was identified as being performed less than 50 percent of the time in the inpatient setting and being primarily performed in the outpatient setting. Interested

parties requested referral to CPT to update the code's descriptor. In response to the disparate site of service and request to update the code's descriptor, CPT created new codes with 000-day global periods to describe this type of service. The codes within this family are differentiated by 3 characteristics: whether the hernia is initial or recurrent, whether it is reducible or strangulated, and the total length of the hernia. CPT also created two new codes that describe parastomal hernia repair and an add-on code for removal of mesh.

The RUC recommendations differentiate the post-operative periods for the codes within this family by whether there is a same-day discharge, overnight stay with a visit on the same date, or whether the patient is admitted to the hospital. We disagree with many of the RUC-recommended work RVUs for the codes within this family that have a post-operative overnight stay built into their valuation. More specifically, we disagree with the RUC-recommended work RVUs for such codes because the RUC did not completely apply the 23-hour policy calculation (finalized in the CY 2011 PFS final rule (75 FR 73226)) in formulating its recommendations. Additionally, we disagree with the RUC-recommended work RVUs for the CPT codes in this family for which the RUC considered the patient to be admitted during the post-operative period because the RUC did not apply the 23-hour policy when formulating its recommendations.

As we noted in the CY 2011 PFS final rule (75 FR 73226), the work RVUs for services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment. Because such services are typically furnished in the outpatient setting, they should not be valued to include inpatient post-operative E/M visits. The level of discharge day management services included in the valuation of such services should similarly not reflect an inpatient discharge and should therefore be reduced. And finally, as discussed in CY 2011 rulemaking, the intraservice time from the inpatient level E/M postoperative visit should be reallocated to the immediate postservice time of the service. The 23-hour policy calculation, when fully applied to the calculation of a work RVU, is used to reduce the value of discharge day management services, remove the inpatient E/M visits, and reallocate the intraservice time to the immediate post-service period. See the CY 2011 PFS final rule (75 FR 73226) for additional in-depth explanation of the 23-hour policy.

For the codes with an overnight stay and an E/M visit on the same date built into their valuation, we believe the RUC only partially applied the 23-hour policy when it applied the policy to the immediate post service times, but not to the calculation of the work RVUs. Instead, we believe the 23-hour policy should be fully applied to the codes in this family that describe outpatient services for which there is an overnight stay during the post-operative period, regardless of the number of nights that a patient stays in the hospital. The services to which the 23-hour policy is usually applied would typically involve a patient stay in a hospital for less than 24 hours, which often means the patient may stay overnight in the hospital. On occasion, the patient may stay in the hospital longer than a single night; however, in both cases (one night or more than one night), the patient is considered to be a hospital outpatient, not an inpatient, for Medicare purposes. In short, we do not believe that the work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies.

The RUC recommended a work RVU of 8.0 for CPT code 15778 (*Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma*). CPT code 15778 was surveyed with having one subsequent hospital visit, CPT code 99232 (*subsequent hospital care/day 25 minutes*) and 25 minutes of immediate post service time. For purposes of calculating the recommended work RVU of 8.0, the RUC considered CPT code 15778 to describe an inpatient service, while we consider CPT code 15778 to describe an outpatient service for purposes of Medicare billing. As noted above, we do not believe that work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies. Therefore, the valuation for this code should not include inpatient work in the post-operative period. See the CY 2022 PFS final rule (86 FR 65090) for further discussion on the 23-hour policy as it relates to outpatient billing. We believe the 23-hour policy should be fully applied to CPT code 15778, and we disagree with the RUC-recommended work RVU of 8.0.

In accordance with the 23-hour policy valuation methodology we established in the CY 2011 PFS final rule, we instead proposed a work RVU of 7.05 for CPT code 15778 and a reallocation of the time associated with the intra-service portion of the inpatient hospital visit to the immediate postservice time of CPT code 15778.

The steps for the 23-hour policy calculation are as follows:

- *Step (1):* CPT code 15778 does not have a hospital discharge day management service; therefore, we will skip this step*.
- *Step (2):* 8.0 − 1.39** = 6.61.
- *Step (3):* 6.61 + (20 minutes × 0.0224)*** = 7.05 RVUs.

*Value associated with ½ hospital discharge day management service

**Value associated with an inpatient hospital visit, CPT code 99232.

***Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

The following CPT codes have a post-operative period that is considered an overnight stay with a visit on the same date: CPT codes 49592 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), 49593 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, reducible*), 49594 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated*), 49595 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, reducible*), 49614 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), and 49615 (*Repair of anterior abdominal hernia(s) (ie,*

epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, reducible). The RUC recommended a work RVU of 9.0 for CPT code 49592, 10.80 for CPT code 49593, 14.0 for CPT code 495944, 14.88 for CPT code 49595, 10.79 for CPT code 49614, and 12.0 for CPT code 496159. CPT codes 49592, 495933, 49614, and 49615 were surveyed with one subsequent inpatient hospital visit at a level of CPT code 99231 (*subsequent hospital care/day 15 minutes*). The RUC applied the 10 minutes of intraservice time from CPT code 99231 to the immediate postservice time of these codes, resulting in a total immediate postservice time of 30 minutes for these codes. CPT codes 49594 and 49595 were surveyed with a subsequent inpatient hospital visit at a level of CPT code 99232. The RUC applied the 20 minutes of intraservice time from CPT code 99232 to the immediate postservice time of both codes, resulting in a total immediate postservice time of 40 minutes.

Much like our concerns regarding the RUC-recommended work RVU for CPT code 15778, we do not believe that the RUC fully applied the 23-hour policy calculation when calculating the work RVUs for these codes and we disagree with the RUC-recommended RVUs. While the RUC removed the 99231 and 99232 inpatient visits included in the post-operative period for these codes, the RUC did not subtract the values of these visits from the work RVUs before making their work RVU recommendations. In the CY 2011 PFS final rule (75 FR 73226), we stated that we do not believe that the post-procedure hospital visits for outpatient services should be at the inpatient level since the typical case is an outpatient who would be ready to be discharged from the hospital in 23 hours or less. However, we agree with the RUC that the intra-service time of the inpatient hospital visit may be included in the valuation for 23-hour stay codes. Therefore, we believe that step 2 of the 23-hour hour policy calculation, which involves deducting the RVUs of the inpatient hospital visits from the starting work RVU value and subsequently reallocating the time associated with the intra-service portion of the inpatient hospital visits to the immediate postservice time of the 23-hour stay code, should be fully applied when calculating the work RVUs for CPT codes 49592, 49593, 49594, 49595, 49614, and 49615.

Using the 23-hour policy calculation described above and in the CY 2011 PFS final rule, we proposed work RVUs of 8.46 for CPT code 49592, 10.26 for CPT code 49593, 13.46 for CPT code 49594, 13.94 for CPT code 49595, 10.25 for CPT code 49614, and 11.46 for CPT code 49615.

The following CPT codes have a post-operative period that the RUC considers to be admitted to a hospital: CPT code 49596 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*), 49616 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated*), 49617(*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, reducible*), 49618 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*), 49621 (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible*), and 49622 (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated*). The RUC recommended a work RVU of 18.67 for CPT code 49596, 15.55 RVUs for CPT code 49616, 16.03 RVUs for CPT code 49617, 22.67 RVUs for CPT code 49618, 13.70 RVUs for CPT code 49621, and 17.06 RVUs for CPT code 49622. CPT codes 49596 and 496182 were surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99233 (*subsequent hospital care/day 35 minutes*). The RUC recommendations include an immediate postservice time of 25 minutes for CPT code 49596 and 30 minutes for CPT code 49618. CPT codes 49616, 49617, and 49622 were surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99232. The RUC recommendations include an immediate postservice time of 25 minutes for 49616, 28 minutes for CPT code 49617, and 25 minutes for CPT code 49622. CPT code 49621 was surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99231 and an immediate postservice time of 25 minutes.

For purposes of calculating the recommended work RVUs, the RUC considered these CPT codes to describe an admitted inpatient service, while we consider the CPT codes to describe outpatient services for purposes of billing. Therefore, we believe that inpatient work in the post-operative period should not be included in the valuation. We believe the 23-hour policy should be applied to these codes. Using the 23-hour policy calculation described above and in the CY 2011 PFS final rule, we proposed a work RVU of 18.67 for CPT code 49596, 15.55 RVUs for CPT code 49616, 16.03 RVUs for CPT code 49617, 22.67 RVUs for CPT code 49618, 13.70 RVUs for CPT code 49621, and 17.06 RVUs for CPT code 49622. We are also proposing revised immediate postservice times for the reallocation of the time associated with the intraservice portion of the inpatient hospital visit. We proposed immediate post service times of 40 minutes for CPT code 49596, 35 minutes for CPT code 49616, 38 minutes for CPT code 49617, 45 minutes for CPT code 49618, 30 minutes for CPT code 49621, and 35 minutes for CPT code 49622.

The following CPT codes have a post-operative period that the RUC considers to be a same day discharge: CPT code 49591 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian*), *any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, reducible*) and 49613 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, reducible*). The RUC-recommended a work RVU of 6.27 for CPT code 49591 and 7.75 for CPT code 49613. We disagree with the RUC-recommended RVU for CPT code 495911 because it falls above the median value for codes with similar

times. We proposed a work RVU of 5.96 RVUs based on the intraservice time ratio, which is the ratio of 90 minutes of intraservice time of a current hernia repair code—CPT code 49560 (*Repair initial incisional or ventral hernia; reducible*) and the 45 minutes of intraservice time for CPT code 49591. The proposed work RVU of 5.96 is also supported by reference CPT code 93453 (*Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed*). CPT code 93453 has a work RVU of 5.99, the same intraservice time as CPT code 49591(45 minutes), and a slightly higher total time of 113 minutes.

For CPT code 49613, we disagree with the RUC- recommended work RVU of 7.75, as it is above the median range compared to codes with similar times. We proposed a work RVU of 7.42 RVUs for CPT code 49613 based off of the intraservice time ratio of 100 minutes of intraservice time for a current hernia repair code—CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*), compared to the 60 minutes of intraservice time for CPT code 49613. The proposed work RVU of 7.42 is also supported by reference CPT code 52353 (*Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)*). CPT code 52353 has a work RVU of 7.50 with the same intraservice time of 60 minutes and a very similar total time of 133 minutes.

CPT code 49623 (*Removal of total or near-total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic)*) is an add-on code. The RUC recommended a work RVU of 5.0 for CPT code 49623. The RUC recommendation is higher than the work RVUs for many other CPT add-on codes with similar times. We proposed a work RVU of 2.61 RVUs for CPT code 49623, based on the reverse building block methodology. The proposed work RVU of 2.61 is also supported by reference CPT code 15774 (*Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 2.50 and the same total time of 45 minutes.

We reviewed the RUC-recommended direct PE inputs for all of the codes within this family. We disagree with the RUC's recommendations of 66 total minutes of clinical staff time for CPT codes 49591 and 49613, 60 total minutes of clinical staff time for CPT codes 49592, 49593, 49594, 49595, 49596, 49614, 49615, 49616, 49617, 49618, 49621, and 49622, and 20 total minutes of clinical staff time for CPT code 15778. In the CY 2023 PFS proposed rule, we noted that the RUC recommended 090-day pre-service times for all of these codes despite surveying all of the services as 000-day services. In the CY 2022 PFS final rule (86 FR 65090), we stated we continue to believe that setting and maintaining clinical labor time and valuation standards provides greater consistency among codes that share clinical labor tasks and could improve relativity of values among codes. Therefore, we believe that the standard clinical labor packages that are in accordance with the surveyed global period continue to be the most appropriate for purposes of clinical labor valuation.

The RUC recommendations for CPT codes 49591 and 49613, and CPT codes 49592, 49593, 49594, 49595, 49596, 49614, 49615, 49616, 49617, 49618, 49621, and 49622, include the standard for 090-day preservice times for clinical labor activities, which is 60 minutes. For 49591 and 49613 in particular, the RUC also recommended an additional 6 minutes in the post service period to conduct patient communications. We disagree with the RUC-recommended 090-day times as these CPT codes were surveyed by the RUC as 000-day services and should have times consistent with 000- day services. Therefore, we proposed the standard clinical labor times for a 000-day extensive package for a total pre-service clinical staff time of 30 minutes for CPT codes 49591 through 49622 with an additional standard 3 minutes of post-service patient communications for 49591 and 49613. CPT code 49623 is an add-on code and does not have RUC-recommended direct PE inputs.

For CPT code 15778, the RUC recommendation is 20 minutes of clinical staff activities, which is standard for an emergent procedure package. We do not agree that the service described by CPT code 15778 should be considered an emergent procedure. Therefore, we proposed the minimal clinical staff package minus pre-service education for CPT code 15778, for a total of 12 clinical staff time minutes.

Comment: We received public comments for this code family that did not support our proposed RVUs. Commenters stated that they do not agree with our ''systemic and formulaic'' reduction in work RVUs by the use of the Reverse Building Block (RBB) methodology. The commenters also stated that our use of the RBB in the context of the 23-hour policy is duplicative and results in inappropriately low valuations, in contrast to their preferred method of magnitude estimation.

Response: We believe that there are multiple appropriate methodologies for calculating work RVUs, including the RBB method, time ratios, increments, and survey data. We finalized in the CY 2011 PFS final rule (75 FR 73328 through 73329), the RBB formula for applying the 23-hour policy to the work RVUs and the times of the outpatient service and the same-day E/M codes. We do not believe that it is duplicative to apply the full 23-hour policy to CPT codes when the RUC recommendations do not account for the appropriate reduction in work RVUs; this is relevant for some of the codes in this family as well as the Intracranial Laser Interstitial Thermal Therapy (LITT) family (CPT Codes 61736 and 61737) discussed in the CY 2022 PFS final rule (86 FR 65090). We continue to believe the entire 23-hour policy calculation, as finalized in the CY 2011 PFS final rule, should be completely and consistently applied where applicable.

Comment: Commenters noted several concerns regarding the application of the 23-hour policy to this code family. Commenters stated that they disagree with the additional application of the 23-hour policy to the CPT codes that the RUC has considered as overnight with a visit on the same date because they believe that this has already been accounted for during the survey process magnitude estimation. Commenters noted that they do not believe that the 23-hour policy should be applied to the codes that the RUC has considered as admitted because the patient will likely become an inpatient. Additionally, the commenters expressed concern that we have added CPT codes 49596, 49616, 49617, 49618, 49621, and 49622 to the Hospital Outpatient Prospective Payment System's Inpatient Only List and the volume being reallocated to the new CPT codes are from inpatient predecessor codes, CPT codes 49561 and 49566, which is contradictory. One commenter noted that the post-operative care will be occurring on the same day as the service and they believe that we did not account for this. Commenters also noted concern about contradictory policies regarding the newly revised E/M CPT codes, 99232, 99233, 99238, and 99239, which they noted now represents the same physician work whether inpatient or outpatient. Commenters opined that the revision to the E/M

codes renders the 23-hour policy invalid. One commenter also expressed concern about our assertion that the 23-hour policy can encompass scenarios where the patient stays multiple overnights in the hospital, as this is contradictory to our ''Two-Midnight rule'' regarding inpatient versus outpatient status.

Response: As stated previously, we believe that it is not duplicative to apply the full 23-hour policy calculation to the CPT codes that the RUC has considered as overnight with a visit on the same date. It is not evident from the RUC recommendations provided to us that the final work RVU was appropriately reduced (per the CY 2011 PFS final rule formula) consistent with the second step of the 23-hour calculation. Therefore, we believe the entire calculation should be applied to the CPT codes that the RUC has considered as overnight with a visit on the same date. We acknowledge that we proposed to add the CPT codes that the RUC has considered as admitted to the Hospital Outpatient Prospective Payment System's Inpatient Only List for 2023. However, we believe that doing so is not inconsistent with our proposals for this family. The RUC recommendations include a request to treat these CPT codes as 000-day global services. As such, regardless of the inpatient status of the patients, we continue to believe that 000-day global service code families allow for separately billable post-operative E/M visits. Therefore, we believe it is still appropriate to subtract the value of the post-operative E/M visit that the RUC recommended as bundled into the valuations of the codes from the valuation of the codes. We also acknowledge that the RUC recommendations include the post-operative work occurring on the same day of the service. In light of that, we intend to reallocate the intraservice time from the removed post-operative E/M visit to the immediate post-service time of the service, as proposed. We believe that the proposed revisions for CPT codes 99221–99223 and 99231–99233 are not inconsistent with our 23-hour policy as it applies to this code family; the RUC recommendations referenced in this rule (from April 2021) explicitly identify many of the codes in this family as being subject to our 23-hour policy. Consistent with discussions in the CY 2011 and CY 2022 PFS final rules cited above, we agree with the RUC that these codes are subject to the 23-hour policy, and we believe it is appropriate to fully apply the 23-hour policy to several of the codes within this family. We again note that the RUC recommendations request this family be 000-day global services, as such, this allows for separately billable E/M visits regardless of the patient's admission status.

We note that we also discussed 000-day global services and separately billable E/M visits in the CY 2022 PFS final rule relative to CPT codes 21315 and 21320 (86 FR 65074). We note that we acknowledge commenter's concerns regarding policy implications as a result of adopting the E/M inpatient/observation revisions and will take that into consideration for future rulemaking. Also consistent with the CY 2011 and CY 2022 final rules, we disagree with the commenter's concerns regarding multiple overnights and the application of the 23-hour policy. We stated in the CY 2022 final rule cited above that the 23-hour policy can encompass several scenarios, including multiple overnight stays (87 FR 45860). We did not propose any changes to the previously finalized 23-hour policy nor a policy regarding ''Two-Midnights''. Therefore, we believe it is still consistent to fully apply the 23-hour policy to the codes within this family that the RUC considers overnight with a visit on the same date and admitted.

Comment: One commenter stated that they have concerns with our CY 2011 PFS final rule policy (75 FR 73226) to reallocate the intraservice time of the inpatient level E/M postoperative visit to the immediate postservice time of the service. The commenter noted that the E/M services furnished post operatively are separate and distinct from the main surgical procedure and there is no difference in work to provide a separate E/M service furnished to a postoperative patient by the surgeon compared to another provider. Additionally, the commenter stated that we have not provided a rationale or evidence for this policy and the components of it, such as the intraservice vs. total time and the chosen intensity. The commenter also noted that this policy of reallocating the intraservice time from the inpatient level E/M postoperative visit to the immediate postservice time of the service is discriminatory to surgeons and the 23-hour policy overall is flawed and not in line with statute.

Response: We acknowledge that some commenters had concerns regarding various aspects of our 23-hour policy and CMS's full application of the policy to the CPT codes in this family. We refer readers to our discussion regarding the policy and its application in the CY 2011 and CY 2022 PFS final rules, cited above. Since we did not propose any changes to our 23-hour policy, its application or calculation, we are not finalizing any changes to the policy for CY 2023.

Comment: Commenters disagreed with our proposed valuation methodologies for several specific codes within the family. For CPT codes 49591 and 49613, commenters disagreed with our use of the intraservice time ratio as a valuation methodology. Commenters noted that using ratios treats all components of physician time as having identical intensities. Commenters also noted that we did not adequately account for the bundled work of the placement of mesh, that previously was reported separately. Commenters also disagreed with our chosen supporting reference codes, as they noted their clinical nature and intensity is not appropriate for purposes of comparison. For CPT code 49623, commenters disagreed with our use of the RBB methodology as the service is currently not described by an existing CPT code and is instead reported using an unlisted code or with modifier -22.

Response: We continue to believe that intraservice time ratios are a valid and appropriate tool for determining work RVUs. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in the resource of time are not accounted for in a RUC-recommended RVU, the obligation to account for that change when establishing the proposed and final work RVUs remains. For more details on our methodology for developing work RVUs, we direct readers to the discussion on time ratios as discussed above in this Valuation of Specific Codes section.

For CPT codes 49591 and 49613, we believe that the RUC recommended work RVUs are overvalued compared to similar codes with similar intraservice times. We also do not believe that our supporting reference codes must have similar clinical characteristics for purposes of comparison due to the inherent relativity of the PFS. Also, for CPT code 49591, we found multiple other supporting reference codes that have similar and even lower intraservice and total times, but RVUs much lower than the RUC recommended value for this code. For example, CPT code 33289 (*Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of*

the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed) was reviewed by the RUC in 2018. This CPT code has 40 minutes of intraservice time, 111 minutes of total time, a work RVU of 6.0 and a nearly identical intensity of 0.115 as compared to the RUC derived intensity of 0.113 for their recommended work RVU value for this code. Therefore, we believe a work RVU of 5.96 for CPT code 49591 is an appropriate valuation based on CPT codes with similar times and intensities. For CPT code 49613, we disagree that our supporting reference code (CPT code 52353) is inappropriate for purposes of comparison. In addition to the similar times, it also has an intensity of 0.101 that is very close to the RUC derived intensity of 0.105 for their recommendation for this code. Therefore, we believe a work RVU of 7.42 for CPT code 49613 is an appropriate valuation based on CPT codes with similar times and intensities.

For CPT code 49623, we disagree that it is inappropriate to use the RBB to reach a work RVU valuation. We believe that there are multiple valuation methodologies that we can use to calculate work RVUs for CPT codes, all of which align with the statutory requirement to value work RVUs based on the relative resources involved in furnishing the service, which include time and intensity. However, we agree with commenters that there are other more appropriate CPT codes that could be used in the RBB calculation for purposes of comparison. For example, CPT code 11008 (*Removal of prosthetic material or mesh, abdominal wall for infection (e.g., for chronic or recurrent mesh infection or necrotizing soft tissue infection) (List separately in addition to code for primary procedure)*) has a total time of 60 minutes and an RVU of 5.0. Using CPT code 11008 in the RBB calculation yields a work RVU of 3.75 for CPT code 49623. We believe that CPT code 11008 is a more appropriate code to use within the RBB calculation for CPT code 49623. We also support a work RVU of 3.75 with a reference code, CPT code 63048 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*), which has the same total time of 45 minutes and work RVU of 3.47. Therefore, we are finalizing a work RVU of 3.75 for CPT code 49623.

Comment: Commenters did not support our proposed practice expense (PE) clinical staff time packages for this code family. Commenters disagreed with using a 000/010-day extensive package and believe that the 090-day clinical staff time package is still appropriate because the change to a 000-day global period from a 090-day global period was requested by the RUC to account for the variable post-operative care and not the procedural clinical staff work that is associated with it. One commenter also noted that in April 2022, the RUC created a new clinical staff time package for 000/010-day global period codes that had previously been 090-day global period codes. Commenters also requested that we accept the RUC's recommendation to use the standard emergent procedure package, with 20 minutes of clinical staff activities e for CPT code 15778.

Response: As stated in the CY 2023 PFS proposed rule (87 FR 45909), we continue to believe that maintaining clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. We reviewed the individual codes in question and concluded that the use of 000-day or 010-day global period standards for ''Extensive use of Clinical Staff'' would be most typical and consistent in these cases. Upon further clinical review, we also continue to believe that the most appropriate clinical staff package for CPT code 15778 is the minimal staff package minus pre-service education. We are pleased to learn that the RUC has developed a new clinical staff package for CPT codes that are transitioning from a 90-day global period. This clinical staff package was not included in the recommendations submitted for this code family.

After consideration of the public comments, we are finalizing the work RVU values for this code family as proposed, with the exception of CPT code 49623, as indicated above. We are also finalizing all PE inputs as proposed.

(2) Removal of Sutures or Staples (CPT Codes 15851, 15853, and 15854)

In October 2021, the CPT Editorial Panel approved the deletion of CPT code 15850 and revised CPT code 15851 (*Removal of sutures or staples requiring anesthesia (ie, general anesthesia, moderate sedation)*), and created two new related CPT add-on codes, 15853 and 15854, to describe *Removal of sutures or staples requiring anesthesia (i.e., general anesthesia, moderate sedation).* The RUC reviewed the three codes: 15851, 15853 and 15854 at the January 2022 RUC meeting.

After reviewing CPT code 15851, we proposed the RUC-recommended work RVU of 1.10 for CPT code 15851. CPT codes 15853 (*Removal of sutures OR staples not requiring anesthesia (List separately in addition to E/M code)*), and 15854 (*Removal of sutures OR staples not requiring anesthesia (List separately in addition to E/M code*) are valued by the RUC as PE-only codes. The RUC did not recommend any work inputs for these two add-on codes and we did not propose any work RVU refinements.

We also proposed the RUC-recommended direct PE inputs for CPT codes 15851, 15853, and 15854 without refinement.

Comment: One commenter expressed support for our proposed valuations for the family of codes that describe the removal of sutures or staples.

Response: We appreciate the commenter's support, and we are finalizing our proposal of the RUC-recommended direct PE inputs for CPT codes 15851, 15853, and 15854 without refinement.

(3) Arthrodesis Decompression (CPT Codes 22630, 22632, 22633, 22634, 63052, and 63053)

In October 2020, the CPT Editorial Panel approved the revision of four codes describing arthrodesis and the addition of two new add-on codes, CPT codes 63052 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)*) and 63053 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)*), to report laminectomy, facetectomy, or foraminotomy during posterior interbody arthrodesis, lumbar to more appropriately identify the decompression that may be separately reported. In January 2021, the RUC reviewed the survey results for the two new codes and expressed concern that the four base codes had not been surveyed along with the two new add-

on codes. The RUC recommended that the entire family be resurveyed and presented for review at its April 2021 meeting. The RUC suggested that until new values could be established, interim values be established for CPT codes 63052 and 63053, which CMS revised for CY 2022 based on the survey data and RUC review available to us at the time of the development of the CY 2022 PFS proposed rule. We have noted in similar circumstances, such as the minimally invasive glaucoma surgery (MIGS) procedures with cataract surgery discussed in the CY 2022 PFS final rule (86 FR 65097), that it is best for entire code families to be surveyed at the same time. We also noted that we finalized a policy in the CY 2015 PFS final rule (79 FR 67602 through 67609) to make all changes in the work and MP RVUs and the direct PE inputs for new, revised, and potentially misvalued services under the PFS by proposing and then finalizing such changes through notice and comment rulemaking, as opposed to initially finalizing changes on an interim final basis.

For CPT codes 22630 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar*), 22633 (*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar*), 22634 (*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment (List separately in addition to code for primary procedure)*), 63052, and 63053, we disagreed with the RUC-recommended work RVUs of 22.09, 26.80, 7.96, 5.70, and 5.00, respectively, because these values do not account for the surveyed changes in time, and we proposed a work RVU of 20.42 for CPT code 22630, a work RVU of 24.83 for CPT code 22633, a work RVU of 7.30 for CPT code 22634, the current work RVU of 4.25 for CPT code 63052 and a work RVU of 3.78 for CPT code 63053. For CPT code 22632 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)*), we agreed with the RUC-recommended maintenance of the current work RVU of 5.22, as there were no surveyed changes in time.

We proposed a work RVU of 20.42 for CPT code 22630 based on the reverse building block methodology to account for the surveyed 8-minute decrease in total time, 10-minute decrease in pre-service time, 30-minute decrease in intraservice time, and 2-minute decrease in immediate post-service time. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would be inappropriate to maintain the current work RVU given the significant decrease in intraservice time without adequate justification of increased intensity. There are currently three CPT code 99231 (*Subsequent hospital care/day 15 minutes*) and four CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter.*) visits bundled in CPT code 22630's 090-day global period and valuation. The RUC recommended that the post-operative period for CPT code 22630 change to include two CPT code 99232 (*subsequent hospital care/day 25 minutes*), one CPT code 99231, one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 visits. The currently bundled post-operative visits total to 6.16 work RVUs, whereas the RUC-recommended changes to the post-operative visits total 6.98 work RVUs, resulting in a 0.82 work RVU increase (if no other changes occurred to CPT code 22630). The proposed work RVU of 20.42 for CPT code 22630 maintains the same IWPUT of 0.067 and maintains the 0.82 work RVU difference between the current and RUC-recommended post-operative period. We believe this proposed work RVU is more accurate than the RUC-recommended work RVU because there was no obvious or explicitly stated rationale in the RUC's recommendations for the change in intensity of intraservice time, and there was a 30-minute decrease in intraservice time for CPT code 22630. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would have been inappropriate to propose the RUC-recommended work RVU for CPT code 22630.

Similarly, we proposed a work RVU of 24.83 for CPT code 22633, based on the reverse building block methodology, to account for the surveyed 56-minute decrease in total time, 20-minute decrease in intraservice time, and 33-minute decrease in post-operative time. The reverse building block methodology accounts for the time and intensity of post-operative work through long-established and agreed-upon times and intensities for bundled post-operative visits, and accurately adjusts for the changes occurring in the post-operative period. There is currently one post-operative CPT code 99232, two CPT code 99233 (*Subsequent hospital care/day 35 minutes*), and three CPT code 99213 visits bundled in CPT code 22633's valuation. The RUC recommended that the post-operative period for CPT code 22633 change to include two CPT code 99232, one CPT code 99231, one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 visits. The currently bundled post-operative visits total to 8.30 work RVUs, whereas the RUC-recommended changes to the post-operative visits total 6.98 work RVUs, resulting in a 1.32 work RVU decrease (if no other changes occurred to CPT code 22633). Using the reverse building block methodology, the proposed work RVU of 24.83 maintains the same IWPUT of 0.080 and the 1.32 work RVU difference between the current and RUC-recommended post-operative period. We believe this proposed work RVU is more accurate than the RUC-recommended work RVU because there was no obvious or explicitly stated rationale in the RUC's recommendations for the change in intensity of intraservice time, and there was a 20-minute decrease in intraservice time for CPT code 22633. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would have

been inappropriate to propose the RUC-recommended work RVU decrease of 0.95, which is only about three-quarters of the established decrease in work RVU of 1.32 and intensity from the changes in the post-operative period alone. We also considered the apparent decrease in intraservice time and the lack of an adequate justification for increased intensity to arrive at our proposed work RVU of 24.83 for CPT code 22633.

We proposed a work RVU of 7.30 for CPT code 22634 based on a comparison to its base code, CPT code 22633. We used the proposed work RVU of 24.83 for the parent CPT code (22633) as the numerator and the current work RVU for CPT code 22633 of 27.75 as the denominator, and multiplied that fraction by the current work RVU of 8.16 for CPT code 22634 to arrive at a proportionate proposed work RVU of 7.30 for CPT code 22634 ((24.83/27.75) * 8.16) = 7.30). The proposed work RVU accounts for the decrease in intraservice time and is well bracketed by CPT code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*), valued at 7.00 work RVUs with an intraservice time of 60 minutes, and CPT code 34833 (*Open iliac artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*), valued at 8.16 work RVUs with an intraservice time of 72 minutes.

CPT codes 63052 and 63053 were new add-on codes to report decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace for CY 2022. The proposed work RVU for CPT code 63052 would maintain the current work RVU, despite a surveyed change in time. In the CY 2022 PFS final rule, we finalized a work RVU of 4.25 for CPT code 63052 for CY 2022 based on a crosswalk to CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*), which has a work RVU of 4.25 and an intraservice time of 45 minutes. Despite a surveyed 5-minute intraservice time increase for CPT code 63052, we believe the crosswalk to CPT code 22853 is still valid, given that only 3 months passed between the two surveys, as it now has the same intraservice time as CPT code 63052, is a spinal procedure, and is an add-on code to the same base codes as CPT code 63052. Commenters on the CY 2022 PFS proposed rule supported the bracket of key reference service CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) and MPC CPT code 34812 (*Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)*), and therefore, we noted that the final work RVU of 4.25 for CY 2022 was supported by the commenters (86 FR 65092). CPT code 22552 has a work RVU of 6.50 and an intraservice time of 45 minutes, and commenters noted that CPT code 22552 has a higher intensity as anticipated for a surgical procedure in comparison with a lumbar procedure. CPT code 34812 has a work RVU of 4.13 and 40 minutes of intraservice time, and commenters noted that this code involves open femoral artery exposure by groin incision and closure of the wound, typically for separately reported delivery of an endovascular prosthesis for an asymptomatic infrarenal abdominal aortic aneurysm. In comparison, exposure and closure for CPT code 63052 are performed as part of the primary arthrodesis code and the intraservice time includes higher intensity bony and soft tissue resection, and therefore, although both codes require the same time, the physician work and intensity of CPT code 63052 is greater than CPT code 34812.

In the CY 2022 PFS final rule, we finalized a work RVU of 3.19 for CPT code 63053 for CY 2022 based on an intraservice time ratio between CPT codes 63052 and 63053 ((30 minutes/40 minutes) * 4.25 = 3.19). We believe this intraservice time ratio between the two CPT codes is still valid, given that only 3 months passed between the two surveys, and therefore, we proposed a work RVU of 3.78 based on the surveyed time changes for CPT codes 63052 and 63053 ((40 minutes/45 minutes) * 4.25 = 3.78) in order to maintain consistency with previous analysis of time and intensity of these two add-on codes. Due to the lack of an obvious or explicitly stated rationale in the RUC's April recommendations for the change in intensity between the January 2021 and April 2021 surveys, we relied on the changes in surveyed time to calculate the proposed work RVUs for CPT codes 63052 and 63053.

We proposed the RUC-recommended PE inputs for CPT codes 22630 and 22633.

Comment: Some commenters disagreed with our proposed work RVUs for CPT codes 22630 and 22633, stating that the changes in time for these CPT codes are attributed to changes in technology that reduced operator time but increased the intensity of the services provided within that time. The commenters stated that routine use of fluoroscopy to obtain intraoperative films may decrease the time required for these procedures, but the surgeon is using that data in real-time to determine the positioning and safety of hardware placement. The commenters also stated that using high-speed electric drills eliminates the routine need to change out air pressure tanks required for pneumatic drills, but the differences in torque and handling change the ''feel'' of a procedure involving a high-speed drill close to the spinal nerves. The commenters stated that the decreases in intraoperative time is due to reduction in time devoted to low-risk and less intense portions of the procedures (for example, waiting on a radiology technician to obtain an intraoperative cross-table lateral film; waiting for X-ray films to be developed after a flat plate film was taken and waiting for air tanks to be changed out for a pneumatic drill). The commenters contended that the decrease in intraservice time is matched by a related increase in the intensity of the procedure itself, as the lower intensity aspects of the procedure have been eliminated, leaving the high-risk elements of the procedures to be provided in less time with greater intensity.

Response: We note that we proposed a work RVU of 20.42 for CPT code 22630 based on the reverse building block methodology to account for the surveyed 8-minute decrease in total time, 10-minute decrease in pre-service time, 30-minute decrease in intraservice time, and 2-minute decrease in immediate post-service time. We believed it would be inappropriate to maintain the current work RVU for CPT code 22630 given the significant decrease in intraservice time and the absence of an adequate justification of increased intensity. However, after consideration of the commenters' rationale for decreased time and increased intensity, we are finalizing the RUC recommended work RVUs of 22.09 and 26.80 for CPT codes 22630 and

22633, respectively, as we believe the RUC recommended work RVUs adequately account for the changes in resources. We appreciate the commenters additional input regarding intensity, but remind interested parties that both time and intensity changes must be addressed in the summary of recommendations. We remind interested parties that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendations appear to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally use one of the methodologies discussed above to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

We note that we proposed a work RVU of 7.30 for CPT code 22634 based on a comparison to our proposed work RVU for its base code, CPT code 22633, which we are not finalizing. Given that we have decided to finalize the RUC recommended work RVU of 26.80 for CPT code 22633, in order to maintain for relativity within the family, we are also finalizing the RUC recommended work RVU of 7.96 for CPT code 22634.

Comment: A few commenters urged CMS to finalize the RUC recommended work RVUs for CPT codes 63052 and 63053, stating that the intraservice time for CPT code 63035 increased by five minutes to a total of 45 minutes and that the time spent performing this procedure is essentially all high-risk. The commenters asserted that the lower intensity surgical exposure activities were already completed with the base code, so the physician work of CPT code 63052 involves only the high intensity, dangerous aspects of neural element and spinal cord decompression. Similarly, some commenters disagreed with our use of an intraservice time ratio to value CPT code 63053. Commenters stated that this approach ignores magnitude estimation and stated that the second survey included more respondents who routinely perform this procedure. Commenters stated that the new survey from April 2021, which included all six codes in the family, generated an intraservice time of 40 minutes, a difference of five minutes between CPT codes 63052 and 63053, which is believed to be a more accurate reflection of the difference in work between laminectomy/facetectomy/foraminotomy with decompression of the first segment and an additional segment versus the January 2021 survey, which generated an intraservice time difference of ten minutes between CPT codes 63052 and 63053.

Response: We agree with the commenters that an intraservice time difference of 5 minutes between CPT codes 63052 and 63053 is a reflection of the difference in work between laminectomy/facetectomy/foraminotomy with decompression of the first segment and an additional segment, and therefore, we proposed the RUC recommended physician time values for CPT codes 63052 and 63053. However, we continue to believe that, despite a surveyed 5-minute intraservice time increase for CPT code 63052, the crosswalk to CPT code 22853 is still valid to support a work RVU of 4.25 for CPT code 63052, given that only 3 months passed between the two surveys, that it now has the same intraservice time as CPT code 22853, are both spinal procedures, and are both add-on codes to the same base codes. We reiterate that commenters on the CY 2022 PFS proposed rule supported the bracket of key reference service CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) and MPC CPT code 34812 (*Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)*), and therefore, we noted that the final work RVU of 4.25 for CY 2022 was supported by the commenters (86 FR 65092). CPT code 22552 has a work RVU of 6.50 and an intraservice time of 45 minutes, and commenters noted that CPT code 22552 has a higher intensity as anticipated for a surgical procedure and in comparison with a lumbar procedure. CPT code 34812 has a work RVU of 4.13 and 40 minutes of intraservice time, and commenters noted that this code involves open femoral artery exposure by groin incision and closure of the wound, typically for separately reported delivery of an endovascular prosthesis for an asymptomatic infrarenal abdominal aortic aneurysm. In comparison, exposure and closure for CPT code 63052 are performed as part of the primary arthrodesis code and the intraservice time includes higher intensity bony and soft tissue resection, and therefore, although both codes require the same time, the physician work and intensity of CPT code 63052 is greater than CPT code 34812. Therefore, we are finalizing a work RVU of 4.25 for CPT code 63052.

We remind commenters that in the CY 2022 PFS final rule, we finalized a work RVU of 3.19 for CPT code 63053 for CY 2022 based on an intraservice time ratio between CPT codes 63052 and 63053 ((30 minutes/40 minutes) * 4.25 = 3.19). We continue to believe this intraservice time ratio between the two CPT codes is still valid, given that only 3 months passed between the two surveys, and therefore, we are finalizing a work RVU of 3.78 based on the surveyed time changes for CPT codes 63052 and 63053 ((40 minutes/45 minutes) * 4.25 = 3.78) in order to maintain consistency with previous analysis of time and intensity of these two add-on codes. We reiterate that, due to the lack of an obvious or explicitly stated rationale in the RUC's April recommendations for the change in intensity between the January 2021 and April 2021 surveys, we relied on the changes in surveyed time to calculate the work RVU for CPT code 63053.

We are finalizing the RUC-recommended PE inputs for CPT codes 22630 and 22633, as proposed.

(4) Total Disc Arthroplasty (CPT Codes 22857 and 22860)

In September 2021, the CPT Editorial Panel created CPT Category I code 22860 to describe *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)* and replace CPT Category III code 0163T (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)*), which prompted CPT codes 22860 and 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar*) to be surveyed for the January 2022 RUC meeting. At the January 2022 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for both CPT codes 22857 and 22860 were erroneous and that the codes should be resurveyed for the April 2022 RUC meeting. Therefore, we proposed to maintain the RUC-recommended work RVU of 27.13 for

CPT code 22857 and contractor pricing for CPT code 22860 for CY 2023. We will revisit the valuations of CPT codes 22857 and 22860 in future rulemaking when we review the April 2022 RUC recommendations, based on our annual review process discussed in the background section of this final rule.

We did not receive comments on our proposals for this code family and we are finalizing the values as proposed.

(5) Insertion of Spinal Stability Distractive Device (CPT Codes 22869 and 22870)

For CPT codes 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*) and 22870 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)*), we proposed to maintain the current work RVUs of 7.03 and 2.34, respectively. We proposed the RUC-recommended direct PE inputs for CPT code 22869 without refinement.

We did not receive comments on our proposals for this code family and we are finalizing the values as proposed.

(6) Knee Arthroplasty (CPT Codes 27446 and 27447)

CPT codes 27446 (*Arthroplasty, knee, condyle and plateau; medial OR lateral compartment*) and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) were reviewed by the RUC in April 2021. We previously reviewed CPT code 27447 in the CY 2021 PFS final rule; (see 85 FR 84609 and 84610 for our previous discussion). The RUC proposed a revised survey instrument to ask about additional pre-operative time and resources spent on pre-optimization patient work. The RUC agreed that the pre-service planning activities are being performed routinely for the typical patient but the inclusion of this work is not reflected in the 090-day global period structure. The RUC indicated that separate planning codes may be developed, or current codes such as the prolonged service codes may be reported for these activities.

We proposed the RUC-recommended work RVU of 17.13 for CPT code 27446. The survey 25th percentile actually showed an increase in work RVU even though there was a decrease in total time. One post facility visit, CPT code 99232 (*Subsequent hospital care/day 25 minutes*), was removed and replaced with CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*) a post-operative visit in the office. Given a decrease in the total time spent and a lower level post-operative visit, it is reasonable that the work RVU went down. There was no change in the global period.

For CPT code 27447, the RUC reaffirmed the same valuation that it recommended for the CY 2021 PFS rulemaking cycle. Since we did not receive any new information regarding this code, we did not propose to change our previously finalized values (see 85 FR 84609 and 84610 for our previous discussion of this code in the CY 2021 PFS final rule). We proposed to maintain a work RVU of 19.60 for CPT code 27447, the value that we previously finalized through rulemaking. We proposed the RUC-recommended direct PE inputs for CPT code 27446 and we proposed to maintain the direct PE inputs for CPT code 27447.

Comment: One commenter, representing interested parties who furnish these services, agreed with the RUC recommendation, but noted that CPT code 27447 has been undervalued since its reduction in 2021 and noted the current work RVU is based on the AMA RUC's recommendations following the 2019 survey. This commenter and other interested parties previously argued to maintain the then current work RVU of 20.72, which was lower than the survey median. The commenter claimed that CPT codes 27447 and 27130 are undervalued due to the RUC and CMS utilizing different percentiles from surveys to assign the work RVUs and recommended that CMS adopt a policy to base work RVUs uniformly on the same percentile of physician survey results as the RUC. We did not make any proposals for CPT code 27130.

The commenter appreciated CMS discussing the concept of pre-optimization time for these services in the proposed rule and provided further clarification with regard to the RUC survey. The commenter noted that the RUC specifically rejected a proposal for a revised survey instrument to ask about additional pre-operative time and resources spent on pre-optimization patient work. Additionally, the use of current prolonged services, CPT codes 99358 and 99359 was suggested; however, it was noted that these codes could not be used in conjunction with CPT codes 27446 and 27447, given the standard of practice includes preservice time over several days and not one single day, as stated in the code descriptor for CPT codes 27446 and 27447. The commenter noted it continues to work with the AMA and CPT to clarify if there are existing codes to bill for pre-optimization time.

The commenter was in support of the proposed RVUs for PE and malpractice for CPT code 27447. The commenter generally supported increased payment rates to facilities for arthroplasty due to the extreme complexity of the procedure, innovations in the standard of care and outcomes, and to recognize increased costs through the COVID–19 public health emergency (PHE). Nevertheless, the ongoing annual increases in Medicare facility payments for arthroplasty present a stark contrast with severely decreasing Medicare physician payments for arthroplasty.

Response: We thank the commenter for their support of our proposal and appreciate the commenters continued engagement with the AMA and the CPT to clarify if there are existing codes to bill for pre-optimization time. We are finalizing the values as proposed for CPT codes 27446 and 27447.

(7) Endovascular Pulmonary Arterial Revascularization (CPT Codes 33900, 33901, 33902, 33903, and 33904)

At the February 2021 meeting of the CPT Editorial Panel, CPT approved a new family of Category I CPT codes to describe percutaneous endovascular repair of pulmonary artery stenosis (PAS) by stent replacement. CPT codes 33900 through 33904 were surveyed by the RUC at the October 2021 RUC meeting.

We disagree with the RUC-recommended work RVU of 14.0 for CPT code 33900 (*Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, unilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We proposed the survey 25th percentile work RVU of 11.03 for CPT code 33900. A work RVU of 11.03 is supported by a bracket of reference CPT codes, including CPT code 61650 and CPT code 61640. CPT code 61650 (*Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance;*

initial vascular territory) has a work RVU of 10.0 and the same intraservice time of 90 minutes and the same total time of 206 minutes. CPT code 61640 (*Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel*) has a work RVU of 12.32 and an intraservice time of 90 minutes and a higher total time of 233 minutes.

There are no direct PE inputs for CPT Code 33900.

We disagree with the RUC-recommended work RVU of 18.0 for CPT code 33901 (*Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, bilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We proposed the survey 25th percentile work RVU of 14.50. A work RVU of 14.50 is supported by a reference CPT code—CPT code 11005. CPT code 11005 (*Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; abdominal wall, with or without fascial closure*) has a work RVU of 14.24 and the same intraservice time of 120 minutes and nearly the same total time of 235 minutes.

There are no direct PE inputs for CPT Code 33901.

We disagree with the RUC-recommended work RVU of 17.33 for CPT code 33902 (*Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, unilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We proposed the survey 25th percentile work RVU of 14.0. A work RVU of 14.0 is supported by a reference CPT code—CPT code 61640. CPT code 61640 (*Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel*) has a work RVU of 12.32 and the same intraservice time of 90 minutes and a higher total time of 233 minutes.

There are no direct PE inputs for CPT Code 33902.

We disagree with the RUC-recommended work RVU 20.0 for CPT code 33903 (*percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, bilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 33901 and 33903 is equivalent to the RUC-recommended interval of 2.0 RVUs. Therefore, we proposed a work RVU of 16.50 for CPT code 33903, based on the recommended interval of 2.0 additional RVUs above our proposed work RVU of 14.50 for CPT code 33901. A work RVU of 16.50 is also supported by a reference code—CPT code 11005. CPT code 11005 (*Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; abdominal wall, with or without fascial closure*) has a work RVU of 14.24 and the same intraservice time of 120 minutes and a higher total time of 265 minutes.

There are no direct PE inputs for CPT Code 33903.

We disagree with the RUC-recommended RVU of 7.27 for CPT code 33904 (*Percutaneous pulmonary artery revascularization by stent placement, each additional vessel or separate lesion, normal or abnormal connections (list separately in addition to code for primary procedure) (use 33904 in conjunction with 33900, 33901, 33902, 33903)*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We proposed the survey 25th percentile work RVU of 5.53. A work RVU of 5.53 is supported by a reference code—CPT code 57267. CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure*) has a work RVU of 4.88 and the same time of 45 minutes.

There are no direct PE inputs for CPT code 33904.

Comment: Commenters disagree with our proposed valuations for all of the codes within this family. Commenters asserted that we failed to properly justify the decrease for each CPT code because we did not provide a clinical rationale. One commenter stated that the RUC intentionally did not use the survey 25th percentile value because the RUC believes the clinical nature is vastly different than currently described by similar coding and more intense. Therefore, commenters noted that we should accept the RUC-recommended survey median values. For CPT codes 33900, 33901, 33902, and 33904, commenters disagreed with our chosen supporting reference codes. They noted that the CPT codes are not clinically similar and the CPT codes that the RUC recommended are more appropriate for purposes of comparison. Commenters also noted that we did not maintain the RUC recommended relativity within the code family that accounts for the change from unilateral to bilateral anatomically. For CPT code 33903, a commenter disagreed with our use of the incremental methodology. The commenter noted that using increments forms a linear relationship between RVUs, which is not appropriate.

Response: We disagree with commenters that supporting reference codes must have similar clinical characteristics to be appropriate for purposes of reaching valuations. We believe that the inherent relativity of the PFS is such that all codes can be used for purposes of comparison, while considering time and intensity. We maintain that the RUC recommended work RVU values for CPT codes 33900–33904 are overvalued relative to codes with similar times and intensities. For example, CPT code 11004 (Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia and perineum), has a work RVU of 10.80, an intraservice time of 90 minutes and a total time of 280 minutes. This is the same intraservice time and a significantly higher total time than CPT code 33900 and is almost 3 RVUs less than the RUC recommended value of 14.0 for this CPT code. We also disagree that we did not maintain relativity within the family. We believe that our proposed RVUs account for the recommended changes in time within the family as the procedure changes from unilateral to bilateral and is further supported by our reference codes with similar times. For example, for CPT code 33903, we used the incremental difference between the RUC recommended values for CPT codes 33901 and 33903 (2 RVUs) to reach our proposed value of 16.50 RVUs for CPT code 33903. This value is higher than the 25th percentile and accounts for the change in intensity from unilateral to bilateral. We also believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service.

We are finalizing our work RVUs for this family as proposed.

(8) Percutaneous Arteriovenous Fistula Creation (CPT Codes 36836 and 36837)

In October 2021, the CPT Editorial Panel created CPT codes 36836 (*Percutaneous arteriovenous fistula creation, upper extremity, single access*

of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) and 36837 (*Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation*) to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach. Previously, CPT coding did not account for percutaneous arteriovenous access creation, as current the CPT codes only describe an open surgical approach. Given that new technologies have been developed that allow for less invasive approaches that utilize percutaneous image-guided methods to approximate a target artery and vein using magnets or mechanical capture, we created HCPCS codes G2170 (*Percutaneous arteriovenous fistula creation (avf), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed*) and G2171 (*Percutaneous arteriovenous fistula creation (avf), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed*) in July 2020 that describe two approaches to percutaneous arteriovenous access creation. The RUC intends for CPT codes 36836 and 36837, which represent two percutaneous approaches to creating arteriovenous access for End-Stage Renal Disease (ERSD) patients during hemodialysis, to replace HCPCS codes G2170 and G2171, and has requested both G2170 and G2171 be deleted. For CY 2023, the RUC recommended a work RVU of 7.50 for CPT code 36836, and a work RVU of 9.60 for CPT code 36837.

We disagreed with the RUC-recommended RVUs for CPT codes 36836 and 36837. We found that the recommended work RVUs were high when compared to other codes with similar time values. The RUC-recommended RVU of 7.50 for 36836 is the second highest RVU for codes with 55 to 65 minutes of intraservice time and 94 to 114 minutes of total time, with RVUs ranging from 2.45 to 8.84. Similarly, the RUC-recommended RVU of 9.60 for 36837 is the third highest RVU for codes with 65 to 85 minutes of intraservice time and 109 to 129 minutes of total time, with RVUs ranging from 4.69 to 10.95. Therefore, we proposed a work RVU of 7.20 for CPT code 36836, and a work RVU of 9.30 for CPT code 36837.

We disagreed with the RUC-recommended work RVU of 7.50 for CPT code 36836 and proposed an RVU of 7.20 that is based on the intra-service time ratio calculation using the second reference code from the RUC survey, CPT code 36905 (*Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*). The proposed RVU of 7.20 is based on the intra-service time ratio using the RUC-recommended 60 minutes intra-service time for CPT code 36836 divided by 75 minutes of intra-service time for CPT code 36905, then multiplying by the RVU of 9.00 for CPT code 36905 ($(60/75) \times 9.00 = 7.20$). We chose to use the second reference code from the RUC survey, CPT code 36905, in this calculation because its intra-service time and total time values were closer to the time values proposed by the RUC for CPT code 36836. We noted that the RUC-recommended RVU of 7.50 is one of the highest values within the range of reference codes we reviewed with the same intra-service time and similar total time. The proposed work RVU of 7.20 is supported by the reference CPT codes we compared to CPT code 36836 with the same 60 minutes of intra-service time and similar total time as CPT code 36836; reference CPT code 47541 (*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (e.g., rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access*) has a work RVU of 6.75, and reference CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture*) has a work RVU of 8.84. Again, we believe 7.20 is a more appropriate value overall than 7.50 when compared to the range of codes with the same intra-service time and similar total time.

Although we disagreed with the RUC-recommended work RVU of 9.60 for CPT code 36837, we concur that the relative difference in work between CPT codes 36836 and 36837 is equivalent to the RUC-recommended interval of 2.10 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we proposed a work RVU of 9.30 for CPT code 36837, based on the RUC-recommended interval of 2.10 RVUs above our proposed work RVU of 7.20 for CPT code 36836.

For the direct PE inputs, we solicited additional information on two equipment items and four supply items. For two of those four supply items, we requested a justification for their inclusion as direct PE inputs. The RUC submitted invoices for two new equipment inputs; one for a Wavelinq EndoAVF generator (EQ403) used for CPT code 36837, and the other for an Ellipsys EndoAVF generator (EQ404) used for CPT code 36836. We solicited comments and requested information that may inform us why the Wavelinq generator (EQ403) is so much more expensive on its invoice as compared with the Ellipsys generator (EQ404) since the former costs $18,580 and the latter costs $3,000.

In addition, the RUC included supply items SD149 (catheter, balloon inflation device) and SD152 (catheter, balloon, PTA) as direct PE inputs for CPT codes 36836 and 36837. We solicited comments and requested information that may inform us if supply items SD149 and SD152 are typical, and how often they are used, for CPT codes 36836 and 36837. Also, the RUC included supply items SF056 (detachable coil) and SF057 (non-detachable embolization coil) as direct PE inputs for CPT code 36837 (one each for SF056 and two each for SF057). We solicited comments and requested

information that may provide us with a justification for keeping supply items SF056 and SF057 as direct PE inputs for CPT code 36837. We need to know if both of these supply items are typical and how often they are used for CPT code 36837. If these supply inputs are not typical for these procedures, we believe that they should be removed from the direct PE inputs.

We proposed to delete HCPCS codes G2170 and G2171 and replace them with CPT codes 36836 and 36837 as recommended by the RUC.

The following is a summary of the comments we received and our responses.

Comment: Many commenters agreed with our proposal to delete HCPCS codes G2170 and G2171, and replace them with CPT codes 36836 and 36837. One of the commenters also stated that they preferred CMS setting the rates for percutaneous creation of an arteriovenous fistula through rulemaking, rather than relying on contractor pricing. Other commenters stated that the contractor-priced payments for HCPCS codes G2170 and G2171 varied widely among the different Medicare Administrative Contractors (MACs), ranging approximately from $6,100 to $12,000 (rounded).

Response: We thank the commenters for their support. We are finalizing our proposal to delete HCPCS codes G2170 and G2171, and replacing them with CPT codes 36836 and 36837. We are establishing the RVUs for CPT codes 36836 and 36837 in this final rule, so the payments for these codes will not be contractor-priced, in contrast to the payments for HCPCS codes G2170 and G2171.

Comment: Several commenters disagreed with our proposed RVU of 7.20 for CPT code 36836 and RVU of 9.30 for CPT code 36837. Several commenters also disagreed with our methodologies for the valuation of the proposed RVUs and stated they do not appropriately reflect the complexity and intensity of physician work associated with these services. Therefore, they post that the statutorily-required intensity component of the work RVU and its role in the valuation of these procedures was overlooked. The commenters preferred that we accept the RUC-recommended RVU of 7.50 for CPT code 36836 and RVU of 9.60 for CPT code 36837 instead. The commenters stated that the proposed RVU is unworkable given the time it takes to perform these procedures and PE involved and that CMS's proposed RVU will cause barriers to patient access to these procedures, and will have a disproportionate impact on patients from underrepresented minority groups. However, there was one commenter that stated even the RUC-recommended RVU of 9.60 for CPT code 36837 was too low. Many commenters stated that CMS is using flawed methodologies for the valuation of codes for 2023, such as the building block methodology, incremental methodology, code comparisons, and time ratio methodology. This includes the intra-service time ratio calculation that informs the proposed work RVU of 7.20 for CPT code 36836 and the incremental methodology used for the proposed RVU of 9.30 for CPT code 36837. Also, the commenters stated that CMS did not provide any rationale or transparency as to how they arrived at the reductions applied to CPT codes 36836 and 36837. The commenters stated that CMS proposes an inconstant combination of inputs to apply, and that this selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity between codes.

Response: We continue to believe that the RVU of 7.20 for CPT code 36836, and the RVU of 9.30 for CPT code 36837, are appropriate RVUs for these procedures. We found that the RUC-recommended work RVUs were high for these codes when compared to other codes with similar time values. The RUC-recommended RVU of 7.50 for 36836 is the second highest RVU for codes with 55 to 65 minutes of intraservice time and 94 to 114 minutes of total time, with RVUs ranging from 2.45 to 8.84. Similarly, the RUC-recommended RVU of 9.60 for 36837 is the third highest RVU for codes with 65 to 85 minutes of intraservice time and 109 to 129 minutes of total time, with RVUs ranging from 4.69 to 10.95.

We disagreed with the RUC-recommended work RVU of 7.50 for CPT code 36836 and proposed an RVU of 7.20 that is based on the intra-service time ratio calculation using the second reference code from the RUC survey, CPT code 36905. In our effort to remain transparent, we provided the following rationale: The proposed RVU of 7.20 is based on the intra-service time ratio using the RUC-recommended 60 minutes intra-service time for CPT code 36836 divided by 75 minutes of intra-service time for CPT code 36905, then multiplying by the RVU of 9.00 for CPT code 36905 ($(60/75) \times 9.00 = 7.20$). We chose to use the second reference code from the RUC survey, CPT code 36905, in this calculation because its intra-service time and total time values were closer to the time values proposed by the RUC for CPT code 36836. We noted that the RUC-recommended RVU of 7.50 is one of the highest values within the range of reference codes we reviewed with the same intra-service time and similar total time. The proposed work RVU of 7.20 is supported by the reference CPT codes we compared to CPT code 36836 with the same 60 minutes of intra-service time and similar total time as CPT code 36836; reference CPT code 47541 has a work RVU of 6.75, and reference CPT code 33991 has a work RVU of 8.84. We continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in the resource of time are not accounted for in a RUC-recommended RVU, the obligation to account for that change when establishing proposed and final work RVUs remains. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277). Again, for CPT code 36836, we believe 7.20 is a more appropriate value overall than 7.50 when compared to the range

of codes with the same intra-service time and similar total time.

For CPT code 36837, although we disagreed with the RUC-recommended work RVU of 9.60, we did concur that the relative difference in work between CPT codes 36836 and 36837 is equivalent to the recommended interval of 2.10 RVUs. Therefore, we proposed a work RVU of 9.30 for CPT code 36837, based on the recommended interval of 2.10 RVUs above our proposed work RVU of 7.20 for CPT code 36836. We continue to believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. Again, for CPT code 36837, we believe a work RVU of 9.30 based on an incremental increase of 2.10 RVUs above CPT code 36836 is a more appropriate value than 9.60.

Comment: A few commenters stated that the proposed RVU of 7.20 for CPT code 36836 and RVU of 9.30 for CPT code 36837 fall below the RUC survey 25th percentile values of 7.50 and 9.60 respectively. Commenters also stated that we need to provide a significant justification when we propose an RVU that is below the 25th percentile.

Response: We remind the commenters that we used an intraservice time ratio, described above, to develop the proposed RVU of 7.20 for CPT code 36836, and that we used a 2.10 incremental increase from the proposed RVU of 7.20 for CPT code 36836 for CPT code 36837, resulting in an RVU of 9.30. The time ratio methodology and the incremental methodology are both valid methodologies for developing the RVUs that we propose, and there is no rule stating that the RVU cannot go below the survey 25th percentile. In addition to the time ratio and incremental methodologies, we also use other methods for developing RVUs, such as the building block methodology and code comparisons. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Several commenters responded to our request for additional information for four direct PE supply items (SD149 (catheter, balloon inflation device), SD152 (catheter, balloon, PTA), SF056 (detachable coil), and SF057 (non-detachable embolization coil)) and two new direct PE equipment items (EQ403 (Wavelinq EndoAVF generator) and EQ404 (Ellipsys EndoAVF generator)). Supply items SD149 and SD152 are direct PE inputs for CPT codes 36836 and 36837, and supply items SF056 and SF057 are direct PE inputs for CPT code 36837. Equipment item EQ403 is a direct PE input for CPT code 36837, and equipment item EQ404 is a direct PE input for CPT code 36836. For the four supply items, we had requested a justification for their inclusion as direct PE inputs and asked if these supply items are typical and how often they are used. For the two new equipment items, we had requested information that may inform us why the EQ403 is so much more expensive on its invoice as compared with the EQ404, since the former costs $18,580 and the latter costs $3,000.

Response: We thank the commenters for responding to our request for information. The majority of commenters that responded to our request for information stated that all four of these supply items are typical and should be included as direct PE inputs for CPT codes 36836 and 36837 as recommended by the RUC. One commenter stated they believe the typical direct PE input for CPT code 36837 is for one SF056 and that SF057 is not a typical use, and also stated that they could not find evidence of typical use (50 percent or greater) for supplies SD149 and SD152 during CPT procedure code 36837.

A few commenters responded to our request for more information on the costs for EQ403 and EQ404. The commenters stated that the specialty societies submitted invoice pricing for supplies and equipment to the RUC, and that they do not have any influence on the prices that vendors set for their products. Some commenters described how each of these equipment items are used. Another commenter stated that typically, the WavelinQ™ EndoAVF generator (E0403) can be acquired through direct purchase or financed through an agreement where the provider agrees to purchase a predetermined number of WavelinQ™ catheters (SD350). The price of the generator (EQ403) can change depending on how many catheters the provider agrees to purchase and/or the type of purchase agreement the provider chooses.

Again, we thank the commenters for responding to our request for information. The majority of the commenters stated that PE supply items SD149 and SD152 are typical direct PE inputs for CPT codes 36836 and 36837; and supply items SF056 and SF057 are typical direct PE inputs for CPT code 36837. After reviewing the information provided by the commenters, we are finalizing the direct PE supply items SD149, SD152, SF056, and SF057 for CPT codes 36836 and 36837 as recommended by the RUC without refinement. We are finalizing direct PE equipment items EQ403 and EQ404 for CPT codes 36836 and 36837 as recommended by the RUC without refinement.

Comment: One commenter was concerned that the proposed work RVU for CPT code 36837 did not include the reimbursement for the coil embolization supply items. The commenter stated that coil embolization at the time of WavelinQ procedure is critical to the success of the arteriovenous fistula. The commenter stated that embolization is a very important step in the success of the procedure and should be taken into account in the fee schedule.

Response: The work RVU is only for the activity of the physician for a procedure code. Supply items SF056 (detachable coil) and SF057 (non-detachable embolization coil) are direct PE inputs for CPT code 36837, and the payment for these supply items is included in the PE RVU. Therefore, the coil embolization supply items are reimbursed and are taken into account in the physician fee schedule, though not in the work RVU.

Comment: A few commenters requested that CMS separately identify and pay for high-cost disposable supplies priced at more than $500 using appropriate HCPCS codes, instead of including these high-cost supplies as direct PE inputs for CPT codes 36836 and 36837. These supply items should then be reviewed annually and updated.

Response: We have received a number of prior requests from interested parties, including the RUC, to implement separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251).

Comment: One commenter submitted an additional invoice associated with

the pricing of the Ellipsys™ Vascular Access Catheter, (SD351) supply. The commenter stated that Medtronic recently has been compelled by rising costs to implement price increases across their portfolio world-wide. Among the many contributing factors, manufacturing labor costs have increased by nine percent, and key materials that are used in making our products are exhibiting double-digit cost increases. One commenter stated that starting in July of 2022, they revised their standard pricing for the Ellipsys™ catheter sold to physicians' offices to reflect rising costs and to achieve parity with prices for catheters in other sites of service (that is, hospital outpatient departments and ASCs). The commenter stated that the price to physician office customers the Ellipsys™ catheter is now $8,950, and submitted an invoice to support this assertion.

Response: We appreciate the submission of additional pricing information this commenter for the SD351 supply. We note that the RUC submitted invoices for this supply item with their recommendations based on information gathered from the specialties that perform this service. While we acknowledge that pricing for the item in question may have changed, we are interested in additional review by other interested parties before finalizing an increase in the price. The submitted invoice would represent an increase from $6000 to $8950 for the SD351 supply, an extraordinary increase in the span of 6 months since the service was reviewed at the January 2022 RUC meeting. We will review the valuations for this service when they are revised by the RUC to reflect the additional costs described by this commenter, including any increases in the price of the SD351 supply, and consider for future updates to this service.

Comment: One commenter expressed concern that CMS is using only a single invoice of $6,000 for SD351 (Ellipsys™ Vascular Access Catheter) and noted this pricing is unrepresentative for this device. The commenter urged CMS to work with the manufacturers to collect additional invoices to arrive at more appropriate pricing for SD351.

Response: We often request that practitioners send us additional invoices for supplies and equipment, which we then use to establish the PE inputs and PE RVUs for specific services. We did receive an additional invoice for SD351 but as noted above, the RUC submitted invoices for this supply item with their recommendations based on information gathered from the specialties that perform this service. We will consider the additional invoice and this new information in future rulemaking.

Comment: A few commenters stated that the direct PE inputs for equipment for CPT code 36836 should reflect the use of EL011 (room, angiography) rather than EL016 (room, ultrasound, vascular). One of these commenters noted that although CPT code 36836 is done under ultrasound, the typical location for this procedure is in an angiography room given the angioplasty performed after the fistula creation more than 90 percent of the time. Another commenter stated that CMS' proposal to use an ultrasound room rather than an angiography room in the development of the PE values for CPT code 36836 is incorrect in their view, as CPT code 36836 typically infers inclusion of a balloon angioplasty among the performed procedures, and in their experience the appropriate venue when a balloon angioplasty is performed is always an angiography room.

Response: We disagree with the commenters and believe that EL016 (room, ultrasound, vascular) is the appropriate direct PE equipment input for CPT code 36836. We reviewed the equipment inputs on the Practice Expense Summary of Recommendation for the non-facility setting, and the PE spreadsheet, provided by the RUC for CPT codes 36836 and 36837. The RUC-recommended EL016 for CPT code 36836, and we agree with the RUC recommendation. Please consider presenting any direct PE equipment input changes for CPT code 36836 to the AMA RUC for review.

After consideration of the public comments, we are finalizing the work RVU values for the Percutaneous Arteriovenous Fistula Creation code family (CPT codes 36836 and 36837) as proposed. We are finalizing the direct PE inputs for CPT codes 36836 and 36837 without refinement. Also, we are deleting HCPCS codes G2170 and G2171 as proposed.

(9) Energy Based Repair of Nasal Valve Collapse (CPT Codes 30468 and 30469)

In September 2021, the CPT Editorial Panel created CPT code 30469 (*Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling*) which is currently reported with an unlisted code. For the January 2022 RUC meeting, both CPT code 30468 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)*) and CPT code 30469 were reviewed. For CY 2023, the RUC recommended no change to the current work RVU of 2.80 for CPT code 30468, and a work RVU of 2.70 for CPT code 30469.

The RUC reviewed the specialty society request to affirm the recent RUC valuations for CPT code 30468, which was surveyed and valued by the RUC in January 2020 for CY 2021. The RUC agreed, so for CY 2023, the RUC is not recommending any change to the current work RVU of 2.80 for CPT code 30468. In addition, the PE Subcommittee reviewed the direct PE inputs and made modifications to the pre-service clinical staff time to CPT code 30468 in accordance with current standards. There was a previous oversight in valuing the direct PE inputs for CPT code 30468. Therefore, 3 minutes of clinical staff time has been added to CPT code 30468 for clinical activity CA005 (complete pre-procedure phone calls and prescription).

We proposed to maintain the current work RVU of 2.80 for CPT code 30468 as recommended by the RUC. We also proposed the RUC-recommended direct PE inputs for CPT code 30468, which now includes clinical activity code CA005, without refinement.

For CPT code 30469, the RUC recommended a work RVU of 2.70 based on a direct work RVU crosswalk from CPT code 31295 (*Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa*). We disagreed with the RUC-recommended work RVU of 2.70. Therefore, we proposed a work RVU of 2.44 for CPT code 30469, which is the same RVU as CPT code 31297 (*Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium*) and has the same 20 minutes of intra-service time and similar total time. We noted that CPT code 31295, which the RUC used as a direct crosswalk for the work RVU for CPT code 30469, has the same 20 minutes of intra-service time and 56 minutes of total time as CPT code 31297. We believe the RUC should have used CPT code 31297 as the crosswalk for CPT code 30469. Both CPT codes 31295 and 31297 were reviewed in 2017 and are in the same code family. The proposed work RVU of 2.44 is supported by the reference CPT codes we compared to CPT code 30469 with the same 20 minutes of intra-service time and similar total time as CPT code 30469; reference CPT code 31233 (*Nasal/sinus endoscopy, diagnostic; with maxillary sinusoscopy (via inferior meatus or canine fossa puncture)*) with an RVU of 2.18, and CPT code 31295 with an RVU of 2.70. Again, we believe 2.44 is a more appropriate value overall than 2.70

when compared to the range of codes with the same intra-service time and similar total time.

We proposed the RUC-recommended direct PE inputs for CPT code 30469 without refinement.

The following is a summary of the comments we received and our responses.

Comment: A few comments supported our proposal to maintain the current work RVU of 2.80 for CPT code 30468.

Response: We thank the commenters for their support, and we are finalizing the RUC-recommended RVU of 2.80 for CPT code 30468 as proposed.

Comment: A few comments disagreed with our proposed work RVU of 2.44 for CPT code 30469. The commenters stated that we did not consider the intensity for CPT code 30469, and that the intensity was a closer match to the RUC-recommended crosswalk CPT code 31295, instead of our proposed comparator code of CPT code 31297. One commenter stated that CPT code 30469 has greater intensity because it involves multiple applications in anatomic locations subject to damage which would worsen the patient's condition. Also, commenters were concerned with maintaining relativity between CPT codes 30468 and 30469, and also stated that the proposed RVU of 2.44 for CPT code 30469 falls below the survey 25th percentile for CPT code 30469.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and we still believe that CPT code 31297 is a valid comparator to CPT code 30469, which has the same 20 minutes of intra-service time and similar total time as CPT code 30469. We also noted that CPT code 31295, which the RUC used as a direct crosswalk for the work RVU for CPT code 30469, has the same 20 minutes of intra-service time and 56 minutes of total time as CPT code 31297. We do not agree with the commenter that we did not consider the intensity for CPT code 30469, and would like to note that the intensity represented by the IWPUT of 0.0853 for CPT code 32197 is similar to the IWPUT of 0.0874 for the 2nd reference code used in the RUC survey, which is CPT code 31238 (*Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage*). For relativity purposes, we note that there were different codes with similar time values the RUC could have used besides CPT code 31295. We continue to believe that the proposed work RVU of 2.44 is supported by the reference CPT codes we compared to CPT code 30469 with the same 20 minutes of intra-service time and similar total time as CPT code 30469; reference CPT code 31233 with an RVU of 2.18, and CPT code 31295 with an RVU of 2.70. Also, we point out that the RUC-recommended RVU of 2.70 was below the 25th percentile on two of the three survey entries provided on the RUC Summary Report for CPT code 30469, and that the lowest 25th percentile value for these three entries was 2.25, which is below our proposed value of 2.44. Therefore, we are finalizing the work RVU of 2.44 as proposed for CPT code 30469.

After consideration of the public comments, we are finalizing the work RVUs for the Energy Based Repair of Nasal Valve Collapse code family (CPT codes 30468 and 30469) as proposed. We are also finalizing the direct PE inputs for codes 30468 and 30469 as proposed, without refinement.

(10) Drug Induced Sleep Endoscopy (DISE) (CPT Code 42975)

In October 2020, the CPT Editorial Panel created CPT code 42975 (*Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic*) to report drug induced sleep endoscopy (DISE) flexible, diagnostic. At the January 2021 RUC Meeting, the RUC requested that this service be resurveyed for the April 2021 RUC Meeting using a standard 000-day survey template. For CY 2023, the RUC recommended a work RVU of 1.95 for CPT code 42975.

We disagreed with the RUC-recommended work RVU of 1.95 for CPT code 42975 and proposed a work RVU of 1.58. We believe the RVU should be lower than the RUC recommendation of 1.95 to reflect the decrease in total time from 68 minutes to 50 minutes. The proposed RVU of 1.58 is based on the total time ratio calculation using the RUC-recommended 50 minutes total time for CPT code 42975 divided by the 48 minutes of total time for CPT code 43197 (*Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*), then multiplying by the RVU of 1.52 for CPT code 43197 ((50/48) × 1.52 = 1.58). We found that CPT code 43197 has the same intra-service time and similar total time as CPT code 42975. Also, CPT code 43197 is a similar endoscopic procedure as CPT codes 42975 and 31579 (*Laryngoscopy, flexible or rigid telescopic, with stroboscopy*). We noted that CPT code 31579 is the first key reference code in the RUC survey. The proposed work RVU of 1.58 is supported by the reference CPT codes we compared to CPT code 42975 with the same 15 minutes of intra-service time and similar total time as CPT code 42975; reference CPT code 43200 (*Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*) with an RVU of 1.42, and CPT code 62272 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)*) with an RVU of 1.58. Again, we believe the proposed RVU of 1.58 is a more appropriate value overall than 1.95 when compared to the range of codes with the same intra-service time and similar total time.

We proposed the RUC-recommended direct PE inputs for CPT code 42975 without refinement.

The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with our proposed RVU of 1.58 for CPT code 42975, and want us to accept the RUC-recommended RVU of 1.95 instead. The commenters stated that they did not understand our rationale that the RVU should be reduced due to the decrease in total time between the two surveys for the January 2021 and April 2021 RUC meetings, especially since an interim RVU of 1.90 was previously accepted by CMS for the 2022 PFS. The commenters stated it is important to note that the interim value accepted by CMS for the 2022 PFS was based on inaccurate survey data, as the immediate post-service time was not captured appropriately in the initial survey of CPT code 42975. Upon resurvey, respondents gave identical intra time and post procedure time. The only difference was the removal of 18 minutes of post time (for the half day discharge management visit) that was included in total time approved on an interim basis in January 2021, which represents the reduction of total time from the January 2021 (68 minutes) to the April 2021 (50 minutes) total time for CPT code 42975. Based on this, the commenters did not understand CMS' rationale that the work RVU should be reduced due to the decrease in total time between the two surveys, and argued that the first survey was invalidated due to the use of the incorrect tool. Respondents therefore were asked about post procedure visits/time, and indicated that a discharge management visit occurs. The standard time for a half day discharge management was then recommended by

one of the specialty societies. The only change in data for the April survey was that respondents were not asked about a discharge management visit, and therefore, they did not indicate that one occurred. Their pre, intra, and immediate post times were almost identical. Therefore, the commenters believe that the RUC-recommended RVU of 1.95 is justified and is appropriate as compared to the key reference services selected and the broader fee schedule of codes with similar times and intensity.

Response: We appreciate the RUC resurveying CPT code 42975. This allowed us to review CPT code 42975 again and revalue it for 2023. We note that when CPT code 42975 was initially valued in January 2021, an incorrect survey instrument was used, thus requiring CPT code 42975 to be resurveyed in April 2021. In January 2021, the RUC questioned the 18 minutes for the ½ discharge day management used by the specialty society to value CPT code 42975, and determined that it was not necessary for this code. When CPT code 42975 was resurveyed for the April 2021 RUC meeting, the total time showed the decrease of 18 minutes due to the removal of the ½ discharge day management. Thus, the total time for CPT code 42975 dropped from 68 minutes to 50 minutes. Therefore, we continue to believe the RVU should be lower than the RUC recommendation of 1.95 to reflect the decrease in total time from 68 minutes to 50 minutes. The proposed RVU of 1.58 is based on the total time ratio calculation using the RUC-recommended 50 minutes total time for CPT code 42975 divided by the 48 minutes of total time for CPT code 43197, then multiplying by the RVU of 1.52 for CPT code 43197 ((50/48) × 1.52 = 1.58). We found that CPT code 43197 has the same intra-service time and similar total time as CPT code 42975. Also, CPT code 43197 is a similar endoscopic procedure as CPT codes 42975 and 31579. We noted that CPT code 31579 is the first key reference code in the RUC survey. The proposed work RVU of 1.58 is supported by the reference CPT codes we compared to CPT code 42975 with the same 15 minutes of intra-service time and similar total time as CPT code 42975; reference CPT code 43200 with an RVU of 1.42, and CPT code 62272 with an RVU of 1.58. Again, we continue to believe the proposed RVU of 1.58 is a more appropriate value overall than 1.95 when compared to the range of codes with the same intra-service time and similar total time. Therefore, we are finalizing the work RVU of 1.58 for code 42975 as proposed.

Comment: One commenter disagreed with our use of a total time ratio to develop the proposed RVU of 1.58 for CPT code 42975, and stated that it neglects to capture the level of intensity. The commenter stated that the methodologies CMS used for the valuation of specific codes for 2023 is flawed, including the total time ratio calculation that informs the proposed work RVU of 1.58 for CPT code 42975.

Response: We disagree with the commenter and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in the resource of time are not accounted for in a RUC-recommended RVU, the obligation to account for that change when establishing the proposed and final work RVUs remains. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: One commenter stated that the proposed RVU of 1.58 for CPT code 42975 falls below the RUC survey 25th percentile of 1.95, and that we need to provide a significant justification when we propose an RVU that is below the 25th percentile.

Response: We disagree with the commenter and would like to remind the commenter that we used a total time ratio, described above, to develop the proposed RVU of 1.58 for CPT code 42975. A total time ratio is one of several valid methodologies we use for developing the RVUs that we propose, and there is no rule stating that the work RVU cannot go below the survey 25th percentile. We believe that changes in work time should be reflected in changes to the work RVU, and note that the total time decreased for CPT code 42975 when it was resurveyed in April 2021.

After consideration of the public comments, we are finalizing the work RVU for the Drug Induced Sleep Endoscopy (DISE) code family (CPT code 42975) as proposed. We are finalizing the direct PE inputs for code 42975 as proposed, without refinement.

(11) Endoscopic Bariatric Device Procedures (CPT Codes 43235, 43290, and 43291)

In February 2021, the CPT Editorial Panel created CPT codes 43290 (*Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon*) and 43291 (*Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)*) for endoscopic bariatric device procedures to the esophagogastroduodenoscopy (EGD) code family. CPT code 43235 (*Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*) is the base code for the EGD family and was surveyed with the new endoscopic bariatric device procedures, 43290 and 43291. All three of these CPT codes were reviewed at the April 2021 RUC meeting. For CY 2023, the RUC recommended an RVU of 3.11 for CPT code 43290, an RVU of 2.80 for CPT code 43291, and maintaining the current work RVU of 2.09 for CPT code 43235.

We proposed the RUC-recommended work RVU of 3.11 for CPT code 43290, the RUC-recommended work RVU of 2.80 for CPT code 43291, and maintaining the current work RVU of 2.09 for CPT code 43235 for this code family.

We proposed the direct PE inputs for CPT code 43235 without refinement. However, we proposed refinements to the direct PE inputs for CPT codes 43290 and 43291.

For CPT code 43290, we proposed refinements to the direct PE inputs for

clinical labor activity codes CA001 (*complete pre-service diagnostic and referral forms) and CA011 (provide education/obtain consent*). We proposed to refine CA001 from 5 minutes to the standard 3 minutes since no explanation was provided to support 5 minutes for this clinical labor activity. We proposed to refine CA011 from 15 minutes to 10 minutes since it was not clear why this much time for education is needed, and we do not believe that the recommended 15 minutes would be typical for the procedure. Also, when we looked at other procedures with clinical labor activity code CA011 we did not find many procedures with more than 12 minutes for this activity. Therefore, we proposed to refine the clinical labor activity times for CA001 and CA011 for CPT code 43290 as described above, and to accept the remaining RUC-recommended direct PE inputs without refinement.

For CPT code 43291, we proposed a refinement to the direct PE input for clinical labor activity code CA016 (*prepare, set-up and start IV, initial positioning and monitoring of patient*) from 10 minutes to the standard 2 minutes. In the PE Summary of Recommendations for non-facility direct PE inputs provided by the RUC, the RUC recommended 8 minutes above the standard 2 minutes for CA016 and stated this clinical labor activity was identical to the 10 minutes for positioning the patient as CPT code 43260 (*Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*). However, our study of this code family could not find 10 minutes of non-facility direct PE inputs for clinical labor activity CA016. Also, CPT code 43260 is only performed in a facility and does not have any non-facility clinical labor times. Therefore, we proposed to refine the clinical labor activity time for CA016 for CPT code 43291 as described above, and to accept the remaining RUC-recommended direct PE inputs without refinement. This proposed reduction of 8 minutes to the CA016 clinical labor activity also carried over to the equipment times for the suction machine (Gomco) (EQ235), the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031), and the multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD) (ES087) which we proposed to reduce by the same 8 minutes.

The following is a summary of the comments we received and our responses.

We did not receive comments on the proposed work RVUs for CPT codes 43235, 43290, and 43291. Therefore, we are finalizing the work RVU of 2.09 for CPT code 43235, the RVU of 3.11 for code 43290, and the RVU of 2.80 for code 43291 as proposed. We did receive comments on the direct PE inputs for CPT codes 43290 and 43291, and those comments and responses are below.

Comment: We received a few comments regarding the PE inputs for CPT code 43290 in the non-facility setting. The commenters requested that we accept the RUC-recommended clinical labor times for CA001 and CA011 in the non-facility setting. The commenters stated that the RUC agreed that the ''Extensive Use of Clinical Staff'' package should be used for CA001 to allow 5 minutes for CPT code 43290. Also, the commenters stated that additional minutes above the standard for CA011 were needed for CPT code 43290 due to the extent of the patient instruction required, and stated 15 minutes should be allowed.

Response: We continue to disagree with the RUC-recommended direct PE inputs for clinical labor activity codes CA001 and CA011 for CPT code 43290. We reviewed the Practice Expense Summary of Recommendation for the facility and non-facility settings. We continue to believe that 3 minutes for CA001, and 10 minutes for CA011, in the non-facility setting is appropriate. Although the RUC recommended 5 minutes for CA001 in the non-facility setting, we note that that the RUC recommended only 3 minutes for CA001 in the facility setting, and not the 5 minutes that would be the standard for the ''Extensive Use of Clinical Staff'' in the facility and non-facility settings. After reviewing the comments, we are still not convinced that the information provided would support the need for 5 minutes for CA001 in the non-facility setting. Also, for clinical labor activity CA011, we continue to believe that 10 minutes is appropriate and that the recommended 15 minutes would not be typical for the procedure. When we looked at other procedures with clinical labor activity code CA011, we did not find many procedures with more than 12 minutes for this activity. After reviewing the comments, we remain unconvinced that the information provided would support the need for 15 minutes for CA011 in the non-facility setting. Therefore, we are finalizing the clinical labor activity times for CA001 and CA011 for CPT code 43290 as proposed.

Comment: The commenters stated that 10 minutes was needed for CA016 for CPT code 43291, instead of the standard 2 minutes, for positioning the patient because no other procedure in this code family is performed in this position, which is why extra time is required. The commenters stated that clinical labor time needed to position the patient is identical to that of CPT code 43260 and described the process as follows: patient is placed face up with their head resting on a pad positioner or pillow and their neck in a neutral position, patient's arms are positioned to maintain a neutral thumb-up or supinated position and may be tucked at their sides or abducted to less than 90 degrees on arm boards, then the patient is intubated while supine and staff must then move the patient into left lateral position.

Response: After reviewing the comments, we are still not convinced that the information provided would support the need for 10 minutes for CA016 for CPT code 43291. We continue to believe that the standard 2 minutes for CA016 is appropriate. We remind the commenters that in our study of CPT code 43260, we could not find 10 minutes of non-facility direct PE inputs for clinical labor activity CA016 as suggested. Also, we remind the commenters that CPT code 43260 is only performed in the facility setting and does not have any non-facility clinical labor times. Therefore, we are finalizing the clinical labor activity time for CA016 for CPT code 43291 as proposed.

After consideration of the public comments, we are finalizing the work RVU values for the Endoscopic Bariatric Device Procedures code family (CPT codes 43235, 43290, and 43291) as proposed. We are finalizing the direct PE inputs for CPT code 43235 as proposed, without refinement. We are finalizing the direct PE inputs for CPT codes 43290 and 43291 as proposed.

(12) Delayed Creation Exit Site From Embedded Catheter (CPT Code 49436)

CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) was finalized as potentially misvalued in the CY 2022 PFS final rule (86 FR 64996) and the code was found to be appropriate to value for the non-facility/office setting. The RUC only reviewed the PE inputs for this service at the January 2022 meeting. The RUC recommended 5 minutes for Clinical Activity Code CA013, line 34 in the non-facility/office setting on the RUC-recommended PE spreadsheet. We disagreed with the RUC-recommended

time, and proposed the standard time of 2 minutes, as an adequate rationale was not provided for the additional time in the global space. The proposed reduction of 3 minutes to the CA013 clinical labor activity also carries over to the equipment times, which we proposed to reduce by the same 3 minutes. Otherwise, we agreed with the RUC-recommended clinical labor times for activity codes CA011 and CA018, and we proposed the remaining refinements as recommended.

The RUC did not recommend any work inputs for this code and we did not propose any work RVU refinements.

We received three comments regarding our proposed direct PE input refinements for CPT code 49436 in response to the CY 2023 PFS proposed rule and those comments are summarized below.

Comment: Two commenters stated that the rationale for the additional 3 minutes under the CA013 clinical labor activity was included in the PE Summary of Recommendations (SOR), which lists the supply items needed to set up the procedure room. The commenters stated that the 36 supply items are mostly sterile and will take at least 3 more minutes to set up than the standard 2 minutes allocated for an E/M service. Another commenter requested that we reevaluate and finalize the RUC-recommended 5 minutes.

Response: We continue to disagree with the RUC-recommended 5 minutes for Clinical Activity Code CA013. The PE SOR did not provide a sufficient rationale for the additional time, and commenters did not provide new data to justify the additional time. This procedure is performed during an office visit, and we believe that the standard 2 minutes adequately accounts for the preparation of supplies, when compared to similar codes in the global space and non-facility/office setting.

After consideration of the public comments, we are finalizing 2 minutes for CA013 as proposed. The proposed reduction of 3 minutes to the CA013 clinical labor activity also carries over to the formula used to calculate equipment times, which we are finalizing to reduce by the same 3 minutes. We agreed with the RUC-recommended clinical labor times for activity codes CA011 and CA018, and we are finalizing the remaining refinements as proposed and recommended.

(13) Percutaneous Nephrolithotomy (CPT Codes 50080 and 50081)

In September 2021, the CPT Editorial Panel revised the descriptors to CPT codes 50080 (*Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (e.g., stone[s] up to 2 cm in a single location of kidney or renal pelvis, nonbranching stones)*) and 50081 (*Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (e.g., stone[s] > 2 cm, branching stones, stones in multiple locations, ureter stones, complicated anatomy)*), that in recent claims data were identified via the site of service anomaly screen, to be performed less than 50 percent of the time in the inpatient setting, but both codes have 090 day global periods, which include post-op inpatient hospital E/M services as a component of their value, typical of major surgery codes. The revised code descriptors also include image guidance and nephrostomy tube placement, which were not present in the old descriptors, and were reported as procedures that were separate from CPT codes 50081 and 50082. These codes have not been reviewed for nearly 30 years.

CPT code 50080 currently has a work RVU of 15.74 with 117 minutes of intra-service time and 359.5 minutes of total time. The RUC recommended a work RVU of 13.50, 90 minutes of intra-service time, and 244 minutes of total time for CPT code 50080, which represents a reduction from the current values. However, the recommended intra-service times dropped by 76.9 percent from the current intra-service time and the RUC recommended work RVU is reduced only by 85.9 percent. Therefore, we disagree with the RUC recommended work RVU and we proposed a work RVU of 12.11 for CPT code 50080 with the RUC recommended 90 minutes of intra-service time and 244 minutes of total time. We noted that our proposed work RVU for CPT code 50080 falls between CPT code 36830 (*Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (e.g., biological collagen, thermoplastic graft)*), with a work RVU of 12.03 and the same intra-service time of 90 minutes, and CPT code 36818 (*Arteriovenous anastomosis, open; by upper arm cephalic vein transposition*), with a work RVU of 12.39 and the same intra-service time of 90 minutes (and both with similar total times to CPT code 50080).

CPT code 50081 currently has a work RVU of 23.50 with 42 minutes of pre-service evaluation time, 0 minutes of pre-service positioning time, 25 minutes of pre-service scrub/dress/wait time, 195 minutes of intra-service time, 27 minutes of immediate post-service time, and 507.5 minutes of total time. The RUC recommended 22.00 work RVUs with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 140 minutes of intra-service time, 44 minutes of immediate post-service time, for a sum of 302 minutes of total time. The RUC-recommended intra-service time and total time for CPT code 50081 are less than the current times for this code and we expect the work RVUs to also be less than the current work RVUs. Though the RUC recommended a work RVU of 22.00 that is less than the current 23.50 work RVU, a substantial reduction in time should be better reflected in the work RVU.

The RUC recommended 13.50 work RVUs for CPT code 50800 and 22.00 for CPT code 50081, with an incremental difference between the two codes of 8.50 work RVUs (22.00 − 13.50 = 8.50). We proposed a work RVU of 20.61 for CPT code 50081, based on the proposed CPT code 50080's work RVU of 12.11 plus the RUC-recommended incremental difference 8.50 work RVUs between CPT code 50080 and CPT code 50081(12.11 + 8.50 = 20.61).

We proposed the direct PE inputs as recommended by the RUC for both codes in the family.

Comment: We received several comments concerning CPT codes 50080 and 50081, all opposing our proposed work RVUs for these services. Commenters pointed out that CPT codes 50080 and 50081 are not the same services that they were when they were last reviewed. They noted that both codes have retained their current work RVUs since CY 2010 and that they now encompass several other procedures that previously could have been separately billable, which has increased their intensity and complexity. These additions include imaging supervision and interpretation, antegrade stent placement, nephrostomy tube placement and antegrade ureteroscopy as have been included in their new descriptors.

Response: We acknowledge that it has been many years since these two CPT codes were last reviewed and percutaneous nephrolithotomy's technologies and methodologies have changed, which may have added complexities to the service, but at the same time, there have been improvements in methods and

efficiencies through research and evaluations of better and best practices. We see evidence of this just in the change in the physician intra-services times for CPT code 50080 with what was 117 minutes, but is now 90 minutes, even with the addition of those services now added to the new descriptor (compared to the previous descriptor for CPT code 50080; *Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; up to 2 cm.).* Similarly, with the change in the physician intra-services times for CPT code 50081 with what was 195 minutes, but is now 140 minutes, even with the addition of those services now added to the new descriptor (compared to the previous descriptor for CPT code 50081; *Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; over 2 cm*). The skills and trainings of the physicians have certainly become more efficient in performing the main task and the additional tasks now bundled into CPT codes 50080 and 50081 using less intra-service time and total time for these procedures.

Comment: Commenters suggested that CMS should consider CPT codes 50080 and 50081 as entirely new codes with their new descriptors describing their bundling and that the old codes are not really comparable to all of the tasks performed in the new code and thus CMS should place more weight in the most recent results from these codes' surveyed work RVUs and their surveyed times, specifically the 25th percentile results.

Response: We do agree that the new descriptors for CPT codes 50080 and 50081 are more detailed and more specific about what is now bundled in with the entirety of the service but the fundamental core of these services are still the same and they are not completely new and different enough to make them incomparable. We still believe that the reductions in physician work times should generally result in reductions in of the work RVUs, as we have proposed. If those additional tasks of imaging supervision and interpretation, antegrade stent placement, nephrostomy tube placement and antegrade ureteroscopy were separately paid from CPT codes 50080 and 50081, those separate claim codes and their typical units of service were not included in the AMA RUC recommendations for consideration to value the bundled service. Having those CPT codes, their work RVUs, and their intra-service minutes would have been useful when we were valuing these services. Commenters reiterated that these services, these additional tasks, are now part of the bundled codes, which lead us to re-review the AMA RUC recommendations. From our re-review of the AMA RUC recommendations, we do note that in the text material accompanying the RUC recommendation for CPT code 76000 (*Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time*) codes or language was struck from the text material. It is unclear if the reference to CPT code 76000 was intentionally deleted, but we note that CPT code 76000 has a work RVU value of 0.30 and an intra-service time of 10.0 minutes and a total time of 20.0 minutes.

Comment: Commenters objected to CMS' selection of comparator codes. Commenters stated that the comparator codes chosen by CMS (for CPT code 50080 which falls between CPT codes 36830 and 36818) do not have similar clinical anatomical basis to CPT codes 50080 and 50081, and that our comparator codes have not taken into account similar levels of work intensities.

Response: We believe our selected comparator codes are relevant in the PFS relative value system and that all services are appropriately subject for comparison to each other. By statute, we are required to consider times and intensities as they are related to work when reviewing and valuating all CPT and HCPCS services.

After review and consideration of all comments on our proposals for CPT codes 50080 and 50081, we believe that the value of CPT code 76000 is not entirely accounted for in our original proposed valuations and we are adding Fluoroscopy's 0.30 work RVUs to both CPT codes 50080 and 50081, since this work was omitted from our proposed valuations. We are finalizing 12.41 work RVUs (12.11 + 0.30) for CPT code 50080 and 20.91 work RVUs (12.11 + 8.50 + 0.30) for CPT code 50081 for CY 2023. We are also finalizing the direct PE inputs as proposed and as recommended by the RUC for both of these codes.

(14) Laparoscopic Simple Prostatectomy (CPT Codes 55821, 55831, 55866, and 55867)

In October 2021, the CPT Editorial Panel added CPT placeholder code 55867 (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) and prompted this family of Laparoscopic Simple Prostatectomy codes for survey and review for the January 2022 RUC meeting.

The RUC recommended a work RVU of 15.18 for CPT code 55821 (*Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages*) with 33 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 120 minutes of intra-service time, and 25 minutes of immediate post-service time, for a sum of 329 minutes of total time. CPT code 55821 currently has a work RVU value of 15.76 with 102.0 minutes of intra-service time and 399.5 minutes of total time. After reviewing this code and relative similar codes in the PFS, we proposed the RUC-recommended work RVU of 15.18 with 315 minutes of total time.

The RUC recommended a work RVU of 15.60 for CPT code 55831 (*Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal*), with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 120 minutes of intra-service time, 25 minutes of immediate post-service time, for a sum of 329 minutes of total time. CPT code 55831 currently has a work RVU value of 17.19 with 114.0 minutes of intra-service time and 422.5 minutes of total time. The RUC notes an additional degree of difficulty with this retropubic incision approach (behind the pubis) compared to the suprapubic approach. After reviewing this code and relative similar codes in the PFS, we proposed the RUC recommended work RVU of 15.60 with 322 minutes of total time.

The RUC recommended a work RVU of 22.46 for CPT code 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*) with 40 minutes of pre-service evaluation time, 15 minutes positioning time, 12 minutes scrub/dress/wait time, 180 minutes of intra-service time, 50 minutes of immediate post-service time, for a sum of 362 minutes of total time. CPT code 55866 currently has a work RVU value of 26.80 with 180 minutes of intra-service time and 422 minutes of total time. The RUC notes that this procedure removes the entire prostate with robotic assistance, and the complexity of nerve sparing when operating with a cancerous

prostate, increases the medical complexity and intensity of this procedure. After reviewing this code and relative similar codes in the PFS, we proposed the RUC recommended work RVU of 22.46 with 362 minutes of total time to CPT code 55866.

The RUC recommended a work RVU of 19.53 for CPT code 55867 (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) with 40 minutes of pre-service evaluation time, 8 minutes positioning time, 11 minutes scrub/dress/wait time, 180 minutes of intra-service time, 50 minutes of immediate post-service time, for a sum of 354 minutes of total time. The RUC offers CPT code 42420 (*Excision of parotid tumor or parotid gland; total, with dissection and preservation of facial nerve)* with a work RVU of 19.53, 180 minutes of intra-service time and 383 minutes of total time)) as a crosswalk to CPT code 55867. After reviewing this code and relative similar codes in the PFS, we proposed the RUC-recommended work RVU of 19.53 with 354 minutes of total time to CPT code 55867.

We proposed the RUC-recommended direct PE inputs for CPT codes 55821, 55831, 55866, and 55867 without refinement.

CMS received two comments for CPT codes 55821, 55831, 55866, and 55867.

Comment: Both comments for these Laparoscopic Simple Prostatectomy codes indicated support for CMS to accept the RUC-recommended work RVUs and the direct PE inputs adjustments.

Response: We thank commenters for taking time to submit comments expressing support for our proposals to accept the RUC-recommendations for CPT codes 55821, 55831, 55866, and 55867.

We are finalizing the RUC-recommended work RVUs and direct PE inputs for these Laparoscopic Simple Prostatectomy codes.

(15) Lumbar Laminotomy With Decompression (CPT Codes 63020, 63030, and 63035)

In October 2018, CPT code 63030 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*) was identified by the AMA as having an anomalous site of service when compared to Medicare utilization data. The Medicare data from 2014 through 2017 indicated that CPT code 63030 was performed less than 50 percent of the time in the inpatient setting, yet included inpatient hospital evaluation and management (E/M) services within its global period. In January 2019, the RUC recommended that this code be reviewed in 2 years (January 2021) to determine if previous changes to differentiate percutaneous, endoscopic, and open spine procedures were effective to correct reporting of this service. In December 2020, the Relativity Assessment Workgroup noted that CPT code 63030 continues to be primarily reported in the outpatient setting, but still includes inpatient hospital visits in its valuation. The specialty society indicated that there is still confusion about this code, and therefore, the RUC recommended that CPT code 63030 be referred to the CPT Editorial Panel to revise the descriptor to mitigate the incorrect reporting in the outpatient setting, but the CPT Editorial Panel did not accept the code change application to differentiate inpatient (63030) versus outpatient (630X0) at the September 2021 CPT meeting. Since this is a site of service issue, CPT code 63030 was surveyed with the code family for the January 2022 RUC meeting.

For CPT codes 63020 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical*), 63030, and 63035 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)*), we disagree with the RUC's recommended work RVUs of 15.95, 13.18, and 4.00, respectively, because they do not account for the surveyed changes in time for CPT codes 63020, 63030, and 63035, and the full application of the 23-hour policy to CPT code 63030. We proposed a work RVU of 14.91 for CPT code 63020, a work RVU of 12.00 for CPT code 63030, and a work RVU of 3.86 for CPT code 63035.

The RUC recommended 40 minutes pre-service evaluation, 20 minutes pre-service positioning, 15 minutes pre-service scrub/dress/wait time, 90 minutes intraservice time, 30 minutes immediate post-service time, and one CPT code 99232 (*subsequent hospital care/day 25 minutes*), one CPT code 99231 (*Subsequent hospital care/day 15 minutes*), one CPT code 99238 (*Hospital discharge day management; 30 minutes or less*), one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter.*) visits in the post-operative period. This results in a 15-minute decrease in the pre-service period, a 30-minute decrease in intraservice time, a 5-minute decrease in immediate post-service time, and a 17-minute increase in the post-operative period. The proposed work RVU of 14.91 is based on the total time ratio calculation using the RUC-recommended 379 minutes of total time divided by the current total time of 412 minutes for CPT code 63020, then multiplying by the current work RVU of 16.20 for CPT code 63020 ((379 minutes/412 minutes) * 16.20 = 14.90). We noted that this is a direct crosswalk to CPT code 27057 (*Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (e.g., gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral*), which has a work RVU of 14.91, identical intraservice and immediate post-service time of 90 minutes and 30 minutes, respectively, and only 10 more minutes of total time. We believe this work RVU more adequately accounts for the decrease in total and intraservice time than the RUC recommended work RVU, and we noted that we considered the reverse building block methodology, which would result in a work RVU of 14.30, but we believed that it decreased the valuation of CPT code 63020 too much, considering the shift in post-operative work to include a longer, more intense office/outpatient visit (CPT code 99214).

We disagree with the RUC-recommended work RVU for CPT code 63030. More specifically, we disagree with the RUC recommended work RVU for CPT code 63030 because the RUC did not completely apply the 23-hour policy calculation (finalized in the CY 2011 PFS final rule (75 FR 73226)) in formulating its recommendations.

Additionally, we disagree with the RUC recommended work RVU for this code for which the RUC considered the patient to be admitted during the post-operative period because the RUC did not fully apply the 23-hour policy when formulating their recommendations. As we noted in the CY 2011 PFS final rule (75 FR 73226), and as we discuss earlier in this section of this final rule (''(1) Anterior Abdominal Hernia Repair (CPT codes 15778, 49591, 49592, 49593, 49594, 49595, 49596, 49613, 49614, 49615, 49616, 49617, 49618, 49621, 49622, and 49623''), the work RVUs for services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment. Because such services are typically furnished in the outpatient setting, they should not be valued to include inpatient post-operative E/M visits. The level of discharge day management services included in the valuation of such services should similarly not reflect an inpatient discharge and should therefore be reduced. And finally, as discussed in CY 2011 rulemaking, the intraservice time from the inpatient level E/M postoperative visit should be reallocated to the immediate postservice time of the service. The 23-hour policy calculation, when fully applied to the calculation of a work RVU, is used to reduce the value of discharge day management services, remove the inpatient E/M visits, and reallocate the intraservice time to the immediate post-service period. We refer readers to the 2011 PFS final rule (75 FR 73226) for an in-depth explanation of the 23-hour policy.

For CPT code 63030, we believe the RUC only partially applied the 23-hour policy when it applied the policy to the immediate post service time, but not to the calculation of the work RVU. Instead, we believe the 23-hour policy should be fully applied to this code that describes outpatient services for which there is an overnight stay during the post-operative period, regardless of the number of nights that a patient stays in the hospital. The services to which the 23-hour policy is usually applied would typically involve a patient stay in a hospital for less than 24 hours, which often means the patient may stay overnight in the hospital. On occasion, the patient may stay in the hospital longer than a single night; however, in both cases (one night or more than one night), the patient is considered to be a hospital outpatient, not an inpatient, for Medicare purposes. In short, we do not believe that the work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies, especially considering the previously discussed site of service anomaly for CPT code 63030.

In accordance with the 23-hour policy valuation methodology we established in the CY 2011 PFS final rule, we are instead proposing a work RVU of 12.00 for CPT code 63030.The steps are as follows:

- Step (1): 13.18 − 0.64 * = 12.54.
- Step (2): 12.54 − 0.76 ** = 11.78.
- Step (3): 11.78 + (10 minutes × 0.0224) *** = 12.00 RVUs.

* Value associated with ½ hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99231.

*** Value associated with the reallocated intraservice time multiplied by the post-service intensity of the 23-hour stay code.

The RUC recommended the maintenance of the current work RVU of 13.18 because there was no change in intraservice time and the 37-minute decrease in total time is largely due to the change in immediate post-service time and post-operative period from the application of the 23-hour policy. We noted that the proposed work RVU of 12.00 is higher than the other valuations that we considered, including the total time ratio work RVU of 11.75 ((305 minutes/342 minutes) * 13.18 = 11.75) and the reverse building block work RVU of 11.45. We noted that the proposed work RVU of 12.00 is well-bracketed by two 90-minute intraservice timed 090-day CPT codes 28725 (*Arthrodesis; subtalar*), with a work RVU of 11.22, and 58720 (*Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)*), with a work RVU of 12.16.

We noted that, in the summary of recommendations (SOR) submitted to CMS by the RUC, the specialty societies assert that the surveyed total time would be the same as the current total time if the 23-hour policy was not fully applied to the immediate post-service time and post-operative period, with only a shift of work from facility to office, but we noted that this is not true. The surveyed total time is 339 minutes, but the RUC recommended 40 minutes for the pre-service evaluation time rather than the specialty societies' surveyed 45 minutes. If the RUC had recommended the survey times, with the pre-service evaluation refinement, the reverse building block work RVU would be 12.62, still less than the RUC-recommended work RVU of 13.18, effectively accounting for the shift from facility to office post-operative visits.

For CPT code 63035, we proposed a work RVU of 3.86 based on the reverse building block methodology to account for the 11-minute increase in intraservice time. We noted that this proposed value is between the surveyed 25th percentile value of 3.50 and the RUC-recommended work RVU of 4.00. We noted that the proposed work RVU is well-bracketed by two 60-minute add-on CPT codes—CPT code 50706 and 63231. CPT code 50706 (*Balloon dilation, ureteral stricture, including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)*), has a work RVU of 3.80, and CPT code 63621 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)*), has a work RVU of 4.00.

For the direct PE inputs, we proposed to remove the 125 minutes of equipment time for EQ168 (light, exam) for CPT codes 63020 and 63030 because the RUC contested the typicality of its use to assess the wound and remove staples. Because it is a standard piece of equipment in a neurosurgeon and orthopedic exam room, and the RUC questioned its typicality, we proposed 0 minutes for EQ168 for CPT codes 63020 and 63030.

We received several comments regarding our proposed work RVUs and two comments regarding our proposed refinement to direct PE input EQ168 (light, exam) for CPT codes 63020, 63030, and 63035 in response to the CY 2023 PFS proposed rule and those comments are summarized below.

Comment: Commenters urged CMS to use valid survey data to establish work RVUs when possible, instead of a calculated value supported by another code with no clinical relevancy. The commenters disagreed with our proposed work RVU of 14.91 for CPT code 63020, stating that the RUC recommended the survey 25th percentile work RVU using magnitude estimation from a valid survey of physicians who perform this service and that it appropriately accounts for the decrease in intraservice time, and therefore, it did not need to be decreased further. Commenters also disagreed with the work RVU crosswalk from CPT code 27057 to CPT code 63020, stating that CPT code 27057 is a rarely performed procedure for a significantly different patient population, thus making it an

inappropriate comparison that discounts the time, work, and intensity required to perform CPT code 63020. Commenters stated that CPT code 63020 requires removal of bone, along with dissection around nerve roots and the spinal cord, whereas CPT code 27057 only requires the soft tissue work of a fasciotomy. Commenters also stated that the physician work described by CPT code 27057 does not entail the same intensity of work required by CPT code 63020, does not include significant risk of paralysis, and does not require routine use of fluoroscopy and image guidance to perform the procedure. Commenters stated that positioning for CPT code 63020 requires use of the Mayfield headrest and is more complex than a routine prone positioning for CPT code 27057. Commenters stated that CPT code 27057 includes gluteal muscle debridement, which is tedious and time consuming, but not as complex as work involving the resection of bone and retraction of spinal nerves.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk. As noted above, we proposed a crosswalk to CPT code 27057 with the support of the total time ratio. We believe that time ratios are a valid and appropriate tool for determining work RVUs. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in the resource of time are not accounted for in a RUC-recommended RVU, the obligation to account for that change when establishing proposed and final work RVUs remains. For more details on our methodology for developing work RVUs, we direct readers to the discussion on time ratios as discussed above in this Valuation of Specific Codes section.

Regarding the commenters' assertion that the RUC-recommended work RVU, which is only a decrease of 0.25 work RVUs from the current valuation of CPT code 63020, accounts for the 15-minute decrease in the pre-service period, a 30-minute decrease in intraservice time, a 5-minute decrease in immediate post-service time, and a 17-minute increase in the post-operative period, and did not need to be further decreased, we reiterate that, although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would be inappropriate to use the RUC-recommended work RVU to value CPT code 63020 given the significant decrease in intraservice time and the absence of an adequate justification of increased intensity. The RUC-recommended work RVU yields an IWPUT of 0.077, whereas the current IWPUT is 0.059. The RUC-recommended work RVU would yield an IWPUT increase of 0.018 with no obvious or explicitly stated rational for an increased intensity. If the RUC's recommendations appear to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally use one of the methodologies discussed above to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure such as a total time ratio.

We continue to believe our proposed work RVU of 14.91 for CPT code 63020 based on the total time ratio calculation and a direct crosswalk to CPT code 27057, which has a work RVU of 14.91, identical intraservice and immediate post-service time of 90 minutes and 30 minutes, respectively, and only 10 more minutes of total time, more adequately accounts for the decrease in total and intraservice time than the RUC recommended work RVU.

We note that while CPT code 63020 requires removal of bone, along with dissection around nerve roots and the spinal cord whereas CPT code 27057 requires the soft tissue work of a fasciotomy, does not include significant risk of paralysis, and does not require routine use of fluoroscopy and image guidance to perform the procedure, CPT code 27057's vignette and service description describes a 75-year old female who is febrile with leukocytosis who is taken to the operating room emergently for fasciotomy(ies) and debridement of necrotic muscle. We note that the typical patient is at risk of acute renal failure and life-threatening rhabdomyolysis. We note that, while we understand that the positioning for CPT code 63020 requires use of the Mayfield headrest and is more complex than a routine prone positioning for CPT code 27057, that difference is accounted for in the difference in pre-service positioning time of 8 minutes, which has longstanding, well-established standardized WPUT of 0.0224 which factors into the reverse building block work RVU of 14.30. Therefore, we continue to believe a direct crosswalk to CPT code 27057 is appropriate to value CPT code 63020 and are finalizing a work RVU of 14.91 for CPT code 63020.

Comment: The commenters disagreed with our proposed work RVU of 12.00 for CPT code 63030, stating that there is concern about contradictory policies regarding the newly revised E/M CPT codes that combined inpatient and observation (outpatient) services. They believe this renders the 23-hour policy invalid.

Response: We believe that adopting the revisions for CPT codes 99221–99223 and 99231–99233 is not inconsistent with our 23-hour policy as it applies to this code family. In this instance, we are reviewing RUC-recommendations that explicitly identify CPT code 63030 as being subject to our 23-hour policy. Consistent with discussions in the CY 2011 and CY 2022 PFS final rules cited above, we agree with the RUC that this code is subject to the 23-hour policy, and we believe it is appropriate to fully apply the 23-hour policy to CPT code 63030. We note that we acknowledge commenters' concerns regarding policy implications as a result of adopting the E/M inpatient/observation revisions and will take that into consideration for future rulemaking. Additionally, we note that we did not propose any changes to the previously finalized 23-hour policy in the proposed rule, and we believe it is still consistent to apply the 23-hour policy, as was recommended by the RUC, for CPT code 63030. We also remind commenters that the 23-hour policy calculation, when fully applied to the calculation of a work RVU, is used to reduce the value of discharge day management services, remove the inpatient E/M visits, and reallocate the intraservice time to the immediate post-service period. We refer readers to the 2011 PFS final rule (75 FR 73226) for an in-depth explanation of the 23-hour policy. For CPT code 63030, we believe the RUC only partially applied the 23-hour policy when it applied the policy to the immediate post service time, but not to the calculation of the work RVU. Instead, we continue to believe the 23-hour policy should be fully applied to this code that describes

outpatient services for which there is an overnight stay during the post-operative period, regardless of the number of nights that a patient stays in the hospital. In short, we continue to believe that the work that is typically associated with an inpatient service should not be included in the work RVUs for the outpatient services to which the 23-hour policy applies, especially considering the previously discussed site of service anomaly for CPT code 63030. Therefore, we are finalizing our proposed work RVU of 12.00 for CPT code 63030.

Comment: Commenters disagreed with our proposed work RVU of 3.86 for CPT code 63035, stating that it was a Harvard valued code with time and work values that were generated from the base code, CPT code 63030. Commenters expressed that the Harvard survey did not include all the surgical specialties that now perform the service, with only 17 responses from neurosurgeons. Therefore, the commenters stated that the previous intraservice time should not be used to arrive at a calculated value. The commenters also expressed concern that CMS did not address the compelling evidence provided by the RUC, and urged CMS to address this rationale.

Response: We believe that it is important to use the recent data available regarding work times, and we note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We remind commenters that the concept of compelling evidence was developed by the RUC as part of its work RVU review process for individual codes. The RUC determines whether there is compelling evidence to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that the RUC developed the concept of compelling evidence for its own review process; an evaluation of ''compelling evidence,'' at least as conceptualized by the RUC, is not part of our review process, as our focus is the time and intensity of services, in accordance with the statute. With that stated, we do consider changes in technology, patient population, and other compelling evidence criteria, as such evidence may affect the time and intensity of a service under review. For example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. We instead focus on evaluating and addressing the time and intensity of services when valuing codes because section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Therefore, we are finalizing a work RVU of 3.86 for CPT code 63035 as proposed.

Comment: Two commenters disagreed with our proposal to remove 125 minutes of equipment time for EQ168 (light, exam) for CPT codes 63020 and 63030, stating that they believe the exam light is needed to check for possible seroma and to examine and take out stitches. The commenters urged CMS not to remove the exam light expense from these code values.

Response: We proposed to remove the 125 minutes of equipment time for EQ168 (light, exam) for CPT codes 63020 and 63030 because the RUC contested the typicality of its use to assess the wound and remove staples. Because it is a standard piece of equipment in a neurosurgeon and orthopedic exam room, and the RUC questioned its typicality, we proposed 0 minutes for EQ168 for CPT codes 63020 and 63030. We note that we found five other 090-day codes in the CPT code 630XX series, CPT codes 63045 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical*), 63046 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic*), 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar*), 63050 (*Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments*), and 63051 (*Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [eg, wire, suture, mini-plates], when performed)*) that do not have time allotted to EQ168, despite their inclusion of ''Monitor wounds and remove sutures/staples'' in their post-service descriptions, therefore we do not believe this is a typical equipment input. Since we have not received new information that contradicts the findings in the RUC Database to indicate that the use of this equipment is typical, we are finalizing 0 minutes for EQ168 for CPT codes 63020 and 63030 as proposed.

(16) Somatic Nerve Injections (CPT Codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 76942, 77002, and 77003)

In May 2021, the CPT Editorial Panel revised the descriptors and billing instructions for CPT codes 64415 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, including imaging guidance, when performed*), 64416 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 64417 (*Injection(s), anesthetic agent(s) and/or steroid; axillary nerve, including imaging guidance, when performed*), 64445 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, including imaging guidance, when performed*), 64446 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 64447 (*Injection(s), anesthetic agent(s); femoral nerve, including imaging guidance, when performed*), 64448 (*Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 77002 (*Fluoroscopic guidance for needle placement*), 77003 (*Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)*) and 76942 (*Ultrasonic guidance for needle placement, imaging supervision and interpretation*). These codes were then surveyed by the RUC in October 2021.

We last finalized values for CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 64448 in the CY 2020 PFS final rule (84 FR 62744 through 62745). In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for codes in the somatic nerve injection family. At its October 2018 meeting, the RUC recommended work RVU and PE inputs for a number of somatic nerve injection codes, including CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 64448. (Note that in 2018, the codes did not include ''including imaging guidance, when performed'' in their descriptors.) During the October 2018 RUC presentation for this family of services, the specialty societies stated that CPT codes 64415, 64416, 64417, 64446, 66447, and 64448 were reported with the imaging code CPT code 76942 more than 50 percent of the time. In reviewing this family of services in the CY 2020 PFS final rule, our finalized work and PE values for the codes did not consider the simultaneous performance of injection and imaging (84 FR 62744). In May 2021, the CPT Editorial Panel revised the codes to include ''with imaging, when performed'' in the descriptors.

When presenting its CY 2023 valuation recommendations, the RUC pointed out that the current values and times for CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 64448 reflect only the work and time of the injection. The revised codes, however, include both injection and imaging. In order to make an equitable comparison between the RUC recommendations and the current values, the RUC suggested we compare the RUC recommendations to values that combined the current work and estimated time of the injection codes and the imaging code with which they are being bundled, CPT code 76942. We agreed with this approach and thank the RUC for providing combined work RVUs and estimated combined times, which we considered as part of the RUC's recommendations.

As part of its recommendations, the RUC reaffirmed its prior recommendations for a number of codes that were previously reviewed or reaffirmed in the CY 2020 PFS final rule, including: CPT codes 64400 (*Injection(s), anesthetic agent(s); trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular)*), 64408 (*Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), 64420 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level*), 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure)*), 64425 (*Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves*), 64430 (*Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve*), 64435 (*Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve*), 64449 (*Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)), and 64450 (Injection(s), anesthetic agent(s); other peripheral nerve or branch*) (84 FR 62744 through 62745); CPT code 64451 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography*) (84 FR 62740); and CPT code 64454 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*) (84 FR 62749). The RUC also reaffirmed its recommendation for CPT code 64455 (*Injection(s), anesthetic agent(s) and/or steroid; plantar common digital nerve(s) (e.g., Morton's neuroma)*), which was reviewed and valued in the CY 2019 PFS final rule (83 FR 58542). The codes the RUC wishes to reaffirm for CY 2023 have not been revised by the CPT Editorial Panel and were not resurveyed by the RUC since their prior valuation. Since we did not receive new information regarding these codes, we acknowledged the RUC's reaffirmation but we did not review the values of these codes in the proposed rule. In the proposed rule, we also noted that the RUC-reaffirmed values for CPT codes 64435 (work RVU of 0.75), 64450 (work RVU of 0.75), 64451 (work RVU of 1.52), and 64454 (work RVU of 1.52) are the same as the current work RVUs that we finalized in the CY 2020 PFS final rule. The RUC reaffirmed work RVU of 0.94 for CPT code 64405 is the current work RVU, which was finalized in the CY 2019 PFS final rule (83 FR 59542) and reaffirmed in the CY 2020 final rule, and the RUC-reaffirmed work RVU of 1.10 for CPT code 64418 is the current work RVU value finalized in the CY 2018 PFS final rule (82 FR 53054) and reaffirmed in the CY 2020 PFS final rule. The RUC reaffirmed a work RVU of 0.75 for CPT code 64455 which is the current work RVU we finalized in the CY 2019 PFS final rule (83 FR 58542).

For CY 2023, we proposed the RUC-recommended work RVUs for CPT codes 64417 (work RVU of 1.31), 64447 (work RVU of 1.34), 64448 (work RVU of 1.68), 77002 (work RVU of 0.54), 77003 (work RVU of 0.60), and 76942 (work RVU of 0.67).

For CPT code 64415, we disagreed with the RUC-recommended work RVU of 1.50 and proposed a work RVU of 1.35, based on the intraservice time ratio calculated using the ''combined'' values for CPT code 64415 and the imaging CPT code 76942 provided by the RUC. (The combined work RVU the RUC offered for comparison was 2.02 (the sum of the work RVUs for both codes: CPT code 64415 is 1.35 and CPT code 76942 is 0.67), and an estimated intraservice time of 15 minutes and total time of 43 minutes.) This proposed work RVU of 1.35 for CPT code 64415 is supported by a crosswalk to CPT code 11982 (Removal, non-biodegradable drug delivery implant), which has a work RVU of 1.34, an identical service time, and a total time that is two minutes lower than CPT code 64415. This value is further supported by a bracket of CPT codes: CPT code 64486

and CPT code 33285. CPT code 64486 (Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)) has a work RVU of 1.27 and identical intraservice and total time values to CPT code 64415, and CPT code 33285 (insertion, subcutaneous cardiac rhythm monitor, including programming) has a work RVU of 1.53, an intraservice time of 10 minutes and a total time of 40 minutes.

We noted that when compared to the current time file information for CPT code 64415, the RUC-recommended intraservice time decreased from 12 to 10 minutes (16.7 percent reduction) and RUC-recommended total time decreased from 40 to 35 minutes (12.5 percent reduction). However, the RUC-recommended work RVU increased by 0.15 which is an 11.1 percent increase. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should not be met with significant increases to work RVUs without adequate justification. Additionally, while we do acknowledge that adding imaging does bundle some additional work into the code, we do not believe that the recoding of the services in this family has resulted in a significant increase in their intensity, only a change in the way in which they will be reported, and through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve efficiencies via elimination of duplicative assumptions of the resources involved in furnishing particular services. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64415 actually decreased from the predecessor code. Thus, we are disinclined to ignore the impact of decreased times on the work RVU. We believe our proposed value of 1.35 appropriately reflects both the additional work and the decrease of time.

We considered proposing a work RVU of 1.27 for CPT code 64415, using CPT code 64486 as a comparison code, since it has the same intraservice and total times as the revised CPT code 64415. However, CPT code 64486, with a work RVU of 1.27, has a lower work RVU than the current work RVU of 64415 (1.35.) We are in general agreement with the RUC that it is important to acknowledge that there is some additional work that comes with adding imaging to this procedure.

For CPT code 64416, we disagreed with the RUC-recommended work RVU of 1.80 and instead proposed a work RVU of 1.65. While we disagreed with the RUC's recommended work RVU, we did agree with the RUC's proposed increment of +0.30 between CPT codes 64415 and 64416. (The RUC recommendation for CPT code 64415 was 1.50, and the recommendation for CPT code 64416 was 1.80.) We found persuasive the RUC's observation that the current increment between CPT codes 64415 and 64416 is unusually small when compared to other sets of related codes in the family. Typically, the codes that add catheter placement in addition to the injection are 0.30–0.36 work RVUs higher than the codes for an injection in the same nerve group or region. Retaining such a narrow interval of 0.15 between CPT codes 64415 and 64416 would create a rank order anomaly within the family in light of adjustments to some of the other codes' work RVUs. Our proposed work RVU of 1.65 for CPT code 64416 is supported by a bracket of CPT codes: CPT code 64448 and CPT code 36573. CPT code 64448 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) has a work RVU of 1.60, 15 minutes intraservice time and 40 minutes total time, and CPT code 36573 (*Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older*) has a work RVU of 1.70, 15 minutes intraservice time and 40 minutes total time.

We noted that, when compared to the current time file, the RUC-recommended intraservice time for CPT code 64416 decreased from 20 to 15 minutes (25 percent reduction) and the RUC-recommended total time decreased from 49 to 44 minutes (10.2 percent reduction). However, the RUC recommended a 0.32 increase in the work RVU, which is a 21.6 percent increase. We noted that the RUC-recommended work RVU of 1.80 would give CPT code 64416 the highest work RVU of the surveyed codes, and would make it among the highest valued codes in the family. We do not believe the RUC-recommended work RVU appropriately accounts for the reductions in the surveyed total time for the procedure, and did not receive specific information explaining why, despite the decrease in time, the value should receive such a significant increase relative to the other surveyed codes. As stated previously, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased significantly, decreases in time should be reflected in the revised work RVUs. As noted in our discussion of CPT code 64415 above, if the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64416, are now actually lower. We believe our proposed work RVU of 1.65 corrects the increment between CPT code 64415 and 64416, while also acknowledging that, the addition of imaging notwithstanding, the times for CPT code 64416 have noticeably decreased.

For CPT code 64445, we disagreed with the RUC-recommended work RVU of 1.39 and instead proposed a work RVU of 1.28, based on the intraservice time ratio calculated using the ''combined'' values for CPT code 64445 and the imaging CPT code 76942 provided by the RUC. (The combined work RVU the RUC offered for comparison was 1.67 (the sum of the work RVUs for both codes: CPT code 64445 is 1.00 and CPT code 76942 is 0.67), and an estimated intraservice time of 13 minutes and total time of 27 minutes.) This proposed value of 1.28 is supported by a comparison to CPT code 64486 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)*), which has a work RVU of 1.27 and intraservice time of 10 minutes and total time of 35 minutes. The value is also supported by a low bracket of CPT code 58100 (*Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)*), with a work RVU of 1.21, identical intraservice time and almost identical total time, and a high bracket

of CPT code 11982 (*Removal, non-biodegradable drug delivery implant*), with a work RVU of 1.34, identical intraservice time and a higher total time of 33 minutes.

We noted that the RUC-recommended intraservice time and total time for CPT code 64445 are identical to the current intraservice and total times in the time file for CPT code 64445. However, the RUC recommended a 0.39 increase to the work RVU. We do not imply that the lack of change to the intraservice and total times means that the work RVU cannot be increased. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, the RUC-proposed increase in the work RVU does not seem justified. As noted in our discussion of CPT code 64415 above, if the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64445, are the same as the predecessor code.

We considered proposing a work RVU of 1.10 for CPT code 64445, using CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*) as a comparison code, with a work RVU of 1.10 and identical intraservice and total times as CPT code 64445. However, we believed this would cause a rank order anomaly within the family. For example, CPT code 64418 (*Injection(s), anesthetic agent(s) and/or steroid; suprascapular nerve*) also has a work RVU of 1.10, but does not include imaging. Again, we generally agree with the RUC that it is important to acknowledge the additional work that comes with adding imaging to this procedure, and to ensure that this additional work is reflected within the relative values of the family, but we still proposed a work RVU of 1.28 for CPT code 64445.

For CPT code 64446, we disagreed with the RUC-recommended work RVU of 1.75 and instead proposed a work RVU of 1.64. This recommended work RVU is 0.36 higher than the proposed work RVU for CPT code 64445 (1.28). We noted that the current increment between the current values of 64445 and 64446 (1.00 and 1.36, respectively) is 0.36. The RUC recommendations for these codes (1.39 and 1.75) preserved this increment. Since the same imaging activity is being added to both codes, we agree with preserving the relationship between the values of CPT codes 64445 and 64446. Our proposed work RVU of 1.64 for CPT code 64446 is supported by a bracket of CPT codes: CPT code 64448 and 36573. CPT code 64448 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) has a work RVU of 1.60, 15 minutes intraservice time and 40 minutes total time, and CPT code 36573 (*Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older*) has a work RVU of 1.70, 15 minutes intraservice time and 40 minutes total time. (We noted that this is the same bracket we suggested to support the proposed value for CPT code 64416. As revised, the intraservice and total times for CPT codes 64416 and 64446 are the same.)

We noted that, compared to the time file for CPT code 64446, the RUC-recommended intraservice time stayed the same (15 minutes) and the total time increased from 40 to 44 minutes (10 percent increase). The RUC-recommended work RVU for CPT code 64446, is 0.39 higher than the current RVU, a 28.7 percent increase. We believe the RUC-recommended work RVU increase is disproportionate to the change in time. Additionally, we noted that the RUC-recommended times result in CPT code 64416 and CPT code 64446 having identical intraservice and total times. We believe it best preserves rank order within the family to assign CPT code 64416 and CPT code 64446 similar work RVUs.

We proposed the direct PE inputs as recommended by the RUC for all of the codes in the Somatic Nerve Injections family.

We would like to correct a typographical error. We note that in several places in the CY 2023 proposed rule at 87 FR 45919, the number ''64488'' in CPT code 64488 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed*) was misidentified as ''64448.''

Comment: A number of commenters expressed support of our proposed work RVUs for CPT codes 64417, 64447, 64448, 77002 77003, and 76942.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concerns about all of our proposed values (including those that aligned with the RUC-recommended valuations), which they did not believe reflected the combined work of both the injection and the imaging. Commenters indicated that the addition of imaging makes the injection procedure more efficient and improves success rates for patients. They also noted that somatic nerve injections are important treatments for pain management and can be an alternative to opioid prescription.

Response: We agree with commenters that somatic nerve injections are a valuable pain management service. However, under allowing the codes (which were frequently being performed simultaneously) meant that there was duplication in payments for components of the practitioner's time, effort, and PE when performing; what was essentially a combined procedure was being billed as though it was two standalone procedures. We agreed with, and appreciated the CPT and RUC's decision to revise and revalue the codes to reflect a bundling of the somatic nerve injection and imaging procedures.

Comment: Commenters disagreed with our proposed work RVUs for CPT codes 64415, 64416, 64445 and 64446 and urged us to accept the RUC recommendations. Commenters disagreed with some of the codes we selected to use as brackets or crosswalks to support our proposed valuations on the basis that the codes we selected did not include imaging.

Response: We disagree that some of the codes used as brackets or crosswalks were inappropriate simply because they did not include imaging. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk.

Comment: Some commenters disagree with our use of time ratios to calculate proposed RVUs for CPT codes 64415 and 64445, stating that they believed the intraservice time ratio did not consider the combined work of both the injections and the imaging described by the revised code descriptors.

Response: We disagree that our use of time ratio calculations was inappropriate. As stated in the proposed rule, we specifically used the RUC's projected ''combined'' RVU and intraservice time for CPT codes 64415 and 64445 when performing our intraservice time ratio calculations. It

was our understanding that the RUC provided this information to demonstrate values reflecting the combined work of the revised codes.

Comment: Some commenters disagree with our use of increments to support our proposed values for CPT codes 64416 and 64446.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes.

Comment: Commenters reiterated that CPT codes 64415, 64416, 64445, and 64446 (revised to add imaging) now describe work that is more intense than the previous codes (which described injections without the imaging). Commenters stated that the RUC recommendations better reflected the intensity of this new work.

Additionally, several commenters provided detailed clinical information explaining that injections to the sciatic nerve (which are described in CPT codes 64445 and 64446) are more intense than injections to the femoral artery (CPT codes 64447 and 64448.) Several commenters also provided clinical information demonstrating that injections to the brachial plexus (which are described by CPT codes 64415 and 64416) are more intense than injections to the sciatic nerve (which are described by CPT codes 64445 and 64446.)

Response: As explained in the proposed rule, we believed that our proposed RVUs for CPT codes 64415, 64416, 64445, and 64446 acknowledged the increased work of the codes while also reflecting their respective changes in time. However, we consider clinical information associated with physician work intensity provided by the RUC and other interested parties as part of our review process, and we found the additional clinical information helpful by providing greater insight into relative intensity within this code family. We note that to determine work RVUs, we must look at both time and intensity. We must also consider relativity: if two codes have the same work time, but one code has a higher intensity, relativity dictates that the higher-intensity code gets more RVUs.

For CPT code 64445 (injection of sciatic nerve, with imaging, if performed), we proposed a work RVU of 1.28; the code had a surveyed intraservice time of 10 minutes. For CPT code 64447 (*injection of femoral artery, with imaging, if performed*), we had proposed a work RVU of 1.34; the code has an intraservice time of 8 minutes. In light of the additional information that injections to the sciatic nerve are more intense than injections to the femoral nerve (coupled with the fact that CPT code 64445 has a longer intraservice time than CPT code 64447), we now agree that the RUC recommendation of 1.39 for CPT code 64445 better supports relativity.

For CPT code 64446 (*injection of sciatic nerve with catheter placement, with imaging, if performed*), we had proposed a work RVU of 1.64; the code has 15 minutes of intraservice time. We proposed a work RVU of 1.68 for CPT code 64448 (injection of femoral nerve with catheter placement, with imaging, if performed); the code has an intraservice time of 15 minutes. In light of the additional information that sciatic nerve injections are more intense than femoral injections (coupled with the fact that CPT codes 64446 and 64448 have the same intraservice time), we now agree that the RUC recommendation of 1.75 for CPT code 64446 better supports relativity.

For CPT code 64415 (*injection to the brachial plexus, with imaging, if performed*), we proposed a work RVU of 1.35; the code has an intraservice time of 10 minutes. As noted above, we now agree with a work RVU of 1.39 for CPT code 64445 (*injection of sciatic nerve, with imaging, if performed*); the code also has 10 minutes of intraservice time. In light of the additional information that brachial nerve injections are more intense than sciatic nerve injections (coupled with the fact that CPT codes 64415 and 64445 have the same intraservice time), we now agree that the RUC recommendation of 1.50 for CPT code 64415 better supports relativity.

For CPT code 64416 (*injection to the brachial plexus with catheter placement, with imaging, if performed*), we proposed a work RVU of 1.65; the code has an intraservice time of 15 minutes. As noted above, we now agree with a work RVU of 1.75 for CPT code 64446 (*injection of sciatic nerve with catheter placement, with imaging, if performed*); the also code has 15 minutes of intraservice time. In light of the additional information that brachial nerve injections are more intense than sciatic nerve injections (coupled with the fact that CPT codes 64416 and 64446 have the same intraservice time), we now agree that the RUC recommendation of 1.80 for CPT code 64416 better supports relativity.

Based on the comments, we are finalizing the work RVUs for CPT codes 64417, 64447, 64448, 77002, 77003, and 76942. and the PE inputs for all codes, as proposed. We are finalizing the RUC recommended work RVU of 1.50 for CPT code 64415; 1.80 for CPT code 64416; 1.39 for CPT code 64445; and 1.75 for CPT code 64446.

(17) Transcutaneous Passive Implant-Temporal Bone (CPT Codes 69714, 69716, 69717, 69719, 69726, 69727, 69729, 69730, and 69728)

In October 2020, the CPT Editorial Panel deleted two codes used for mastoidectomy and replaced them with four new codes for magnetic transcutaneous attachment to external speech processor. The CPT Editorial Panel made additional revisions to differentiate implantation, removal, and replacement of the implants. The RUC submitted interim recommendations to CMS for six codes in this family following the January 2021 RUC meeting, and we proposed and finalized the recommended work RVU for all six of these codes in the CY 2022 PFS final rule (86 FR 65099 through 65100). For CY 2023, the CPT Editorial Panel established three additional new codes and the coding structure of the family was changed to describe the different techniques more appropriately for transcutaneous passive implant procedures that vary in time and intensity depending on the indication for the procedure, device chosen, and patient anatomy. The nine codes in the family were surveyed again for the January 2022 RUC meeting and new recommendations were submitted to CMS.

We proposed the RUC-recommended work RVU for six of the nine codes in the Transcutaneous Passive Implant-Temporal Bone family. We proposed a work RVU of 9.03 for CPT code 69716 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor within the mastoid and/or resulting in removal of less than 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 9.97 for CPT code 69729 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 9.46 for CPT code 69719 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 mm2 surface area of bone*

deep to the outer cranial cortex), a work RVU of 10.25 for CPT code 69730 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 7.38 for CPT code 69727 (*Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 mm2 surface area of bone deep to the outer cranial cortex*), and a work RVU of 8.50 for CPT code 69728 (*Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*).

We disagreed with the RUC's recommended work RVU for the other three codes in the family for the procedures describing percutaneous attachment to external speech processor. We disagreed with the RUC's recommended work RVU of 8.00 for CPT code 69714 (*Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we instead proposed a work RVU of 6.68 based on a crosswalk to CPT code 38305 (*Drainage of lymph node abscess or lymphadenitis; extensive*). In reviewing CPT code 69714, we noted that the recommended intraservice time is decreasing from 40 minutes to 30 minutes (25 percent reduction), and the recommended total time is decreasing from 182 minutes to 146 minutes (20 percent reduction); however, the RUC-recommended work RVU is only decreasing from 8.69 to 8.00, which is a reduction of just over 8 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 69714, we believed that it was more accurate to propose a work RVU of 6.68 based on a crosswalk to CPT code 38305 to account for these decreases in the surveyed work time.

We also disagreed with the recommended work RVU of 8.00 because it results in an intensity which is anomalously high in relationship to the rest of the code family. At the recommended work RVU of 8.00, the intensity of CPT code 69714 is increasing by nearly 50 percent as compared with the survey conducted last year, and the resulting intensity of the service would be significantly higher than any of the other codes in the family. We did not agree that this intensity would be typical given that the percutaneous form of implant described by CPT code 69714 should have the lowest intensity of the three types described in this code family. The implantation procedure described by this code should also typically have lower intensity than the revision/replacement procedures elsewhere in the family. We believed that the intensity of CPT code 69714 is more accurately described at our proposed work RVU of 6.68 based on a crosswalk to CPT code 38305. This code shares the same intraservice time of 30 minutes as CPT code 69714 and has a higher total time of 186 minutes; we agreed that CPT code 69714 is more intense than CPT code 38305 which was offset by our crosswalk code having an additional office visit in its global period.

We disagreed with the RUC's recommended work RVU of 8.48 for CPT code 69717 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we instead proposed a work RVU of 7.91 based on a crosswalk to CPT code 46262 (*Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fistulectomy, including fissurectomy, when performed*). In reviewing CPT code 69717, we noted that although the intraservice time remains essentially unchanged (decreasing from 45 minutes to 44 minutes), the recommended total time is decreasing from 187 minutes to 159 minutes (15 percent reduction). However, the RUC-recommended work RVU was only decreasing from 8.80 to 8.48, which is a reduction of less than 4 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 69717, we believed that it was more accurate to propose a work RVU of 7.91 based on a crosswalk to CPT code 46262 to account for these decreases in the surveyed work time.

We also disagreed with the recommended work RVU of 8.48 because it resulted in a higher intensity than the other two revision/replacement codes (CPT codes 69719 and 69730) in this family. CPT code 69717 describes the percutaneous form of implant which should have the lowest intensity of the three revision/replacement codes in this family, however at the recommended work RVU of 8.48 it would have the highest intensity of this group. While the intensity at the recommended work RVU for CPT code 69717 is nowhere near the anomalous nature of the intensity at the recommended work RVU for CPT code 69714, we still believed that the intensity would be more typical at the proposed work RVU of 7.91. This proposed valuation restores the relationship between the three revision/replacement codes by placing the intensity of CPT code 69717 slightly lower than CPT codes 69719 and 69730. Therefore, we believed that the intensity of CPT code 69717 was more accurately described at our proposed work RVU of 7.91 based on a crosswalk to CPT code 46262. This code has nearly the same intraservice time of 45 minutes as CPT code 69717 and has a higher total time of 179 minutes; we agreed that CPT code 69717 is more intense than CPT code 46262 which was offset by our crosswalk code having an additional office visit in its global period.

We disagreed with the RUC's recommended work RVU of 7.50 for CPT code 69726 (*Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we instead proposed a work RVU of 6.36 based on a crosswalk to CPT code 67912 (*Correction of lagophthalmos, with implantation of upper eyelid lid load (e.g., gold weight)*). In reviewing CPT code 69726, we noted that the recommended intraservice time was increasing from 30 minutes to 35 minutes (17 percent increase), and the recommended total time was increasing from 148 minutes to 150 minutes (1 percent increase); however, the RUC-recommended work RVU was increasing from 5.93 to 7.50, which was an increase of just over 26 percent. Although we did not imply that the increase in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believed that since the two components of work are time and intensity, modest increases in time should be appropriately reflected in modest increases to work RVUs. In the case of CPT code 69726, we believed that it was more accurate to propose a work RVU of 6.36 based on a crosswalk

to CPT code 67912 to account for these increases in the surveyed work time.

We also disagree with the recommended work RVU of 7.50 because it resulted in an intensity which is anomalously high in relationship to the rest of the code family and created a rank order anomaly within the work RVUs. CPT code 69726 describes the percutaneous form of the removal procedure which should have the lowest intensity of all nine codes in this family. However, the intensity of CPT code 69726 at the recommended work RVU of 7.50 would be the second-highest in the family, even higher than CPT code 69730 which describes the revision/replacement procedure with magnetic transcutaneous attachment resulting in removal of greater than or equal to 100 square mm surface area of bone. We did not agree that this would be typical and we believed that the intensity would be more accurate at our proposed work RVU of 6.36. We also noted that the recommended work RVU of 7.50 for CPT code 69726 creates a rank order anomaly within the family as it would be higher than the recommended work RVU of 7.38 for CPT code 69727 which describes a more complex procedure and has higher surveyed work times. Therefore, we believed that the work and intensity of CPT code 69726 were more accurately described at our proposed work RVU of 6.36 based on a crosswalk to CPT code 67912. This code has nearly the same intraservice time of 40 minutes as CPT code 69726 and has a higher total time of 166 minutes; we agreed that CPT code 69726 is more intense than CPT code 69726 which was offset by our crosswalk code having an additional office visit in its global period.

We proposed the direct PE inputs as recommended by the RUC for all nine codes in the Transcutaneous Passive Implant-Temporal Bone family.

Comment: Several commenters disagreed with CMS' use of the current work RVUs and work times when reviewing the codes in the Transcutaneous Passive Implant-Temporal Bone family. Commenters stated that CMS was comparing work RVUs and work times to an interim recommendation that was made interim due to a flawed survey process. Commenters stated that the RUC reviewed this family of services and determined that they needed to be resurveyed with a revised Reference Service List (RSL) to encompass a larger range of relative values, specifically to include the lower end of the RVU spectrum. Commenters stated that CMS should not use the interim recommendations as a base to arrive at new work RVUs for the codes in this family.

Response: We disagree with the commenters that it was inappropriate to use the current work RVUs and work times that were active for CY 2022 when evaluating the codes in the Transcutaneous Passive Implant-Temporal Bone family. As we stated earlier in the Methodology for Establishing Work RVUs portion of this section, we believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. Even if the work RVUs and work RVUs for the codes in the Transcutaneous Passive Implant-Temporal Bone family were recommended to CMS on an interim basis, they were used for payment throughout CY 2022 and are appropriately subject to comparisons when evaluating the updated recommendations for CY 2023. We also note that we proposed and finalized those interim work RVUs and work times as recommended by the RUC without refinement.

Furthermore, the use of older work RVUs and older work times that predate the interim recommendations from CY 2022 would not have changed the analysis that we performed indicating that several of the codes in the Transcutaneous Passive Implant-Temporal Bone family were overvalued as recommended by the RUC. For example, CPT code 69714 previously had a work RVU of 14.45 and an intraservice work time of 90 minutes before its CY 2022 interim review. If we were to use these values as the basis for our review, the recommended intraservice time would decrease from 90 minutes to 30 minutes (67 percent reduction) however, the RUC-recommended work RVU would only decrease from 14.45 to 8.00, which is a reduction of just under 45 percent. Regardless of whether the starting point of comparison is the interim CY 2022 values or the historic CY 2007 values, we continue to believe that several of the codes in this family are more accurately described using our proposed work RVUs.

Comment: Several commenters disagreed with the CMS proposed work RVU of 6.68 for CPT code 69714 and stated that CMS should instead finalize the RUC-recommended work RVU of 8.00. Commenters disagreed that the recommended intensity for CPT code 69714 was too high and stated that the code describes an intense and complex surgery on a highly sensitive sensory organ, operating in a small space where millimeters of difference lead to cerebrospinal fluid leak and intracranial vascular injury. Commenters disagreed with the CMS crosswalk to CPT code 38305 and stated that CPT code 69714 requires more physician work as it is a more intense service than CPT code 38305, which instead describes the less intense work of draining a lymph node abscess. Commenters also stated that CPT code 38305 was last reviewed 22 years ago and is not widely performed, and therefore, should not be used as a crosswalk code.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 6.68 is a more accurate choice for CPT code 69714. As we stated in the proposed rule, since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. The survey for CPT code 69714 found that the typical intraservice time required to perform the procedure had significantly decreased (from both the historic and interim work time values) and we believe that this decrease in work time should be reflected in a corresponding decrease in the work RVU. Even if the decrease in work time was due to greater efficiencies in delivering the service, this decrease in work time should be reflected in the work RVU for the service in question.

We also disagree with the commenters and continue to believe that CPT code 38305 is an appropriate choice as a crosswalk for CPT code 69714. CPT code 38305 describes the extensive drainage of a lymph node abscess or lymphadenitis procedure; we stated in the proposed rule that we agreed that CPT code 69714 is more intense than CPT code 38305 which is offset by our crosswalk code having an additional office visit in its global period. We also emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are

appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

We also disagreed with the recommended work RVU of 8.00 because it results in an intensity which is anomalously high in relationship to the rest of the code family. At the recommended work RVU of 8.00, the intensity of CPT code 69714 is increasing by nearly 50 percent as compared with the survey conducted last year (and by more than 60 percent as compared with the historic pre-interim survey intensity), and the resulting intensity of the service would be significantly higher than any of the other codes in the family. We do not agree that this intensity would be typical given that the percutaneous form of implant described by CPT code 69714 should have the lowest intensity of the three types described in this code family. The implantation procedure described by this code should also typically have lower intensity than the revision/replacement procedures elsewhere in the family. Aside from stating that CPT code 69714 describes an intense surgery and pointing out that it had a higher intensity than CPT code 69717 at the proposed work RVU, commenters did not respond to our analysis that the recommended work RVU of 8.00 resulted an anomalously high intensity. As such, we continue to believe that the proposed work RVU of 6.68 for CPT code 69714 is a more accurate choice than the RUC-recommended work RVU of 8.00.

Comment: Several commenters disagreed with the CMS proposed work RVU of 7.91 for CPT code 69717 and stated that CMS should instead finalize the RUC-recommended work RVU of 8.48. Commenters stated that for the procedures described by CPT code 69717, the practitioner must work with a variety of delicate structures in a very small space just behind the ear which makes these procedures very intense and complex to perform. Commenters stated that the work per unit time as recommended by the RUC for CPT code 69717 was already lower than CPT codes 69719 and 69730. Commenters disagreed with the CMS crosswalk to CPT code 46262 and stated that CPT code 69717 requires more physician work than CPT code 46262. Commenters also stated that CPT code 46262 was last reviewed 22 years ago and is not widely performed, and therefore, should not be used as a crosswalk code.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 7.91 is a more accurate choice for CPT code 69717. As we stated in the proposed rule, since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. The survey for CPT code 69717 found that the typical intraservice time required to perform the procedure had significantly decreased (from both the historic and interim work time values) and we believe that this decrease in work time should be reflected in a corresponding decrease in the work RVU. Even if the decrease in work time was due to greater efficiencies in delivering the service, this decrease in work time should be reflected in the work RVU for the service in question.

We also disagree with the commenters and continue to believe that CPT code 46262 is an appropriate choice as a crosswalk for CPT code 69717. CPT code 46262 describes a hemorrhoidectomy with fistulectomy which requires a similar level of risk and complexity to the patient; we stated in the proposed rule that we agreed that CPT code 69717 is more intense than CPT code 46262 which is offset by our crosswalk code having an additional office visit in its global period. We also emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

We also disagreed with the recommended work RVU of 8.48 because it results in a higher intensity than the other two revision/replacement codes (CPT codes 69719 and 69730) in this family. CPT code 69717 describes the percutaneous form of implant which should have the lowest intensity of the three revision/replacement codes in this family, however at the recommended work RVU of 8.48 it would have the highest intensity of this group. While the intensity at the recommended work RVU for CPT code 69717 is nowhere near the anomalous nature of the intensity at the recommended work RVU for CPT code 69714, we still believe that the intensity would be more typical at the proposed work RVU of 7.91. Commenters stated that the work per unit time as recommended by the RUC for CPT code 69717 was already lower than CPT codes 69719 and 69730 but otherwise did not respond to our discussion of the intensity of the code and how it related to the other revision/replacement codes in this family. As such, we continue to believe that the proposed work RVU of 7.91 for CPT code 69717 is a more accurate choice than the RUC-recommended work RVU of 8.48.

Comment: Several commenters disagreed with the CMS proposed work RVU of 6.36 for CPT code 69726 and stated that CMS should instead finalize the RUC-recommended work RVU of 7.50. Commenters stated that for CPT code 69726, the practitioner must work with a variety of delicate structures in a very small space just behind the ear which makes these procedures very intense and complex to perform. Commenters disagreed with the CMS crosswalk to CPT code 67912 and stated that CMS should not apply this crosswalk because CPT code 67912 is an infrequently performed service that has not been reviewed by the RUC or CMS in 20 years, has disparate times from the survey code, and typically involves less physician work.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 6.36 is a more accurate choice for CPT code 69726. As we stated in the proposed rule, since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. The survey for CPT code 69726 found that the typical intraservice time required to perform the procedure had significantly decreased and we believe that this decrease in work time should be reflected in a corresponding decrease in the work RVU. Even if the decrease in work time was due to greater efficiencies in delivering the service, this decrease in work time should be reflected in the work RVU for the service in question.

We also disagree with the commenters and continue to believe that CPT code 67912 is an appropriate choice as a crosswalk for CPT code 69726. CPT code 67912 describes a correction of lagophthalmos, with implantation of upper eyelid lid load; we acknowledged in the proposed rule that the work times were not an exact match with CPT code 69726 but closely matched the intraservice and total times. We also stated in the proposed rule that we agreed that CPT code 69726 is more intense than CPT code 69726 which is offset by our crosswalk code having an additional office visit in its global period. We also emphasize that we

continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

We also disagreed with the recommended work RVU of 7.50 because it results in an intensity which is anomalously high in relationship to the rest of the code family and creates a rank order anomaly within the work RVUs. CPT code 69726 describes the percutaneous form of the removal procedure which should have the lowest intensity of all nine codes in this family. However, the intensity of CPT code 69726 at the recommended work RVU of 7.50 would be the second-highest in the family, even higher than CPT code 69730 which describes the revision/replacement procedure with magnetic transcutaneous attachment resulting in removal of greater than or equal to 100 square mm surface area of bone. We did not agree that this would be typical and we believe that the intensity would be more accurate at our proposed work RVU of 6.36. We also noted in the proposed rule that the recommended work RVU of 7.50 for CPT code 69726 created a rank order anomaly within the family as it would be higher than the recommended work RVU of 7.38 for CPT code 69727 which describes a more complex procedure and has higher surveyed work times. Commenters did not respond to our discussion of the anomalously high intensity of CPT code 69727 at the recommended work RVU or explain why it should create a rank order anomaly within the family. As such, we continue to believe that the proposed work RVU of 6.36 for CPT code 69726 is a more accurate choice than the RUC-recommended work RVU of 7.50.

After consideration of the comments, we are finalizing the work RVUs for all nine codes in the Transcutaneous Passive Implant-Temporal Bone family as proposed. We did not receive any comments on the direct PE inputs and we are also finalizing them as proposed.

(18) Contrast X-Ray of Knee Joint (CPT Code 73580)

CPT code 73580 (*Radiologic examination, knee, arthrography, radiological supervision and interpretation*) was first identified via the high-volume growth screen in 2008. In 2021, the Relativity Assessment Workgroup (RAW) noted that code 73580 was never surveyed and remains CMS/Other sourced, and recommended that it be surveyed. CPT code 73580 was then surveyed. We proposed the RUC-recommended work RVU of 0.59. We also proposed the RUC-recommended direct PE inputs without refinement.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed the RUC-recommended work RVU of 0.59 for CPT code 73580. We are finalizing as proposed the RUC-recommended direct PE inputs without refinement.

(19) 3D Rendering With Interpretation and Report (CPT Code 76377)

We nominated this code in the CY 2020 PFS final rule as potentially misvalued, stating that we believe it is of the same family as CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*), which was reviewed at the April 2018 RUC meeting. CMS requested that CPT code 76377 also be reviewed to maintain relativity within the code family (84 FR 62625). The specialty societies maintain that these services are more accurately viewed as separate code families. Furthermore, the RUC cites changes in technique and patient population as compelling evidence to maintain a physician work RVU of 0.79 despite a 5-minute recommended reduction in physician total time compared to the current physician time.

We proposed the RUC recommended work RVU of 0.79 for CPT code 76377; however, we reiterate that we continue to believe that CPT code 76376 and 76377 would be more appropriately viewed as belonging to the same code family and we request that they be surveyed together.

We proposed the RUC-recommended direct PE inputs without refinement.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed the RUC-recommended work RVU of 0.79 for CPT code 76377. We are finalizing as proposed the RUC-recommended direct PE inputs without refinement.

(20) Neuromuscular Ultrasound (CPT Codes 76881, 76882, and 76883)

Since their creation in 2011, CPT codes 76881 (*Ultrasound, complete joint (i.e., joint space and peri-articular soft-tissue structures), real-time with image documentation*) and 76882 (*Ultrasound, limited, joint or other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation*) have been reviewed numerous times as New Technology/New Services by the Relativity Assessment Workgroup (RAW). In October 2016, the RAW reviewed these codes and agreed with the specialty societies that the dominant specialties providing the complete (CPT code 76881) versus the limited (CPT code 76882) ultrasound of extremity services were different than originally thought, causing variation in the typical PE inputs. The RAW recommended referral to the Practice Expense Subcommittee for review of the direct PE inputs and the CPT Editorial Panel to clarify the introductory language regarding the reference to one joint in the complete ultrasound. The PE Subcommittee reviewed the direct PE inputs for CPT codes 76881 and 76882 and adjusted the clinical staff time at the January 2017 RUC meeting, and the CPT Editorial Panel editorially revised CPT codes 76881 and 76882 to clarify the distinction between complete and limited studies and revised the introductory guidelines to clarify reference to one joint in the complete ultrasound procedure in June 2017. In October 2021, the CPT Editorial Panel approved the addition of CPT code 76883 for reporting real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity, and the revision of CPT code 76882 to add focal evaluation. CPT codes 76881 and 76882 were identified as part of the neuromuscular ultrasound code family with CPT code 76883 and surveyed for the January 2022 RUC meeting.

For CPT codes 76881, 76882, and 76883, we disagreed with the RUC-recommended work RVUs of 0.90, 0.69, and 1.21, respectively, as we believed they did not account for the surveyed time changes or appropriate comparisons for the new add-on code, CPT code 76883, and proposed a work RVU of 0.54 for CPT code 76881, a work RVU of 0.59 for CPT code 76882, and a work RVU of 0.99 for CPT code 76883.

CPT code 76881 represents a complete evaluation of a specific joint in an extremity. This service requires ultrasound examination of all the following joint elements: joint space (for example, effusion), peri-articular soft-tissue structures that surround the joint (that is, muscles, tendons, other soft-tissue structures), and any identifiable abnormality. In some circumstances, additional evaluations such as dynamic imaging or stress maneuvers may be

performed as part of the complete evaluation. The RUC recommended 5 minutes of pre-service time, 20 minutes of intraservice time, and 5 minutes of post-service time, based on the survey. The RUC discussed the 5-minute increase in intraservice time and determined that the increase relates to the change in the dominant specialty provider since the creation of the code, as previously there was 15 minutes of intraservice time for the radiologist to scan and/or review the sonographer-obtained images. Now, the rheumatologist is performing the scanning and it takes 20 minutes for the typical patient. For rheumatology, physicians typically scan the patients with portable ultrasound devices rather than utilizing sonographers as originally described in the 2010 survey. The RUC noted that this code is reported with an office E/M visit 58.9 percent and a non-facility office E/M visit 66.3 percent of the time; the RUC stated that CPT code 76881 is imaging-specific so the physician work described would not overlap with the E/M service, but we disagreed, as the descriptions of pre-service and post-service work directly overlap. The description of pre-service work for CPT code 76881 states ''Review pertinent clinical information. Review any prior applicable imaging studies.'' Pre-service work for CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), the most common E/M code reported with CPT code 76811, includes ''Review interval correspondence, referral notes, medical records, and diagnostic data generated since the last visit.'' Post-service work of CPT code 76881 is described as ''Discuss significant findings with the referring physician. Review and sign final report,'' whereas the post-service work for CPT code 99214 includes ''Arrange diagnostic testing and referral if necessary. Document the encounter in the medical record, spending time to further refine the differential diagnosis, workup, or treatment plan as necessary. Coordinate care by discussing the case with other physicians and members of the health care team and write letters of referral if necessary. Perform electronic data capture and reporting to comply with quality payment program and other electronic mandates. Review and analyze interval testing results and refine the differential diagnosis, workup, and treatment plan based on these results. Order additional testing based on these results. Communicate results and plan modifications with patient and/or family.'' We believed there was overlap in pre-service and post-service work between the E/M visit and CPT code 76881, and therefore, we proposed 0 minutes for the pre-service and post-service time rather than the RUC-recommended 5 minutes of pre-service and post-service time. The proposed work RVU of 0.54 was the reverse building block valuation based on the removal of the 5 minutes of pre-service and post-service time, with a long-standing intensity of 0.0224 (10 minutes * 0.0224 work/minute = 0.224 work RVUs). The proposed work RVU accounted for the 0.224 work RVU decrease as a result of the removal of pre-service and post-service time, and the increase of 5 minutes of intraservice time, while maintaining the same IWPUT of 0.027, as there was no discussed change in intensity. The specialty societies and the RUC asserted that there was an increase of 5 minutes as a result of the intraservice work changing due to a change in dominant specialty providing the service (from radiology to rheumatology), but did not present a change in intensity. We noted that the specialty societies used CPT code 76700 (*Ultrasound, abdominal, real time with image documentation; complete*) with a work RVU = 0.81, 11 minutes of intra-service time, and 21 minutes total time, as a reference code because it has identical pre- and post-service time but less intra-service time than the surveyed code and is a clinically similar ultrasound code. We noted that this is not an appropriate reference code as it is billed alone 72.8 percent of the time, and therefore, the valuation of CPT code 76700 accounts for pre- and post-service work that would not overlap with an E/M visit like we believed the pre- and post-service work did for CPT code 76881.

CPT code 76882 represents a limited evaluation of a joint or focal evaluation of a structure(s) in an extremity other than a joint (for example, soft-tissue mass, fluid collection, or nerve[s]). This evaluation includes assessment of a specific anatomic structure(s) (for example, joint space only [effusion] or tendon, muscle, and/or other soft-tissue structure[s] that surround the joint) that does not assess all the elements included in CPT code 76881, although it does include all surrounding anatomy and any associated pathology or contralateral comparison as indicated. The RUC discussed the four-minute increase in intraservice time and determined that the increase relates to the change in dominant supplier of this service since the creation of the code, as there is currently 11 minutes of intraservice time that included scanning performed only by the podiatrist, and now the radiologist works with the sonographer to obtain and interpret the images in addition to the physician performing additional scanning as needed. Because radiologists no longer use portable ultrasound devices as originally described in the 2010 survey or in the 2017 PE update, the RUC and specialty societies assert that the physician work (time) has changed due to supervision of the sonographer in addition to the radiologist performing the scanning. The specialty societies and RUC also noted that ultrasound technology has evolved immensely since 2010, including proliferation of high-frequency ultrasound probes dedicated to musculoskeletal imaging, as well as producing images with higher fidelity and more detail, whereby the number and quality of images that can be reviewed and the pathology to evaluate have greatly increased since 2010. Therefore, the typical patient requires 15 minutes of intraservice time. While we agreed with the RUC that 15 minutes of intraservice time is warranted for CPT code 76882, we noted that there was no information indicating a change in intensity, and therefore, for CPT code 76882, we proposed the reverse building block work RVU of 0.59 to account for the 4-minute increase in intraservice time and the maintenance of the current IWPUT of 0.024.

We noted that commenters may raise concern about a potential rank order anomaly with the proposed work RVUs of 0.54 and 0.59 for CPT codes 76881 and 76882, respectively, but we noted that the IWPUT of each code adequately reflects the increased intensity of intraservice work for the complete ultrasound (CPT code 76881; IWPUT = 0.027) versus the limited/focal ultrasound (CPT code 76882; IWPUT = 0.024), and the lesser work RVU of 0.54 for CPT code 76881 stemmed from the removal of the presumed overlapping pre- and post-service time with the E/M visits that are typically performed. The RUC noted that consistency of intensity measures is demonstrated across the range of codes ascending from the limited code (CPT code 76881) to the new, most complex code (CPT code 76883). By proposing work RVUs that maintain the current IWPUTs, we maintained relativity both among the neuromuscular ultrasound family, as well as the larger family of ultrasound

imaging codes. We also noted that the difference between the RUC-recommend IWPUTs and our proposed IWPUTs for CPT codes 76881 and 76882 was the same, where CPT code 76882 had an IWPUT that is 0.003 less than the IWPUT of CPT code 76881.

CPT code 76883 will be available for CY 2023 to report real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity. This code will entail examination of a nerve throughout its length, within one extremity, including evaluation of multiple areas for potential nerve compression, measurement of cross-sectional areas, evaluation of echogenicity, vascularity, mobility including dynamic maneuvers when indicated, evaluation for any associated muscular denervation, with comparison to unaffected muscles or nerves within that extremity as needed. CPT code 76883 also requires permanently recorded images and cine loop and a written report containing a description of each of the elements evaluated. The RUC recommended 7 minutes of pre-service time, 25 minutes of intra-service time and 7 minutes of post-service time as supported by the survey. The RUC clarified that this service would not typically be reported with an office E/M visit. The RUC arrived at a recommended work RVU of 1.21 by comparing the pre-, intra-, and post-service times to those of CPT code 76881, which we proposed to modify due to presumed overlapping work in the pre- and post-service time with E/M visits. When we compared the proposed times of 0 minutes of pre-service time, 20 minutes of intraservice time, and 0 minutes of post-service time, and a work RVU of 0.54 for CPT code 76881, and the proposed times of 7 minutes of pre-service time, 25 minutes of intraservice time, and 7 minutes of post-service time for CPT code 76883, we arrived at a reverse building block work RVU of 0.99.

For the direct PE inputs, we proposed to remove the 2 minutes of clinical labor time for CA006 (*Confirm availability of prior images/studies*), the 1 minute of clinical labor time for the CA007 (*Review patient clinical extant information and questionnaire*), and the 2 minutes for CA011 (*Provide education/obtain consent*) for CPT code 76881 because these RUC recommendations describe clinical labor activities that presumably overlapped with the E/M visit that is typically billed with CPT code 76881. We proposed the direct PE inputs as recommended by the RUC for CPT codes 76882 and 76883.

We received several comments regarding our proposed work RVUs, pre- and post-service time, and direct PE input refinements for CPT codes 76881, 76882, and 76883 in response to the CY 2023 PFS proposed rule and those comments are summarized below.

Comment: Some commenters stated that the pre- and post-service work of CPT code 76881 should not be removed simply because it may be billed in conjunction with an E/M code. One commenter stated that if a rheumatologist decides to order the more expensive MRI instead of performing an ultrasound, the pre- and post- ordering time is quick, whereas, for musculoskeletal ultrasound (MSKU), the pre-service time includes detailed review of other studies and discussion with the patient that are not normally included as part of the E/M visit. The post-service work includes labelling, storing, documenting the results. The commenter stated that none of this would be part of the normal E/M coding for a visit. Another commenter stated that the physician work associated with an E/M visit is separate and distinct from the physician work associated with the imaging services reported by CPT code 76882. Furthermore, the commenter asserted that the E/M visit and ultrasound require different cognitive and technical skills by the rendering physician. When these services are performed in the same encounter, the physician work is neither overlapping nor duplicative, and should be separately accounted for.

Response: After review of the commenters' statements, CPT code 76881's pre- and post-service descriptions, and similar imaging codes that are typically reported with an E/M visit which allow for pre- and post-service time, we agree with the commenters' assertion that the 5 minutes of pre- and post-service time is appropriate for CPT code 76881. We also agree that, while the service descriptions of the E/M visit and CPT code 76881 may match, CPT code 76881's activities likely reflect image-specific activities that do not overlap with the E/M visit's activities; therefore, we are finalizing physician work time as the RUC recommended, with 5 minutes of pre-service evaluation time and 5 minutes of immediate post-service time.

Comment: Some commenters stated that these CPT codes are typically furnished by rheumatologists with the following direct PE inputs: (1) expensive, high quality, high frequency ultrasound machines with power Doppler capability rather than an inexpensive, handheld/portable device as included in the direct PE inputs; (2) a sonographer specially trained in MSKU rather than a physician or a standard x-ray technician as included in the direct PE inputs; and (3) a dedicated exam/imaging room in which to perform this service. One commenter submitted responses and synthesized conclusions from a limited survey of direct PE inputs typical of rheumatologists. More commenters noted that the RUC decided to reduce the PE portion of the technical component of CPT code 76881 by over 90 percent, phased in over time. The commenters continued by stating that there is another proposed decrease to 0.27 PE RVUs for CY 2023 based on a flawed assumption regarding the type of ultrasound services provided in the non-facility setting. The commenters stated that many clinics maintain and use a dedicated ultrasound room, a non-portable ultrasound room and a PACS system, as well as two dedicated sonographers. The commenters stated that even practices that use portable ultrasound units will utilize a dedicated ultrasound room and PACS system, and employ, or contract the services of, a sonographer or other highly trained, typically highly credentialed, clinical staff. One commenter stated that the January 2022 RUC recommendations indicate rheumatology as the dominant specialty in the non-facility setting, but they incorrectly assumed that portable ultrasound is the typical equipment used by rheumatologists. This commenter stated that, of the 88 providers who submitted surveys for CPT code 76881 or the 100 providers that submitted surveys for CPT code 76882, no information was provided regarding the level of rheumatologists' input, and therefore, the commenter asserted that there is no way of knowing if rheumatologists were appropriately queried, despite the acknowledgement that they are the dominant specialty for CPT code 76881. This commenter submitted an attachment that claims that the dedicated medical sonographer's labor cost per hour is $47.50 and that they spent $80,017.24 on ultrasound technology and $3,003.00 in maintenance of the ultrasound technology per year. Another commenter stated that rheumatology was not part of the PE survey in 2017 and none of the RUC members who sat on the PE subcommittee in 2017 performed MSKU in their offices at the time of the survey. The commenter stated that we stated that the ''transition period [to phase in the cuts year over year as finalized for CY 2018] would allow us to obtain more stakeholder input on the appropriate PE inputs and specialty assumptions for these

services,'' and that we expected to consider this for future rulemaking. The commenter noted that their comments on the CY 2019 PFS proposed rule were deemed out of scope and that no further action was taken to obtain PE values.

Response: We appreciate the commenters' survey collection efforts to reflect rheumatologists' costs in performing CPT codes 76881, 76882, and 76883, and the concern regarding the accounting of rheumatologists' typical clinal labor and equipment in the January 2022 RUC recommendations. We share the commenters concerns that the recommended PE inputs may not fit within the family of services as currently valued given concerns raised by commenters. In consideration of commenters' concerns and survey data, including early feedback on how the PE inputs for these services may not be reflective of what will be considered typical in how these services may be furnished, we encourage the RUC and other interested parties to reconsider the PE inputs of the neuromuscular ultrasound family, including the new code, in the near term.

We note that we did not make any proposals related to CPT codes 76881 or 76882 in the CY 2019 PFS proposed rule, therefore the comments were appropriately deemed out of scope at that time, and at that time, rheumatology was not the dominant specialty, therefore, we would have considered PE inputs of the dominant specialty to be typical when performing these CPT codes at that time. We encourage the commenters to coordinate with the RUC to provide the survey data to facilitate a reconsideration of PE inputs given the shift in dominant specialty and recent changes that were made by the RUC PE Subcommittee.

Because the RUC has standardized procedures for PE and physician surveys, and the fact that the surveyors' results differ so drastically from the RUC recommendations, we encourage the RUC and other interested parties to reconsider the PE inputs of the neuromuscular ultrasound family, which we would consider in future rulemaking if submitted. While the submission of the survey data is appreciated, we note that no invoices were submitted, and therefore, we encourage collaboration with the RUC PE subcommittee and the submission of specific invoices to support the surveys' results and robust data to show the typicality of these PE inputs.

Comment: One commenter asserted that they utilize a dedicated diagnostic medical sonographer with specific musculoskeletal training, high quality machines that cost around $40 thousand each (based on a recent purchase of a GE LOGIQ™ E ultrasound machine for a Veteran Affairs Hospital that cost $44,110 after a government discount), and a dedicated ultrasound scanning room due to patient draping requirements and machine optimization.

Response: We appreciate the commenters' input regarding CPT codes 76881, 76882, and 76883. We encourage the RUC and other interested parties to reconsider the PE inputs of the neuromuscular ultrasound family, as they differ significantly from the RUC recommended direct PE inputs as submitted for the CY 2023 PFS proposed rule. After a reconsideration by the RUC and interested parties regarding the PE inputs, we would be interested in engaging with interested parties to obtain invoices to support accurate pricing for PE inputs that may be altered for this family of codes.

Comment: Many commenters urged CMS to pause all proposed reductions to CPT codes 76881 and 76882 to allow collaboration between the RUC and interested parties' on how rheumatologists currently utilize or plan to utilize MSKU since the rheumatology community has never been surveyed by the RUC on their typical PE investments in their ultrasound programs. Commenters stated that rheumatologists were not included in the 2017 survey when PE cuts were recommended by the RUC and finalized for CY 2018.

Response: We believe it is imperative that the RUC and interested parties reconsider the PE inputs for CPT codes 76881, 76882, and 76883 in the near term, as commenters have submitted survey responses that differ significantly from the RUC recommended direct PE inputs. There are also significant discrepancies between the RUC assumption that rheumatologists typically scan patients themselves, versus varying commenters agreeing with this assumption, and some arguing that rheumatologists utilize a highly trained sonographer to scan patients. There are also significant commenter and RUC discrepancies regarding typical equipment used for these CPT codes. We note that in the CY 2018 PFS final rule (82 FR 53058 through 53059), we sought comment on whether a portable ultrasound unit would be a more accurate PE input for CPT codes 76881 and 76882, given that the dominant specialty for both of these services was podiatry based on available 2016 Medicare claims data. At that time, we did not finalize our proposal to include an ultrasound room, and instead finalized the RUC recommended equipment, with the exception of the ultrasound room, which we replaced with a portable ultrasound unit based on the RUC's determination, as expressed through its recommendations for CY 2018, that a portable unit is the equipment type that is typical for podiatry, which was the dominant specialty furnishing CPT code 76882 at the time. Commenters disagreed with our proposals and RUC recommendations, stating that the shift of PE from CPT code 76881 to CPT code 76882 was based on inaccurate assumptions regarding the typical equipment used in furnishing these services. These commenters noted that the equipment used to furnish the two procedures is identical and that the RUC-recommended direct PE inputs for CPT code 76881, which were developed based on the assumption that the dominant specialty furnishing the service is podiatry, do not reflect the equipment inputs utilized by rheumatologists such as an ultrasound room and PACS workstation. Given the changes in dominant specialty for these CPT codes from 2010 to 2017, and again from 2017 to 2022, we recommend that the RUC and interested parties reconsider the PE inputs for each code based on the dominant specialty for each CPT code, based on the most recent year's Medicare claims data, and consideration of survey responses submitted to CMS in response to the CY 2023 PFS proposed rule.

Comment: Many commenters expressed the importance of MSKU in controlling the prescribing of expensive biologic medications, streamlining patient care, reducing delays in patient care that result from scheduling alternative imaging tests (not on the initial encounter) and subsequent follow up visits to act on the tests results, and obtaining sensitive, safe non-traumatic images for pediatric patients. Commenters stated that MSKU benefits patients and families by allowing them to see their anatomy in real time, which aids the patients' confidence in their physician and diagnosis. Commenters also stated that MSKU aids minorities and underserved areas where access to MSKU extends the ability to care for patients who may otherwise not be able to travel for MRI or CT services due to cost or additional time required to schedule and attend subsequent visits for the imaging and follow up, which can extend the time to initiate treatment by months.

Response: We appreciate the commenters' input on the value of CPT codes 76881, 76882, and 76883, and agree with the commenters that these services play an integral part in high

quality, cost effective, expedient imaging, diagnosis, and care for a variety of patient populations. For this reason, we believe it is imperative that the RUC and interested parties reconsider the PE inputs for CPT codes 76881, 76882, and 76883 in the near term.

In order to maintain relativity among this family of codes after being compelled by the commenters' assertion that the pre- and post-service time for CPT code 76881 does not overlap with an E/M visit, and finalizing the RUC-recommended work RVU and PE inputs for CPT code 76881, we are also finalizing the RUC recommended work RVUs and PE inputs for CPT codes 76882 and 76883. Therefore, for CPT codes 76881, 76882, and 76883, we are finalizing work RVUs of 0.90, 0.69, and 1.21, respectively. As mentioned above, we are finalizing 5 minutes of pre-service evaluation time and 5 minutes of immediate post-service time for CPT code 76881. Similarly, we are finalizing the inclusion of 2 minutes of clinical labor time for CA006 (*Confirm availability of prior images/studies*), 1 minute of clinical labor time for the CA007 (*Review patient clinical extant information and questionnaire*), and 2 minutes for CA011 (*Provide education/obtain consent*) for CPT code 76881 for the direct PE inputs, as recommended by the RUC, because we are compelled by the commenters' assertion that these activities are imaging-specific and do not overlap with an E/M visit. We are finalizing the direct PE inputs as recommended by the RUC for CPT codes 76882 and 76883, as proposed. We reiterate our recommendation that the RUC and interested parties reconsider the PE inputs in the near term. We also remind interested parties that we have established an annual process for the public nomination of potentially misvalued codes. This process provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention, as detailed in section II.C. of this final rule. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. While this process is available to interested parties, we encourage the RUC and other interested parties to reconsider the PE inputs of the neuromuscular ultrasound family as a whole, including the new code, in the near term, as we have already reviewed comments for this final rule and survey data that may indicate that the PE inputs for these services may not be reflective of what will be considered typical in how these services may be furnished.

(21) Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474)

Especially in the context of the current PHE for COVID–19, it is evident that consistent beneficiary access to vaccinations is vital to public health. As discussed in the CY 2021 PFS proposed rule (85 CFR 50162), many interested parties raised concerns about the reductions in payment rates for the preventive vaccine administration services that had occurred over the past several years. The codes for immunization administration services include CPT codes 90460, 90471, and 90473, as well as the three Healthcare Common Procedural Coding System (HCPCS) codes that describe the services to administer the Part B preventive vaccinations other than the COVID–19 vaccine: G0008 (influenza), G0009 (pneumococcal), and G0010 (HBV). Until CY 2019, we generally had established payment rates for these immunization administration services based on a direct crosswalk to the PFS payment rate for CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for the crosswalk code for CY 2018, and because the reductions in overall valuation for that code have been subject to the multi-year phase-in of significant reductions in RVUs, the payment rate for these vaccine administration codes has been concurrently reduced. Further, because the reduction in RVUs for the crosswalk code, CPT code 96372, was significant enough to be required to be phased in over several years under section 1848(c)(7) of the Act, the reductions in overall valuation for the vaccine administration codes were likewise subject to reductions over several years. As we noted in Table 21 of the CY 2022 PFS proposed rule (86 FR 39222), the national payment rate for administering these preventive vaccines has declined more than 30 percent since 2015.

We have attempted to address the reduction in payment rates for the Part B preventive vaccine administration HCPCS G-codes in the last three PFS rulemaking cycles. In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver these vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008, G0009 and G0010 (84 FR 62798).

In the CY 2021 PFS proposed rule, we proposed to crosswalk CPT codes 90460, 90471, and 90473, as well as HCPCS codes G0008, G0009 and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*) (85 FR 50163). In the proposed rule, we noted that CPT code 36000 is a service with a similar clinical vignette, and that the additional clinical labor, supply, and equipment resources associated with furnishing CPT code 36000 were similar to costs associated with these vaccine administration codes. We also noted that this crosswalk would have resulted in a payment rate for vaccine administration services that is approximately the same as the CY 2017 rate that was in place prior to the revaluation of CPT code 96372 (the original crosswalk code). In the CY 2021 PFS final rule, we did not finalize the proposed policy, and instead finalized a policy to maintain the CY 2019 payment amount for CPT codes 90460–90474, as well as HCPCS codes G0008, G0009 and G0010 (85 FR 84628). In the final rule, we also noted that we continued to seek additional information that specifically identifies the resource costs and inputs that should be considered to establish payment for vaccine administration services on a long-term basis.

For the CY 2022 rulemaking cycle, we requested feedback from interested parties that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act (influenza, pneumococcal, HBV, and COVID–19) for physicians, NPPs, mass immunizers and certain other providers and suppliers. We invited commenters to submit their detailed feedback to a series of questions and requests that we believed would assist us in establishing payment rates for these services that could be appropriate for use on a long-term basis; we direct readers to the full discussion of this topic in the CY 2022 PFS final rule (86 FR 65179 through 65193). For CY 2022, we finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine covered under the Medicare Part B preventive vaccine benefit at section 1861(s)(10) of the Act. We explained that since the

administration of the preventive vaccines described under section 1861(s)(10) of the Act is not included within the statutory definition of physicians' services, the payment rates we established for these services in the CY 2022 PFS final rule are independent of the PFS, and will be updated as necessary independently of the valuation of any specific codes under the PFS (86 FR 65186). We discuss the current payment policy for administration of preventive vaccines and our proposals for CY 2023 in section II.H. of this final rule.

We note that as we considered payment policies to ensure adequate access to the Part B preventive vaccines, including consideration of resource costs, the RUC surveyed and reviewed CPT codes 90460–90474 at the April 2021 meeting and submitted recommendations to CMS for our consideration in the CY 2023 rulemaking cycle.

We proposed the RUC-recommended work RVU for all six codes in the Immunization Administration family. We proposed a work RVU of 0.24 for CPT code 90460 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered*), a work RVU of 0.18 for CPT code 90461 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered*), a work RVU of 0.17 for CPT code 90471 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)*), a work RVU of 0.15 for CPT code 90472 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)*), a work RVU of 0.17 for CPT code 90473 (*Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)*), and a work RVU of 0.15 for CPT code 90474 (*Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)*).

For the direct PE inputs, we proposed to remove 1 minute of clinical labor time for the CA008 (*Perform regulatory mandated quality assurance activity (pre-service)*) activity for CPT codes 90460 and 90471–90474. The RUC recommendations describe these activities as ''Checking historical and current temperatures for vaccine refrigerator; recording temperatures; reporting temperatures; vaccine inventorying; ordering vaccines; completing required Vaccines for Children (VFC) paperwork; receiving vaccines; inspecting/logging vaccines and putting them in the vaccine refrigerator; creating lot numbers in EHR.'' Checking refrigerator temperatures, vaccine inventorying, and filling out vaccine paperwork are administrative tasks which are not individually allocable to a particular patient for a particular service. We removed this 1 minute of clinical labor time as these administrative tasks are forms of indirect PE. We also refined the equipment times for CPT codes 90460 and 90471–90474 to conform to our established policies for non-highly technical equipment.

In consideration of the information provided in the recommendation for these services, we proposed the RUC's recommended work RVUs and direct PE inputs (with minor refinements) for these vaccine administration services. However, we continue to seek additional information from commenters that specifically identifies the resource costs and inputs that should be considered to establish payment for these vaccine administration services on a long-term basis, consistent with our policy objectives for ensuring maximum access to immunization services.

Comment: Many commenters stated that they supported the proposal of the RUC-recommended work RVUs for all six codes in the Immunization Administration family.

Response: We appreciate the support for our proposed work RVUs from the commenters.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVUs and thanked CMS for its emphasis on the importance and value of vaccines. The commenter also stated that CMS should adopt a site-neutral approach for all Part B vaccines and apply the OPPS payment rate in all sites of service. The commenter stated that the vaccine administration service is remarkably similar across all of the intramuscular injected Part B vaccines; the commenter stated that it is essentially the same service regardless of the type of vaccine, across all of the various sites of service and that the infrastructure and necessary supplies and staff are fundamentally the same regardless of where a vaccine is administered. The commenter stated that annual updates to the vaccine administration payment rates based on OPPS claims data is a reliable and data-based method for updating the payment rate which would prevent the issues that have occurred in the past with the crosswalk to CPT code 96372.

Response: We appreciate the support for our proposed work RVUs from the commenter. We did not propose and we are not finalizing the OPPS payment rates for the Immunization Administration codes as we do not have data at the moment that indicates these services are identical regardless of the site of service and type of provider. We note for the commenter that we proposed work RVUs and direct PE inputs for the Immunization Administration codes to ensure that they would be resource-based and not dependent on crosswalks to other CPT codes for valuation.

Comment: One commenter disagreed with the proposed valuation of the Immunization Administration codes and stated that the proposed payment rates were insufficient to cover the resource costs associated with providing these services. The commenter stated that the RUC methodology does not result in adequate payment rates for these vaccine administration services and requested that CMS assign the $30 Part B vaccine administration payment rate to the Part D vaccine administration services as well. The commenter stated that there was no policy rationale for a large difference in payment rates between the proposed Part B vaccine administration payment rate and the proposed payments rates for the Part D vaccine administration services and requested that CMS finalize a payment of $30 for CPT codes 90460, 90461, 90471, 90472, 90473, and 90474.

Response: We disagree with the commenter that the RUC methodology used to value the Immunization Administration codes does not result in adequate payment rates for these services. We remind the commenter that under Medicare Part B, the statute requires CMS to value physician services using a resource-based system based on the time and intensity of the services involved. (See section 1848(c)(1)(A) of the Act.) We believe that the RUC recommended values for these codes, with minor refinements to the direct PE inputs to conform with our standard equipment time methodology, are reasonable and will establish resource-based payments for these services as required by the statute.

Comment: Several commenters disagreed with the proposal to remove 1 minute of clinical labor time for the CA008 (Perform regulatory mandated

quality assurance activity (pre-service)) activity for CPT codes 90460 and 90471–90474 as a form of indirect PE. Commenters stated that clinical staff immunization confirmation protocols have changed since the Immunization Administration codes were last valued due to the explosion in the number of new vaccines introduced since 2009. Commenters stated that practitioners typically give orders for the antigen but not the particular brand and presentation, and determining which of these vaccine products to use is a clinical staff decision based on the patient's age and vaccination history and potentially complicated by restrictions. Commenters stated that some vaccines have different dosing requirements based on age, and that while in some cases it is acceptable to use the alternative brand in stock if the original brand is not known, in other cases using only the brand from the original dose is acceptable. Commenters stated that each time a vaccine is administered clinical staff must follow these immunization confirmation protocols, and therefore, the commenters believe that these clinical staff activities are appropriately attributed to direct PE.

Response: We appreciate the additional information provided by the commenters describing the decisions that the clinical staff must make when carrying out these regulatory mandated quality assurance activities. Based on this additional information, we agree that these quality assurance activities constitute a form of clinical judgment that is individually allocable to the Immunization Administrative services as a form of direct PE. We are therefore not finalizing our proposal and will restore the 1 minute of clinical labor time for the CA008 activity for CPT codes 90460 and 90471–90474.

Comment: Several commenters disagreed with the proposal to refine the equipment times for CPT codes 90460 and 90471–90474 to conform to the established CMS policies for non-highly technical equipment. Commenters stated that in February 2008, the RUC recommended and CMS finalized the use of total clinical staff time as the time of medical equipment use for the service of vaccine administration. Commenters stated that this established an exemption specific to the service of vaccine administration and that CMS should finalize the RUC's equipment time recommendations for each piece of medical equipment as established by this 2008 exemption.

Response: We disagree with the commenters and continue to believe that the equipment times for CPT codes 90460 and 90471–90474 should conform to the established policies for non-highly technical equipment. While the commenters are correct that we finalized the RUC-recommended direct PE inputs for these codes in the CY 2009 PFS final rule (73 FR 69736), we did not establish an exemption to the standard equipment times for the Immunization Administration codes. We did not apply the established policies for non-highly technical equipment during our CY 2009 review of these codes solely because those established policies had not been developed yet; the higher equipment times for CPT codes 90460 and 90471–90474 are an artifact of the age of their last review date, not an exemption to our standard policies. As we have noted with regards to the standardization of clinical labor tasks, we believe that setting and maintaining standard equipment time formulas helps provide greater consistency among codes and improves relativity across the wider fee schedule. Updating older equipment times and bringing them into accordance with the established equipment time formulas is a standard part of our review process and the Immunization Administration codes are no exception to that rule. We continue to believe that the equipment times for CPT codes 90460 and 90471–90474 should conform to the established policies for non-highly technical equipment in order to maintain relativity between codes.

After consideration of the comments, we are finalizing the work RVUs inputs for all six codes in the Immunization Administration family as proposed. We are finalizing the direct PE inputs as proposed aside from restoring 1 minute of clinical labor time for the CA008 activity for CPT codes 90460 and 90471–90474 as described above.

(22) Orthoptic Training (CPT Codes 92065 and 92066)

In October 2019, the RUC identified CPT code 92065 (*Orthoptic and/or pleoptic training, with continuing medical direction and evaluation; performed by a physician or other qualified health care professional*) as needing review because it was Harvard Valued (that is, the value of the code had not been reviewed since the implementation of the Resource-Based Relative Value Scale (RBRVS)) and its utilization surpassed 30,000 in each of several recent years. At its January 2020 meeting, during review of CPT code 92065, the RUC noted that the use of ''and/or'' in the descriptor defined different patient populations and treatment techniques and recommended that the code be reviewed by the CPT Editorial Panel (CPT) in order to create two separate codes. Additionally, based upon review and analysis of survey data, specialty societies decided to submit a new code change application for the February 2021 CPT meeting.

During the February 2021 meeting, CPT noted that the services of CPT code 92065 are delivered in two different ways: directly by the practitioner and by a technician under the supervision of the practitioner. In response to this observation, CPT suggested that two codes be created to identify who furnishes the orthoptic service. Identifying in the code descriptor who furnishes the services would ensure more accurate valuation of both the work and the PE associated with the service. The CPT formally revised code 92065 and created new CPT code 92066 to describe orthoptic services furnished under the supervision of a physician or qualified health care professional.

During its April 2021 meeting, the RUC revalued the work associated with the services of CPT code 92065 (*Orthoptic training; performed by a physician or other qualified health care professional*) and valued the PE inputs for new CPT code 92066 (*Orthoptic training; performed by a physician or other qualified health care professional under supervision of a physician or other qualified health care professional*). CPT code 92066 is valued as a PE-only code.

After reviewing CPT code 92065, we proposed to accept the RUC-recommended work RVU of 0.71. We also proposed to accept the RUC-recommended direct PE inputs for CPT code 92065. We proposed to accept the RUC-recommended direct PE inputs for CPT code 92066 as well.

Comment: We received a few comments in response to our proposals for CPT codes 92065 and 92066. Commenters expressed support of our proposal to accept the RUC-recommended work RVUs and the direct PE inputs adjustments.

Response: We thank commenters for taking time to submit their support of the RUC-recommendations for CPT codes 92065 and 92066.

We are finalizing the RUC-recommended work RVU of 0.71 for CPT codes 92065 and the RUC-recommended direct PE inputs for both CPT codes 92065 and 92066.

(23) Dark Adaptation Eye Exam (CPT Code 92284)

CPT code 92284 (*Dark adaptation examination with interpretation and report*) was identified in July 2020 as Harvard Valued with a utilization of over 30,000 claims. In January 2021, the

RUC recommended that the code be surveyed for the April 2021 RUC meeting. The RUC reviewed the survey results for the procedure and noted that the 25th percentile work value of 0.45 was greater than the code's current value. The RUC recommended a work RVU of 0.14, based on a direct work RVU crosswalk from CPT code 76514 (*Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)*). We disagreed with the RUC-recommended work RVU of 0.14 for CPT code 92284. We found that the recommended work RVU did not adequately reflect reductions in physician time, since this diagnostic screening is usually completed during an E/M visit and largely consists of interpreting machine generated results. Instead, we proposed a work RVU of 0.00 for CPT code 92284, which is comparable to other ophthalmic screening tests; such as 99172 (*Visual function screening, automated or semi-automated bilateral quantitative determination of visual acuity, ocular alignment, color vision by pseudoisochromatic plates, and field of vision (may include all or some screening of the determination[s] for contrast sensitivity, vision under glare)*) and 99173 (*Screening test of visual acuity, quantitative, bilateral*). Alternatively, we considered using a total-time methodology with a work RVU of 0.03 and a reverse building block methodology with a work RVU of 0.06. We solicited comments and requested information that may inform why CPT code 92284 should include additional valuation as this procedure is included in an E/M visit.

For the direct PE inputs, we proposed to refine the equipment time for the lens set (EQ165) from 24 minutes to 15 minutes and motorized table (EF030) from 24 minutes to 15 minutes. The reduction in time for both equipment types is proposed to match the RUC-recommended 15 minutes in Clinical Activity Code CA021. We solicited public comment to provide further rationale for the additional 9 minutes recommended.

We received a few comments regarding our proposed work RVUs and direct PE inputs for CPT code 92284 in response to the CY 2023 PFS proposed rule and those comments are summarized below.

Comment: Commenters disagreed with the comparison to CPT codes 99172 and 99173, stating that these reference codes assume there is no physician work involved with the service, and therefore, do not serve as appropriate clinical comparisons to the surveyed CPT code 92284. Instead, these commenters agree with the RUC-recommended crosswalk to CPT code 76514 as a closer clinical comparison, based on work RVU, intra-service time, and intensity of physician/optometrist work involved with this service.

Commenters did not support the proposed alternative methodologies, stating that the total-time and reverse building block methodologies do not appropriately value the physician work and total time required in CPT code 92284. In addition, the commenters stated that use of these alternative methodologies would mean that we are choosing an inconsistent combination of inputs to apply, and that this selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.

One commenter acknowledged that we noted the physician work largely consists of interpreting machine-generated results, stating that they agreed with the RUC-recommended intraservice time of 3 minutes, which was a reduction from the surveyed intraservice time of 15 minutes. The commenter noted that this represents a change in technology which allows technicians to administer the test, a change with which most survey respondents were not familiar. Another commenter asked that we consider upholding the RUC recommendations for all CPT codes covered in this rule, especially CPT code 92284.

Response: We disagree with commenters and continue to believe that CPT codes 99172 and 99173 are appropriate comparator codes for CPT code 92284. These reference codes also account for the screening nature of CPT code 92284, which is usually performed in conjunction with an E/M visit that accounts for the physician work. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

We also clarify for the commenters that our review process is not arbitrary in nature and includes a variety of methodologies and approaches used to develop work RVUs, including the use of building block and total-time methodologies. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data.

When considering the intraservice time, we do not agree with the commenter, and continue to believe that complex work is not performed to analyze the machine generated results. In our review, we focus on evaluating and addressing the time and intensity of services, but we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We also have reason to believe that the new technology has led to greater efficiencies in the service which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU.

Comment: Commenters urged CMS to accept the RUC-recommended direct PE inputs for CPT code 92284 and provided additional rationale to explain the additional 9 minutes of equipment time for the lens set (EQ165) and motorized table (EF030). Commenters stated that in addition to the 15 minutes that the equipment is in use during performance of the test, there is an additional 9 minutes of clinical activities where the equipment is unavailable for use with another patient. These activities all occur in the room with the testing equipment, lens set, and table.

Response: We appreciate the additional information provided by the commenters to clarify the equipment time. We are persuaded by the comments that explained the standard default equipment formula was used and RUC PE direct input benchmarks for clinical staff time were used for CA011, CA013, CA014, and CA024, which results in 24 minutes when combined with the 15 minutes of CA021. Therefore, we are not finalizing our proposed refinement to the equipment time for the lens set (EQ165) and motorized table (EF030), and will finalize the RUC-recommended time of 24 minutes.

After careful consideration of the public comments, we are finalizing a work RVU of 0.00 for CPT code 92284 as proposed. For the direct PE inputs,

we are not finalizing our proposed refinements to the equipment time and are instead finalizing the RUC-recommended direct PE inputs for CPT code 92284.

(24) Anterior Segment Imaging (CPT Code 92287)

For CPT code 99287 (*Anterior segment imaging with interpretation and report; with fluorescein angiography*), we proposed the RUC-recommended work RVU of 0.40.

We proposed the RUC-recommended direct PE inputs for CPT code 92287 without refinement.

Comment: Commenters supported our proposed valuation for CPT code 92287.

Response: We acknowledge and appreciate the support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.40 and the RUC-recommended direct PE inputs for CPT code 92287 as proposed.

(25) External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In the CY 2021 PFS proposed rule (85 FR 50164), we proposed to adopt the RUC's work RVU recommendations for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*), 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*), and 93248 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation*).

We noted that the recommendations for this family of codes contained one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item. Instead, we received pricing information from two sources: a weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Interested parties also submitted a series of invoices from the clinical study marketplace with a price of $595, which we rejected as we typically require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item.

After consideration of the information, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we received pricing information to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. We believed the kit to be the closest match from a pricing perspective to employ as a proxy until we would be able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply. In response to our proposal, we received conflicting information from commenters and in the CY 2021 PFS final rule (85 FR 84631), we ultimately finalized contractor pricing for CY 2021 for the four codes that included this supply input (CPT codes 93241, 93243, 93245, and 93247) to allow additional time to receive more pricing information.

We noted that interested parties have continued to engage with CMS and the MACs on payment for this service. We remained concerned that we continued to hear that the supply costs as initially considered in our CY 2021 PFS proposal were much higher than they should be. At the same time, we also heard that the resource costs, as reflected in the contractor-based payments, do not adequately cover the incurred cost for the SD339 supply that is used to furnish these services. In consideration of continued access to these services for Medicare beneficiaries, we once again solicited public comments and information in the CY 2022 PFS proposed rule (86 FR 39179) to support CMS' future rulemaking to establish a uniform national payment that appropriately reflects the PE inputs that are used to furnish these services. During the comment period, we received invoices and additional information for use in pricing the SD339 supply from the commenters.

Based on this information, we finalized an updated price of $200.15 for the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply in the CY 2022 PFS final rule based on the average of the ten invoices we received (86 FR 65125). We believed that the invoice data for this supply item, which ranged from a minimum price of $179.80 to a maximum price of $241.99, suggested that our updated price of $200.15 was more accurate than the suggested crosswalk to the SD214 supply at a price of $325.98. We believed that considering a potential impact to payment for other services under the PFS, a proposal to establish national payment for these services based on this new pricing information should take into account broader feedback from interested parties. Therefore, we did not finalize national pricing at this time and finalized our proposal to maintain contractor pricing for CPT codes 93241, 93243, 93245, and 93247 for CY 2022.

For CY 2023, we received a series of additional invoices for the SD339 supply from two impacted parties. Each of the invoices priced the supply item at either $265.00 or $226.38; we therefore proposed to average together these prices and establish a proposed price of $245.69 for the SD339 supply. We noted that we believe that this represents the most typical price for the supply based on the invoice data that has been provided over the past 2 years. We also proposed national pricing for CPT codes 93241, 93243, 93245, and 93247 for CY 2023 now that the SD339 supply has an established price. The proposed CY 2023 RVUs for these CPT codes are displayed in Addendum B on the CMS website under downloads for the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

Comment: Many commenters stated their support for the proposal of national pricing for CPT codes 93241,

93243, 93245, and 93247. Commenters detailed the clinical benefits of external extended ECG monitoring, such as offering easy access to patients by having inventory readily available at the point of care, being able to return the device in a postage paid box thus preventing a return trip to the hospital or doctor's office, and having the option for a monitor that provides greater than 24–48 hours of data that providers need access to for clinical decision making. Commenters stated that the proposal of national pricing would help to provide greater stability in payment for these services and ensure continued access to care for beneficiaries.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters submitted additional invoices associated with the pricing of the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply. Commenters stated that they believe these additional invoices would help better capture the market-based costs associated with the SD339 supply.

Response: We appreciate the submission of invoices with additional pricing information from the commenters in helping to determine the most accurate price for the SD339 supply. We averaged together the price of the new invoices with the invoices that we had previously received prior to the publication of the CY 2023 PFS proposed rule. After averaging together these 21 invoices, we are finalizing an updated price of $260.35 for the SD339 supply.

Comment: Several commenters stated that they supported the proposal of national pricing and the proposed price of $245.69 for the SD339 supply; however they noted that the result does not adequately reflect the cost of delivering these services by independent diagnostic testing facilities (IDTFs). Commenters stated that KPMG, in conjunction with AdvaMed, performed and presented a detailed cost analysis to CMS and individual MACs requesting a reevaluation of the PE inputs. Commenters stated that this analysis segregated costs into three categories: (1) cost of goods sold including costs directly related to the devices, supplies, production overhead and shipping; (2) direct labor, including manufacturing a product or provision of a service and clinical services; and (3) other indirect costs (IT support, finance, rent), and stated that all three categories were necessary to fully account for and understand the resources expended by an IDTF to provide LT–ECG services. Commenters also stated that these three categories did not consider the consumption of non-device assets used in the delivery of LT–ECG (for example, software and processing) or the costs associated with the purchase of capital equipment, regulatory, and research and development expenses. This cost analysis summed to $300.68 for the total cost of providing LT–ECG services, including capital expenditures and research and development costs; a separate commenter submitted a related cost analysis that summed to $283.89. Commenters requested that the Extended External ECG Monitoring services be priced in accordance with the updated costs from the AdvaMed/KPMG analysis as the CMS proposed pricing does not adequately account for all the costs associated with manufacturing and delivery of the associated monitoring services (for example, software and processing) that are necessary for efficient and effective delivery of services.

Response: We appreciate the presentation of these additional cost analyses from the commenters for use in pricing the Extended External ECG Monitoring codes. However, we did not propose to use these external cost analyses in valuing these codes and they do not fit easily within the framework of how our PE methodology operates. As the commenters noted, these cost analyses include delivery, software, and processing expenses which are typically considered to be forms of indirect PE under our methodology. These indirect expenses would not be included in the invoice pricing of the SD339 supply which we sought comment upon in the proposed rule. The commenters also explicitly stated that their cost analyses for providing Extended External ECG Monitoring services included costs associated with research and development, which are not costs that we include when determining the price of a service under our PE methodology, as they are not connected to the furnishing of the service itself.

More broadly, our PE allocation currently makes use of a ''bottom up'' methodology that sums the typical and medically necessary resources associated with each service and uses them to calculate the PE RVU. The cost analyses submitted by the commenters are forms of a ''top down'' analysis which have not been used as the basis of our PE methodology since we finalized the changes to the current system in CY 2007. (For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).) This is not to say that the cost analyses submitted by the commenters are irrelevant to the process of valuing the Extended External ECG Monitoring services, as they can be a useful tool in determining accurate market-based pricing. However, they cannot be directly utilized to determine the most accurate price for the SD339 supply, especially given that these cost analyses include additional expenses such as delivery, processing, and research/development costs which would not typically be considered direct expenses under our PE methodology.

We also note that the AdvaMed/KPMG cost analysis submitted by the commenters with a total cost of $300.68 for the Extended External ECG Monitoring services includes research and development costs of $38.50 in its total expenses. As stated above, our PE methodology does not recognize research and development costs when determining the prices of services, only those resources individually allocable to the service which are both typical and medically necessary. When these are removed, the resulting total cost of $262.18 closely matches our proposed pricing for the External ECG Monitoring services. We believe that these cost analyses ultimately reinforce the accuracy of our proposals after excluding the costs which would not be included under our PE methodology.

Comment: A commenter had a series of questions regarding the invoices used to establish the pricing for the SD339 supply. The commenter outlined six different scenarios asking whether these invoices constituted health insurance claims, entire technical services billed by IDTFs, individual single-use patches, and several related scenarios. The commenter requested additional information about the invoices used for pricing the SD339 supply based on these different scenarios.

Response: As detailed above, we received 21 invoices which we averaged together under our typical pricing methodology which resulted in a price of $260.35 for the SD339 supply. We reviewed each invoice and determined that the price was associated with an individual extended external ECG patch, not health insurance claims or entire technical services. We did separately receive ''top down'' cost analyses from several commenters, as discussed above, but these were not invoices for the SD339 supply, and therefore, we did not include them as part of the averaged invoice price.

Comment: A commenter asked CMS to explain why the CY 2023 proposed

rule used a new batch of invoices to price the SD339 supply which superseded rather than added to the CY 2022 final rule's batch of invoices for the same supply. The commenter stated that CMS did not explain what about the new invoices was superior and more likely to be representative and valid of national costs for the SD339 supply. The commenter requested that CMS provides more detail about what the invoice data they have received are, and why CMS has included or excluded when specifying the input.

Response: When we use invoices to update supply and equipment pricing, we find ourselves typically working with a small amount of submitted invoice data. It is not uncommon to use a single invoice to update supply and equipment pricing for lack of additional invoices associated with the item in question. The limited amount of invoice data sometimes results in making use of invoices across different calendar years in order to get a more representative sample of market-based pricing. However, our preference is always to use more recent pricing information whenever possible since it will be more reflective of current market-based pricing for the item in question.

In the case of the SD339 supply, we received a large quantity of invoices (21 in total) from multiple different interested parties. Because we had an abundance of invoice data associated with this supply, we averaged together the invoices from the CY 2023 cycle and did not need to include the older invoices from the CY 2022 cycle. We did not include them for the simple reason that they constituted older pricing which was less reflective of current market pricing. We typically do not exclude any invoices in making supply and equipment pricing determinations, however we do not believe that it would be accurate to use older, outdated data when we have readily available invoices which are more current.

Comment: A commenter stated that an underlying problem for establishing appropriate payment rates for External Extended ECG Monitoring is the IDTF model itself, which does not easily fit into the CMS methodology for paying for physician services. The commenter stated that the current PE methodology is based on outdated data from the 2006 PPI Survey performed by the American Medical Association and mostly focuses on expenses related to the traditional physician office which the commenter stated that they did not believe to be comprehensive or accurate. The commenter urged CMS to develop a survey appropriate for IDTFs, especially IDTFs that perform remote monitoring, which would capture unique components of the IDTF cost structure such as expenses related to research and development and unique challenges and regulatory requirements related to AI and software as a service (SaaS).

Response: We agree with the commenter on the need for comprehensive and accurate data for use in our PE methodology. We continue to be interested in potential approaches that can be used to update aspects of the PE methodology, which is why we solicited comments on Strategies for Updates to Practice Expense Data Collection and Methodology in the PE section of the rule. We direct readers to section II.B.5. of this final rule for the full discussion of this topic along with additional comments that we received.

After consideration of the comments, we are finalizing national pricing for CPT codes 93241, 93243, 93245, and 93247 along with an updated price of $260.35 for the SD339 supply.

(26) Cardiac Ablation (CPT Codes 93653, 93654, 93655, 93656, and 93657)

The technologies and clinical practices associated with Cardiac Ablation Services have changed enough over the past decade (since 2011 when they were first developed) that the specialty societies recommended referring theses codes to the CPT Editorial Panel to have the code descriptors for Cardiac Ablation Services updated to create new and more complete descriptors reflecting the fact that many of these services are commonly performed together and should be incorporated and bundled. From the survey results presented to CMS last year, the RUC advisory committee believes that many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to understand that services that are separately billed, were now combined into the existing codes (since CPT did not issue new codes for the revised descriptors). Since then, the RUC has re-surveyed these Cardiac Ablation codes in April 2021 for re-review. In the interim, the work RVUs for the newly bundled CPT codes were maintained at their current values until the new recommendations were presented for CY 2023.

The RUC re-surveyed and reviewed CPT code 93653 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry*), and recommends a work RVU of 15.00 with 31 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 120 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 199 minutes of total time. CPT code 93653 currently has a work RVU value of 14.75 with 23 minutes of pre-service evaluation time, 1 minutes positioning time, 5 minutes scrub/dress/wait time, 180 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 239 minutes of total time. The time and the physician's work of CPT add-on code 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure*) with a work RVU of 5.23 and 90 minutes of total time, and CPT add-on code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)*) with a work RVU of 1.50 and 20 minutes of total time are bundled within CPT code 93653. When all three codes are separately considered, they currently sum up to 21.48 work RVUs, much greater than the 15.00 work RVUs that the RUC has recommended. These codes also add up to much more physician total time than the RUC-recommended 199 minutes.

After reviewing this code and relative similar codes in the PFS, we proposed a comparator CPT code 37229 (*Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed*) with a work RVU of 13.80 and a similar intra-service time of 120 minutes and similar pre-service evaluation, pre-service positioning, pre-service scrub/dress/wait times, and

immediate post-service times, for a sum of 188 minutes of total time for a 000 day global period, compared to the RUC-recommended 199 minutes of total time for CPT code 93653. We proposed a work RVU of 13.80 for the bundled CPT code 93653.

The RUC re-surveyed and reviewed CPT code 93654 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed*), and recommends a work RVU of 18.10 with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 200 minutes of intra-service time, 33 minutes of immediate post-service time, for a sum of 291 minutes of total time. CPT code 93654 currently has a work RVU value of 19.75 with 23 minutes of pre-service evaluation time, 1 minutes positioning time, 5 minutes scrub/dress/wait time, 240 minutes of intra-service time, 40 minutes of immediate post-service time, for a sum of 309 minutes of total time. CPT code 93654 is currently and continues to be a bundled code. The RUC recommended intra-service times and total times for CPT code 93654 are less than the current times for this code, and the RUC-recommended work RVUs are also less than the current work RVUs. Though the RUC recommended a work RVU of 18.10, it is still a relatively high value compared to the existing 19.75 value. The RUC recommended a work RVU of 15.00 for CPT code 93653, and 18.10 for CPT code 93654, with a relative increment between them of 3.10 work RVUs. We proposed to maintain the relative increment RVU difference of 3.10 between CPT code 93653 and CPT code 93654, so because we proposed a work RVU of 13.80 for CPT code 93653, we proposed a work RVU of 16.90 (13.80 plus 3.10) for CPT code 93654, with 200 minutes of intra-service time and 291 minutes of total time.

CPT add-on code 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)*) has a current work RVU of 5.50 with a physician intra-service time of 60 minutes as finalized last year, from a previous value of 7.50 work RVUs with 90 minutes of physician intra-service time. The RUC recommended the re-surveyed intraservice time of 60 minutes and 7.00 work RVUs. The primary change to CPT code 93655 is the reduction of the intraservice time of about 67 percent, which we use as a guide to determine a work RVU. We compared CPT add-on code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*), also with 60 minutes of intraservice and total time and a work RVU of 5.50 to CPT add-on code 93655 and we believed that it is a more accurate valuation than the RUC's work RVU comparison to CPT add-on code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure))* with a work RVU of 8.00 and an intra-service and total time of 60 minutes, and to CPT add-on code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 7.00 and an intra-service and total time of 60 minutes. After reviewing this code and relative similar codes in the PFS, we proposed to maintain the current work RVU for CPT code 93655 of 5.50 with a physician intra-service time of 60 minutes, as finalized last year (86 FR 65108).

The RUC re-surveyed and reviewed CPT code 93656 (*Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed*), *and* recommends a work RVU of 17.00 with 35 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 180 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 263 minutes of total time. CPT code 93656 currently has a work RVU of 19.77 with 23 minutes of pre-service evaluation time, 1 minute positioning time, 5 minutes scrub/dress/wait time, 240 minutes of intra-service time, 40 minutes of immediate post-service time, for a sum of 309 minutes of total time. CPT code 93656 has bundled within it, the time and the physician's work of CPT add-on code 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure*) with a work RVU of 5.23 and 90 minutes of total time and CPT add-on code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)*) with a work RVU of 1.44 and 25 minutes of total time. When all three codes are separately considered, they sum up to 26.44 work RVUs, which is much greater than the 17.00 work RVUs that is recommended and has much more physician total time than the RUC recommended 263 total time minutes.

The RUC recommended intra-service times and total times for CPT code 93656 that are less than the current times for this code and we expect the work RVUs to also be less than the current work RVUs. Though the RUC recommended a work RVU of 17.00, it is still a high value compared to the existing 19.77. The RUC recommended the work RVU for CPT code 93653 as 15.00, and for CPT code 93656 as 17.00, with a relative increment between them of 2.00 work RVUs. As a better valuation for CPT code 93656, we proposed a work RVU of 13.80 for CPT code 93653 plus the relative increment RVU difference of 2.00 that the RUC is maintaining between CPT code 93653 and CPT code 93656 (15.00 subtracted from 17.00 equals 2.00). This would value CPT code 93656 at 15.80 (13.80 plus 2.00) work RVUs for 180 minutes of intra-service time and 263 minutes of total time, which we propose for CY 2023.

CPT add-on code 93657 (*Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to*

code for primary procedure)) has a current work RVU of 5.50 with a physician intra-service time of 60 minutes as finalized last year (86 FR 65108). The previous work RVU was 7.50 with 90 minutes of physician intraservice time. The RUC recommended the re-surveyed intra-service time of 60 minutes and 7.00 work RVUs. The primary change to CPT add-on code 93657 is the reduction of the intra-service time from before the re-survey and the current RUC-recommended time, from 90 minutes to 60 minutes, which is a reduction of about 67 percent, and which we used as a guide to determine an appropriate work RVU. We compare CPT add-on code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*), also with 60 minutes of intra-service and total time, and a work RVU of 5.50, to CPT add-on code 93657, and believe that this is a more accurate comparison for valuation than the RUC's work RVU comparison to CPT add-on code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure))* with a work RVU of 8.00 and an intra-service and total time of 60 minutes, and to CPT add-on code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 7.00 and an intra-service and total time of 60 minutes. After reviewing this code and relative similar codes in the PFS, we proposed to re-affirm the current work RVU of 5.50 with a physician intraservice time of 60 minutes for CPT add-on code 93657, as finalized last year (86 FR 65108).

The RUC did not recommend, and we did not propose, direct PE inputs for CPT codes 93653–93657.

We received many comments concerning CMS' proposed work RVUs for these Cardiac Ablation CPT codes 93653, 93654, 93655, 93656, and 93657.

Comment: Commenters were uniformly against the CMS proposed work RVUs for these codes and urged CMS to accept the AMA RUC-recommended values supported by a robust survey. Commenters argued that the CMS proposed work RVUs for these services are inappropriately low for the long lengths of time required to perform these services, and also neglect to account for the higher intensity of the physician's work with a live beating heart.

Response: Since CY 2011, when these codes were first developed and valued, there is no doubt that cardiac ablation technologies and clinical practices have changed and matured, and thus, these codes were brought to our attention by the AMA RUC for an overdue review. Over the last decade, there have been improvements in the related technologies, new informative results from ongoing research in cardiac ablation, and physicians who have improved their skills and experience and training, all contributing to better methodologies that are refined, to an improved new standard for cardia ablation. They are now performing these services faster, more efficiently, more safely, and more effectively, with better outcomes. This also includes the elimination of duplications of effort, procedure overlaps, and ineffective past practices. Of course, on the other hand, some new techniques and methodologies may require performing concurrent procedures making the better service more complex and more demanding. With all this said, we do agree that cardiac ablation is a complicated and comparatively intensive set of procedures that does take a good amount of time to complete, and that the subsequent changes over the last 10 years have recognized the need to now bundle these services to reflect current typical practices.

At present, the cardiac ablation base CPT codes and their accompanying CPT codes that are paying separately, sum to a total work RVU of 21.48. CPT code 93653 paying 14.75 work RVUs; with CPT code 93613 paying 5.23 work RVUs; and CPT code 93621 paying 1.50 work RVUs. Since the AMA CPT Panel and the RUC are recommending the bundling of these three service codes into CPT code 93653, their recommended work RVUs for CPT code 93653 is 15.00, and is 69.8 percent of the original summed value of 21.48. We further refined the newly bundled work to 13.80 work RVUs and that is 64.2 percent of the original summed value, reflecting what we perceived as improvements and efficiencies gained in how these procedures are now furnished.

Comment: Commenters disagreed with the CMS proposed work RVUs for the cardiac ablation add-on codes and urged CMS to accept the AMA RUC-recommended values.

Response: We remind commenters that those work RVU values were accepted and finalized in last year's rule (86 FR 65108). We accepted the RUC-recommended reductions in physician time from 90 minutes to 60 minutes of intra-service and total time, with a final work RVU of 5.50 for CPT code 93655. We accepted the RUC-recommended reductions in physician time from 90 minutes to 60 minutes of intra-service and total time, with a final work RVU of 5.50 for CPT code 93657, and we see no reason change those final values.

We note that it is challenging to make definitive conclusions about comparisons of relative intensity of work for the same unit of time, especially without seeing objective or competing viewpoints for some or most of the procedures that currently have similar valuations. In developing the PFS, CMS works to mitigate any perceived or explicit bias against or for any organ system or type of services, which may distort actual importance to beneficiaries' health and safety. We also note that levels of intensity can be mathematically different with the shifting of pre-service minutes or immediate post service minutes, to or from intra-service minutes, where intensity values are derived.

After review and consideration of all comments on our proposals for CPT codes 93653, 93654, and 93656, we are persuaded by these comments, and we are finalizing RUC-recommended values of 15.00, 18.10, and 17.00, respectively. CPT add-on codes 93655 and 93657 both remain finalized at 5.50 work RVUs from last year.

(27) Pulmonary Angiography (CPT Codes 93569, 93573, 93574, 93575, 93563, 93564, 93565, 93566, 93567, and 93568)

In May 2021, the CPT Editorial Panel revised CPT code 93568 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure*) which resulted in the creation of four new related CPT add-on codes. CPT add-on codes 93563 to 93567 were surveyed with the four new codes, as part of the same code family.

The RUC surveyed and reviewed CPT code 93563 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (List separately in*

addition to code for primary procedure)), and recommends a work RVU of 1.11 for 15 minutes of intra-service and total time for this add-on service. The current work RVU is 1.11 for 25 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64494 (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)*), with a work RVU of 1.00 for 15 minutes of intra-service and total time. CPT code 64494 is a good comparator in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93563. Therefore, we proposed a work RVU of 1.00 and 15 minutes of intra-service and total time for add-on CPT code 93563.

The RUC surveyed and reviewed CPT code 93564 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (e.g., aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (e.g., internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization (List separately in addition to code for primary procedure)),* and recommends a work RVU of 1.13 for 18 minutes of intra-service and total time for this add-on service. The current work RVU is 1.13 for 25 minutes of intra-service and total time, so there is a reduction of 7 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 31632 (*Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (List separately in addition to code for primary procedure)*) with a work RVU of 1.03 for 18 minutes of intra-service and total time. CPT code 31632 is a good comparator in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93564. Therefore, we proposed a work RVU of 1.03 and 18 minutes of intra-service and total time for add-on CPT code 93564.

The RUC surveyed and reviewed CPT code 93565 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (List separately in addition to code for primary procedure)*), *and* recommends a work RVU of 0.86 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.86 for 20 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)*) with a work RVU of 0.50 for 10 minutes of intra-service and total time. CPT code 64421 is a good comparator code in terms of both the new physician time and due to the proportional work RVU as compared to CPT code 93565. Therefore, we proposed a work RVU of 0.50 and 10 minutes of intra-service and total time for add-on CPT code 93565.

The RUC surveyed and reviewed CPT code 93566 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)*) *and* recommends a work RVU of 0.86 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.86 for 20 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)*) with a work RVU of 0.50 for 10 minutes of intra-service and total time. CPT code 64421 is a good comparator code in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93566. Therefore, we proposed a work RVU of 0.50 and 10 minutes of intra-service and total time.

The RUC surveyed and reviewed CPT code 93567 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)*), and recommends a work RVU of 0.97 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.97 for 15 minutes of intra-service and total time, so there is a reduction of 5 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 74248 (*Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic examination)*) with a work RVU of 0.70 for 10 minutes of intra-service and total time. CPT code 74248 is a good comparator code in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93567. Therefore, we proposed a work RVU of 0.70 and 10 minutes of intra-service and total time.

The RUC surveyed and reviewed CPT code 93568 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure)*), and recommends a work RVU of 0.88 for 13 minutes of intra-service and total time for this add-on service. The current work RVU is 0.88 for 20 minutes of intra-service and total time, so there is a reduction of 7 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we agree with the RUC recommendation and proposed a work RVU of 0.88 with 13 minutes of intra-service and total time for add-on CPT code 93568.

For the first of the related four new add-on codes to this family, CPT code 93569 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral (List separately in addition to code for primary procedure)*), the RUC recommended a work RVU of 1.05 for 11 minutes of

intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 78434 (*Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)*) with a work RVU of 0.63 for 11 minutes of intra-service and total time. CPT code 78434 is a good comparator code in terms of both the physician time, and due to the proportional work RVU, as compared to CPT code 93569. Therefore, we proposed a work RVU of 0.63 and 11 minutes of intra-service and total time for add-on CPT code 93569.

For the second of the related four new add-on codes to this family, CPT code 93573 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral (List separately in addition to code for primary procedure)*), the RUC recommended a work RVU of 1.75 for 18 minutes of intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric and that this service is bilateral. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be HCPCS code G0289 (*Arthroscopy, knee, surgical, for removal of loose body, foreign body, debridement/shaving of articular cartilage (chondroplasty) at the time of other surgical knee arthroscopy in a different compartment of the same knee (List separately in addition to code for primary procedure)*) with a work RVU of 1.48 for 20.5 minutes of intra-service and total time and that this service is bilateral. G0289 has 2.5 minutes of additional physician intra-service time, so we adjusted the comparator work RVU from 1.48 to 1.30. Therefore, we proposed 1.30 work RVUs for 18 minutes of intra-service and total time for add-on CPT code 93573.

For the third of the related four new add-on codes to this family, CPT code 93574 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization. (List separately in addition to code for primary procedure)*), the RUC recommended a work RVU of 1.84 for 20 minutes of intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 93598 (*Measurement of output of blood from heart, performed during cardiac catheterization for evaluation of congenital heart defects (List separately in addition to code for primary procedure)*) with a work RVU of 1.44 for 20 minutes of intra-service and total time. CPT code 93598 is a good comparator code in terms of both the physician time, and due to the proportional work RVU, as compared to CPT code 93574. Therefore, we proposed 1.44 work RVUs for 20 minutes of intra-service and total time for add-on CPT code 93574.

For the last of the related four new add-on codes to this family, CPT code 93575 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, each distinct vessel)*), the RUC recommended a work RVU of 1.92 for 20 minutes of intra-service and total time for this add-on service. The RUC describes this service and the physician's work as very time-intensive and complicated, and the typical patient for this service is pediatric. We agree with the RUC recommendations and proposed a work RVU of 1.92 with 20 minutes of intra-service and total time for add-on CPT code 93575.

The RUC did not recommend, and we did not propose, direct PE inputs for CPT codes 93563–93575.

Numerous comments were submitted concerning this family of pulmonary angiography codes all against the CMS-proposed RVU values.

Comment: Commenters noted that CMS is equating reductions in physician times with reductions in work RVUs, with this family of codes, without regard to the intensity or complexity of these pulmonary procedures, or that some of these codes are primarily typical with pediatrics and congenital heart disease. Commenters recommended that CMS reconsider their proposed values as being too low and to accept the AMA RUC recommended values.

Response: As commenters know, we are obligated to take into account changes in physician times and intensity with changes in work RVUs. We appreciate all of the time and efforts commenters place into their extensive comments in responding to our proposals and we do review these comments in detail to improve our proposals where warranted. When we observe reductions in physician times and no significant change to the procedure's description of work and no change in the procedure's work RVU, or we see recommendations of increases in the procedure's work RVU, we wonder how the intensity of the procedure has changed. Improvements in these procedure's technologies and physicians' training in new skills and methods do contribute to faster, and more efficient outcomes and would result in the reduction of a procedure's work time. At the same time, where duplicate and overlapping efforts are eliminated, new techniques can also introduce complexities that would contribute to the work's intensity without the addition of work time. However, these add-on codes reduce physician work times, and the nature of the PFS relative value system is such that all services are subject to comparisons to one another.

However, we do agree with the commenters' point regarding CPT code 93569 and our proposed work RVU value of 0.63. Our proposed work RVU creates a rank order anomaly within this family of codes whose patients are pediatrics. The AMA RUC-recommended work RVUs between CPT code 93569 and CPT code 93573 reflect about a 67 percent difference between the two codes. Our proposed work RVU for CPT code 93569 of 0.63 is about a 106 percent higher than our proposed work RVU of 1.30 for CPT code 93573, which created a large difference. To correct this error and to maintain that RUC-recommended interval difference between these two codes, we are finalizing a corrected work RVU of 0.78 for CPT code 93569, by applying that RUC-recommended interval difference between CPT codes 93569 and 93573 (1.30 divided by 1.67 = 0.78). This aligns with the intra-service minutes difference between CPT codes 93569 (11 minutes) and 93573 (18 minutes) and the comparator CPT code 58110 (*Endometrial sampling (biopsy) performed in conjunction with colposcopy (List separately in addition to code for primary procedure*)), with similar physician intra-service minutes and a similar work RVU of 0.77. After review and consideration of all comments on our proposals for these Pulmonary Angiography codes, we are finalizing all work RVUs as proposed except for CPT code 93569, whose work RVU we are adjusting from 0.63 to 0.78 for CY 2023.

(28) Quantitative Pupillometry Services (CPT Code 95919)

The CPT Editorial Panel approved a new Category I CPT code to replace the sunset Category III (CPT code 0341T Quantitative pupillometry with interpretation and report, unilateral or bilateral) and 92499 (Unlisted ophthalmological service or procedure for reporting this service).

We did not propose the RUC-recommended work RVU of 0.25 for CPT code 95919, as we believe this is an overestimation based on a comparison to other codes with similar time values, particularly the key reference code CPT code 92081 (*Visual field examination, unilateral or bilateral, with interpretation and report; limited examination (e.g., tangent screen, Autoplot, arc perimeter, or single stimulus level automated test, such as Octopus 3 or 7 equivalent*). In the interest of maintaining relativity with similarly timed codes, we are instead proposing a work RVU of 0.18 with a crosswalk to CPT code 92504 (*Binocular microscopy (separate diagnostic procedure)*). We noted that this value falls between the work RVUs of 0.17 for CPT code 94010 (*Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and 0.20 for CPT code 77081 (*Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)*); both codes have identical intraservice times and similar total times.

We proposed the RUC-recommended direct PE inputs without refinement.

Comment: Commenters did not support our proposed work RVU of 0.18 rather than the RUC-recommended 0.25. A commenter asserted that the RUC survey results are robust and that CMS did not furnish evidence that this service is appropriately valued below the 25th survey percentile. Another commenter stated that CPT code 92504 is a less appropriate crosswalk than the RUC's crosswalk of CPT code 72190 as it does not match the pre/intra/post times and because it was last revalued in 2010.

Response: The RUC-recommended RVU of 0.25 was high in comparison to the range of RVUs for the comparison CPT codes with the same intra-service time and similar total times, and therefore, we believe that CPT code 92504 is a valid crosswalk. We continue to believe that, particularly given that this service is likely to be performed multiple times in a single day, the RUC-recommended value represents a slight overestimation of intensity. We acknowledge that the work times were not an exact match with CPT code 92504 but closely matched the intraservice and total times, and we continue to believe that this is an appropriate crosswalk.

We are finalizing as proposed a work RVU of 0.18 for CPT code 95919 and the RUC-recommended direct PE inputs without refinement.

(29) Caregiver Behavior Management Training (CPT Codes 96202 and 96203)

CPT code 96202 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; each additional 15 minutes (List separately in addition to code for primary service*)), are new codes created by the CPT Editorial Panel during its February 2021 meeting. The two codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's daily life. According to the CPT Summary of Recommendations, during the face-to-face service time, caregivers are taught how to structure the patient's environment to support and reinforce desired patient behaviors, to reduce the negative impacts of the patient's diagnosis on the patient's daily life, and to develop highly structured technical skills to manage patient behavior. As a means of identifying work values for CPT codes 96202 and 96203, three specialty societies sent surveys to a random sample of a subset of their members. Based upon survey results and after discussion, the RUC recommended a work RVU of 0.43 per identified patient service for CPT code 96202. The RUC noted that this recommendation is based upon a median group size of six caregivers and includes 10 minutes pre-time, 60 minutes intra-time, and 20 minutes post-time for a total time of 90 minutes. For CPT code 96203, the 15-minute add-on code, the RUC recommended a work RVU of 0.12, which is also based upon a median group size of six. After reviewing the caregiver training codes, we stated in the proposed rule that CPT codes 96202 and 96203 are not payable under the PFS. We noted that in past rulemaking, we have explained that we read section 1862(a)(1)(A) of the Act to limit Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an individual Medicare beneficiary's illness or injury or that improve the functioning of an individual Medicare beneficiary's malformed body member. For example, in the CY 2013 PFS final rule (77 FR 68979), when discussing payment for the non-face-to-face care management services that are part of E/M services, we stated that Medicare does not pay for services that are furnished to parties other than the beneficiary. We listed as an example, communication with caregivers. Because the codes for caregiver behavior management training describe services furnished exclusively to caregivers rather than to the individual Medicare beneficiary, we did not review the RUC-recommended valuation of these codes or propose to establish RVUs for these codes for purposes of PFS payment. However, recognizing our focus on ensuring equitable access to reasonable and necessary medical services, we requested public comment about the services described by these two codes. First, we sought comment on the ways in which a patient may benefit when a caregiver learns strategies to modify the patient's behavior. We also sought comment on how current Medicare policies regarding these caregiver training services may impact Medicare beneficiary health. Finally, we sought comment about how the services described by these codes might be bundled into Medicare covered services as incident to services or as practitioner work that is part of some care management codes.

Below is a summary of the comments received.

Comment: Most commenters recommended that CMS pay for caregiver behavioral management training services and to use the RUC-recommended values for purposes of payment. Several appreciated CMS displaying the RUC-recommended values. Several commenters asked CMS to reconsider its position on the caregiver behavior management training codes, noting that there is extensive

empirical support for caregiver behavior management training, and that these services are a component of the standard of care for treatment of several health behavior issues. Many commenters asserted that although the patient is not present when this training is provided, these codes have many specific, direct benefits for the patient. The RUC commented that these codes allow for reporting the physician/QHP work and/or time associated with the evidence-based behavioral management/modification training of parent/caregivers, which is performed in tandem with the diagnostic and intervention services furnished directly to the ''identified patient'' that support the patient's optimal level of function.

Some commenters asserted that CMS' proposed application of section 1862(a)(1)(A) of the Act was not appropriate given the well-established evidence of the direct effect the provision of these services on the health outcomes associated with specific chronic conditions, including a reduction in disruptive and problematic behaviors for children with ADHD, improved weight management for individuals with obesity, and better management of patients with dementia.

One commenter noted that if the patient's presence is a requirement for these services, it becomes a barrier to this care for patients with particular health conditions. One commenter indicated that these services are specifically intended to prepare caregivers to implement necessary elements of care plans. This commenter also suggested that not paying for these services would contribute to health inequities issue because in many cases the patients at issue have dementia and other disorders that place them at great social and economic disadvantage.

Commenters also noted that there are other CPT codes, several paid separately under the PFS, that describe services that do not include direct contact with the patient but are still considered integral to the patient's care, including care management services and interprofessional consultations.

Commenters also expressed broad support for the role of caregivers in the health of individuals, indicating that the caregiver's play a critical role in supporting patient care and that caregiver engagement is an important part of the individual patient's plan of care. Other commenters noted that these services when delivered in groups without the patient present have clear advantages over services delivered individually. The commenters suggested that caregiver engagement will help reduce costs and improve access to care. Other commenters stated these services enable caregivers to better address the patient's needs and provide assistance to perform activities of daily living and family caregivers who play a huge role in the patient's long-term care; and many family caregivers are supporting patients with complex care, and expressed fear of making a mistake, with concern being the greatest for managing medications, using meters and monitors, and performing wound care. Several commenters noted that caregiver behavior training is evidence-based and providing training will promote improved outcomes.

A few commenters suggested that CMS might consider adding a caregiver training element to the appropriate chronic care management code and would be pleased to explore with CMS how to implement this service.

Response: We appreciate the response from commenters. We acknowledge the important role that caregivers can have in overall care, especially for Medicare beneficiaries. We also acknowledge the idea that broadly increasing the resources provided to caregivers could have beneficial results on general well-being in addition to reductions in the need for medical or institutional interventions.

However, under section 1862(a)(1)(A) of the Act, Medicare payment is generally limited to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or that improve the functioning of a malformed body member. We sought feedback on the ways in which a patient may benefit when a caregiver learns strategies to modify the patient's behavior. We also sought comment regarding how Medicare policies regarding these caregiver training services may impact Medicare beneficiary health.

Commenters responded by explaining how the training services provided directly to the caregiver treat beneficiary's health conditions. Commenters also explained how the lack of access to these standard treatments would have a disproportionately negative effect on beneficiaries with particular conditions and the practitioners who treat them. Commenters have highlighted that behavioral management/modification training of parents/caregivers, when furnished in tandem with other diagnostic and intervention services related to specific treatment, can be integral to the treatment of a beneficiary's specific condition. Commenters have also pointed out that to the extent that this service is integral to evolving standards of care for people with certain conditions, lack of payment for this service under the PFS would likely result in an inappropriate payment disparity that would have a detrimental impact on access to care for particular beneficiaries and the physicians and other qualified health care professionals that treat them.

We note that in the proposed rule we reiterated that Medicare does not pay for services that are furnished to parties other than the beneficiary. Over the past decade or more, in specific circumstances, we have made payment for some care furnished to beneficiaries through direct involvement of parents, guardians, or caregivers, as well as through interactions with other medical professionals or clinical staff rather than the beneficiary in-person. These circumstances include when the lack of coding and payment for services historically not paid for separately give rise to inappropriate payment disparities that do not reflect the relative resources involved in furnishing treatment, given the changes in medical practice that have led to more care coordination/team-based care, and the idea that the resources involved in those aspects of care are not adequately reflected in current coding/payment. In these cases, we have created coding and separate payment for services such as transitional care management (77 FR 68978), chronic care management (79 FR 67715), behavioral health integration services (81 FR 80226), and virtual check-in services (83 FR 59483). In some cases, we have also specifically made payment for services provided directly to caregivers when, in current practice and in specific circumstances, they are an integral part of ongoing treatment for some patients (81 FR 80331). In the CY 2017 PFS final rule, we noted that we believe that CPT codes 96160 and 96161, Patient, Caregiver-focused Health Risk Assessment codes, describe services that, in particular cases, can be necessary components of services furnished to Medicare beneficiaries. We recognized that in current medical practice, practitioner interaction with caregivers is an integral part of treatment for some patients. Accordingly, the descriptions for several payable codes under the PFS include direct interactions between practitioners and caregivers. We agreed with commenters, that there are circumstances where this service is an essential part of a service to a Medicare beneficiary. Therefore, we assigned active payment status to both codes for CY 2017.

Based on public comments, we believe there could be circumstances, captured in the medical record, where

separate payment for these services may be appropriate. We will continue to consider and contemplate which circumstances or services and for which beneficiaries it would be appropriate to furnish and receive payment for these types of services in future notice and comment rulemaking.

We appreciate the thoughtful feedback submitted by the public on this matter. We intend to address these codes more thoroughly during the CY 2024 rulemaking process as we review other coding and valuation changes.

(30) Cognitive Behavioral Therapy Monitoring (CPT code 98978).

See the Remote Therapeutic Monitoring (RTM) section II.I. of this final rule for a review of new device code, CPT code 98978.

(31) Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS Codes G0442 and G0444)

Interested parties have raised concerns with the portion of the code descriptors that require a certain number of minutes to bill for the HCPCS codes G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0444 (*Annual depression screening, 15 minutes*). Over the past several years, AAFP and the ACP have requested that CMS revise the code descriptors to state ''up to 15 minutes'' instead of the current ''15 minutes,'' allowing practitioners to efficiently furnish the service. As currently described, claims for the service are said to be denied by MACs in instances where records suggest that a full 15 minutes was not reached by the practitioner when furnishing the service. Both codes were high in volume for 2019 and 2020, with over 700,000 reported services in our Medicare claims data.

Medicare Part B coverage for such screenings originated from a national coverage determination (NCD) from 2011 and 2012. We believe that these screenings may not require a full 15 minutes to perform for the typical patient, so we believed that it would be appropriate to propose to revise the descriptors to specify that screening times of 5 to 15 minutes would be the typical range to furnish these services. This will establish a lower time limit for both HCPCS codes G0442 and G0444. Therefore, we proposed to modify the descriptor for HCPCS code G0442 to read ''*Annual alcohol misuse screening, 5 to 15 minutes*'' and for HCPCS code G0444 to read ''*Annual depression screening, 5 to 15 minutes*.''

We received a number of comments concerning the adjustments to the descriptors of HCPCS codes G0442 and G0444.

Comment: Commenters were all in favor of the descriptor changes made for these codes and for the clarification of these services. The commenters universally expressed their support and a few recommended that CMS should re-review the valuations for these services to ensure proper payment.

Response: We thank commenters for their supporting comments on the descriptor adjustments to HCPCS codes G0442 and G0444. When substantial descriptor changes are made to some CPT codes, that does signal to CMS to re-review all aspects of a service and to possibly align for proper payment. These descriptor changes were to HCPCS codes and they do not change the currently established payments for them. They are just a clarification for the claims process to smooth out any possible misunderstanding of conditions of payment and our original intent in allowing payments for these services.

After review and consideration of all comments regarding our proposals for HCPCS codes G0442 and G0444, we are finalizing our descriptor changes as proposed, to ''Annual alcohol misuse screening, 5 to 15 minutes'' for HCPCS code G0442 and to ''Annual depression screening, 5 to 15 minutes.'' for HCPCS code G0444.

(32) Insertion, and Removal and Insertion of New 180-Day Implantable Interstitial Glucose Sensor System (HCPCS Codes G0308 and G0309)

For the CY 2021 PFS final rule (85 FR 84645), we established national pricing for 3 Category III CPT codes that describe continuous glucose monitoring. Category III CPT codes 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*), 0447T (*removal of implantable interstitial glucose sensor from subcutaneous pocket via incision*), and 0448T (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*) describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from a subcutaneous pocket. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provide glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The direct PE inputs for CPT code 0446T include a 90-day supply item, SD334 (implantable interstitial glucose sensor), and a 90-day smart transmitter proxy equipment item, EQ392 (heart failure patient physiologic monitoring equipment package). The direct PE inputs for CPT code 0448T include only the 90-day SD334 interstitial glucose sensor.

For CY 2022, based on requests from interested parties for CMS to allow beneficiaries critical access to a newly approved 180-day continuous glucose monitoring system, CMS established two new HCPCS codes to describe the new 180-day monitoring service. Specifically, CMS established HCPCS code G0308 (*Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training*) and G0309 (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation*). The newly approved 180-day continuous glucose monitoring system extends the monitoring period from the previous 90 days to allow for a longer monitoring period between replacement of the sensor. We believe it is important for beneficiaries to have continued access to this service during the transition from a 90- to 180-day monitoring period where the 90-day sensor may become obsolete. Therefore, effective July 1, 2022, HCPCS codes G0308 and G0309 are contractor priced. We solicited information and invoices from interested parties on the costs of the 180-day interstitial glucose supply and 180-day smart transmitter equipment direct PE inputs for HCPCS codes G0308 and G0309 to ensure proper payment for these physician's services, for consideration of national payment amounts for CY 2023. We noted that the 90-day supply item, SD334, is currently priced at $1,500 based on information we received from interested parties. The 90-day smart transmitter, EQ392, is currently priced at $1,000 and assigned a time value of 25,290 minutes derived from 60 minutes per hour times 24 hours per day times 90 days per billing quarter divided by 1 minute of equipment use of every 5 minutes of time. HCPCS code G0308 includes the smart transmitter and interstitial glucose sensor and HCPCS code G0309 includes the interstitial glucose sensor only.

Comment: Commenters supported our creation of G codes G0308 and G0309 to describe the new 180-day interstitial continuous glucose monitor. Commenters also requested that we

delete the G codes effective January 1, 2023 and revalue CPT codes 0446T and 0448T to include direct PE costs for the new sensor and transmitter, since the current 90-day sensor and transmitter has become obsolete. We also received invoices and pricing information from a commenter to support their requested PE revaluation.

Response: We agree with commenters that we should delete G codes, G0308 and G0309, effective January 1, 2023 to ensure accurate payment for the new 180-day Continuous Glucose Monitoring device. We also agree to revalue the PE inputs for the existing CPT codes, 0446T and 0448T. The invoices that we received from a commenter list a supply increase (SD334) from $1,500 to $3,000, which would be a supply input for both 0446T and 0448T. The invoices also list the equipment (EQ392) as having an increase in equipment minutes, but not a change in the cost of the transmitter itself. The increase in equipment minutes applies only to CPT code 0446T. The physician work remains the same for both codes, therefore there is no change to work RVUs.

In consideration of the comments and invoices received, we are finalizing changes to codes G0308, G0309, 0446T, and 0448T. G codes G0308 and G0309 will be deleted effective January 1, 2023. CPT codes 0446T and 0448T will have supply input SD334 valued at $3,000. CPT code 0446T equipment EQ392 will have equipment minutes equal to 60 minutes * 24 hours * 30 days * 6 months/1 out of every 5 minutes = 51,840 minutes.

(33) Chronic Pain Management and Treatment (CPM) Bundles (HCPCS G3002 and G3003, Formerly GYYY1 and GYYY2, Respectively)

(a) Background and Proposal

In the CY 2022 PFS proposed rule (86 FR 39104, 39179 through 39181), we solicited comments on and explored refinements to the PFS that would appropriately value chronic pain management and treatment (CPM) for the purpose of future rulemaking. In our solicitation, we described Federal efforts for more than a decade to effectively address pain management as a response to the nation's overdose crisis,[10] such as the National Pain Strategy [11] and the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF) Report.[12] As we noted in our CY 2022 comment solicitation, several sections of the Support for Patients and Communities Act of 2018 [13] (SUPPORT Act) describe actions the Department of Health and Human Services has been directed to take to improve pain care, such as section 2003, which amended Medicare's Annual Wellness Visit [14] to include a review of factors for evaluation related to pain for patients using opioid medications; section 6086, the Dr. Todd Graham Pain Management Study; [15] and section 6032, which required CMS to furnish a Report to Congress and develop a related Action Plan to review coverage and payment policies in Medicare and Medicaid related to the treatment of opioid use disorder and for non-opioid therapies to help manage acute and chronic pain.[16] In the section 6032 Report and the Action Plan, CMS included a recommendation to explore the possibility of establishing a new bundled payment under the Medicare Physician Fee Schedule for integrated multimodal pain care that could include certain elements such as diagnosis, a person-centered plan of care, care coordination, medication management, and other aspects of pain care.

As described in Goal 3 of CMS' 2022 Behavioral Health Strategy [17] (Strategy), CMS intends to improve the care experience for individuals with acute and/or chronic pain, expand access to evidence-based treatments for acute and chronic pain, and increase coordination between primary and specialty care through payment episodes, incentives, and payment models. In late 2019, the CMS Office of Burden Reduction & Health Informatics launched the ''Chronic Pain Stakeholder Engagement,'' which focused on understanding access to covered treatment and services for people living with pain. [18] CMS recently released information gathered from interested parties through this Engagement using qualitative research methods and the human-centered design process, to uncover provider burden, and identify opportunities to improve access to covered services by illustrating the experiences of people living with, and treating, chronic pain. The intent of this project was to highlight the most prominent barriers people with pain face in accessing care, and the factors influencing clinicians that can affect people with chronic pain, the quality of their care, and their quality of life.

In the context of the Biden-Harris' Administration's commitment to equity,[19] and the inclusion of equity as a pillar of CMS' Strategic Vision,[20] disparities exist in pain treatment due to bias in treatment, language barriers, cultural norms, and socioeconomic status. We are also aware that pain is a factor in suicidality and suicide, prioritized in the Surgeon General's Call to Action to Implement the National Strategy for Suicide Prevention [21] and in HHS' work to implement ''988'',[22] the new national dialing code for suicide and crisis assistance that was implemented nationally this year.

In coordination with all of these initiatives, we also have continued to explore refinements to the PFS that would appropriately value CPM. In the CY 2022 PFS proposed rule, we sought comment on whether we should approach CPM through a standalone code or E/M add-on coding, and about the specific activities that are involved in CPM, how we might value such a code or service, the settings where this care is provided, the types of practitioners that furnish this care, and whether the service or any components of it could or should be furnished as ''incident to'' [23] services under the direction of the billing practitioner by other members of the care team (86 FR 39182). We received just under 2,000 comments on this comment solicitation, including comments from provider associations, federations, and societies that represent health care professionals; organizations that educate, connect, and advocate for people with pain; State-based health care organizations, medical societies and associations; cancer care centers; health care companies; device manufacturers; pain care providers; and people living with pain. Almost all commenters were supportive of our efforts to carefully consider an approach to coding and payment for care for CPM. Many commenters supported the creation of separate coding and payment for CPM under the PFS. We summarized

[10] *https://www.hhs.gov/overdose-prevention/.*

[11] *https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf.*

[12] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[13] *https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf.*

[14] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html.*

[15] *https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence.*

[16] *https://www.cms.gov/sites/default/files/2022-4/SUPPORT%206032%20Action%20Plan_Final_061521_Clean.pdf.*

[17] *https://www.cms.gov/cms-behavioral-health-strategy.*

[18] *https://www.cms.gov/About-CMS/OBRHI.*

[19] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[20] *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[21] *https://www.hhs.gov/sites/default/files/sprc-call-to-action.pdf.*

[22] *https://www.samhsa.gov/find-help/988.*

[23] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMatters Articles/downloads/se0441.pdf.*

these comments, expressed appreciation for the commenters' attention to informing our approach to payment and coding for comprehensive CPM services, and thanked the commenters for their comments in the CY 2022 PFS final rule (86 FR 65129).

Generally, commenters agreed that efforts are needed to effectively support the complex needs of beneficiaries with chronic pain. Commenters emphasized that there are numerous conditions giving rise to chronic pain and that people presenting with chronic pain respond variably to various treatment modalities, and often require longer office visit times, and longer follow-up coordinating care with social workers and case managers, mental and behavioral health support, communications with emergency department physicians and nurses, and numerous medication adjustments. One commenter stated that beneficiaries with complex chronic pain conditions may require a lot of time for correct dosing of medications and counseling, and that such time is not captured effectively using existing E/M codes. This commenter also believed that separate coding and payment for chronic pain management could help with better understanding of the treatment of chronic pain than when the service is reported with existing visit codes and would allow for valuation based on the resources involved in furnishing these specific services to people with chronic pain, enhancing the likelihood of appropriate payment, especially for non-face-to-face time involved with the service.

A few commenters expressed preference for using existing E/M codes and the creation of codes to be used in conjunction with E/M codes. One commenter suggested that CMS either clarify or modify existing codes so they can support services for patients with chronic pain or significant acute pain, as well as beneficiaries with a chronic disease and a behavioral health condition, stating that using the existing codes would avoid any concerns about overpayment for patients with both a chronic disease and pain, while also making it more feasible for small practices to employ care management staff and provide customized care management services for all the patients who need them.

One commenter who was agreeable with various approaches to payment suggested that the guidelines for Cognitive Assessment and Care Plan Services code 99483 include ''chronic pain syndromes'' in the ''assessment of factors that could be contributing to cognitive impairment'' and that these codes could be reported by physicians who consult with a pain specialist about their patient's pain. This commenter also suggested that Transitional Care Management could also potentially include pain management following inpatient care to help prevent acute pain from progressing to chronic pain. Other commenters also likened CPM services to chronic care management services. We believe that chronic care management codes, which, except for Principal Care Management, specify that the chronic condition being managed is expected to last at least one year or until death, would not properly describe the condition of many beneficiaries with chronic pain, which could potentially improve with treatment and intervention, or recur after improvement. For example, the 11th revision of the World Health Organization's International Classification of Diseases and Related Health Problems define chronic pain as persistent or recurring pain lasting longer than 3 months.[24]

Commenters included feedback about other specific activities involved in the management of patients with chronic pain in addition to those we specified in the comment solicitation. Commenters also identified codes that CMS might examine as models for payment, either as stand-alone timed codes or monthly bundles. Commenters suggested which practitioners should be able to bill such CPM codes, which practitioners should be able to furnish CPM services incident to the services of a physician or other practitioner, and expressed views on adding CPM services to the Medicare Telehealth Services List and obtaining beneficiary consent for CPM services.

We agree with commenters who believe that E/M codes may not reflect all the services and resources required to furnish comprehensive, chronic pain management to beneficiaries living with pain. While we agree in principle that it might be appropriate to establish bundled all-inclusive coding with monthly payment for a broader set of CPM services, we do not have data at the present time on the full scope of services and resource inputs involved in care for patients with chronic pain to support development of a proposed monthly bundled all-inclusive rate. We do believe that E/M codes do not appropriately reflect the time and other potential resources involved in furnishing comprehensive CPM for beneficiaries with chronic pain. Beginning in the CY 2014 PFS final rule (78 FR 74414 through 74427), we recognized that the resources involved in furnishing comprehensive care to patients with multiple chronic conditions are greater than those required to support care in a typical E/M service. In response, we finalized a separately payable HCPCS code G0316 (*Chronic Care Management (CCM) services furnished to patients with multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient; 20 minutes or more per in 30 days of chronic care management services provided by clinical staff and directed by a physician or other qualified health care practitioner*). The following year, in the CY 2015 PFS final rule (79 FR 67715 through 67730), we refined aspects of the existing CCM policies and adopted separate payment for CCM services under CPT code 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; Comprehensive care plan established, implemented, revised, or monitored*). In the CY 2017 PFS final rule (81 FR 80244), we adopted CPT codes 99487 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month)* and 99489 *(CCCM services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional,*

[24] *https://icd.who.int/en.*

per calendar month (List separately in addition to code for primary procedure)). Then, in the CY 2019 PFS final rule (83 FR 59577), we adopted a new CPT code, 99491 *(CCM services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*), to describe at least 30 minutes of CCM services performed personally by a physician or NPP. In the CY 2020 PFS final rule (84 FR 62690), we established payment for an add-on code to CPT code 99490 by creating HCPCS code G2058 *(CCM services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month).* We also created two new HCPCS G codes, G2064 and G2065 (84 FR 62692 through 62694), representing comprehensive services for a single high-risk disease (that is, principal care management). In the CY 2021 PFS final rule (85 FR 84639), we finalized a RUC-recommended replacement code for HCPCS code G2058 with the identical descriptor, CPT code 99439, and assigned the same valuation as for G2058. For CY 2022, the RUC resurveyed the CCM code family, including CCCM and Principal Care Management (PCM), and added five new CPT codes: 99437 (*CCM services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99424 (*PCM services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*), 99425 (*PCM services for a single high risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure*), 99426 (*PCM, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*), and 99427 (*PCM services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*).

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who directly performs the services (that is, clinical staff, or the physician or NPP), and the time spent furnishing the services. The RUC-recommended values for work RVUs and direct PE inputs for these codes in CY 2022 were derived from a recent RUC specialty society survey. We proposed to accept the RUC-recommended values, considered public comments, and finalized the proposed values for the 10 CCM/CCCM/PCM codes.

In consideration of the supportive comments we received last year in response to our comment solicitation, clinical expertise within CMS, and internal input from CMS staff and from our HHS operating division partners, we proposed to create separate coding and payment for CPM services beginning January 1, 2023. We recognize that there is currently no existing CPT code that specifically describes the work of the clinician who performs comprehensive, holistic CPM. We also believe the resources involved in furnishing CPM services to beneficiaries with chronic pain are not appropriately recognized under current coding and payment mechanisms. As noted above, we do not believe that E/M codes and values appropriately reflect time involved in furnishing CPM for beneficiaries with chronic pain. CMS has authority under section 1848 of the Act to establish codes that describe services furnished by clinicians and suppliers that bill for physicians' services, and to establish payment amounts for those services that reflect the relative value of the resources involved in furnishing them. We also expect that creating separate coding and payment for CPM will help facilitate the development of data regarding the prevalence and impact of chronic pain in the Medicare population, where conditions including osteoarthritis, cancer, and other similar conditions that cause pain over extended periods of time are common.[25] Such information can assist us in identifying potential coding and valuation refinements to ensure appropriate payment for these services. We also believe that the comprehensive care management involved in CPM services may potentially prevent or reduce the need for acute services, such as those due to falls [26] and emergency department care [27] associated with chronic pain—for example, sickle cell disease or migraine pain—and also have the potential to reduce the need for treatment for concurrent behavioral health disorders, including substance use disorders. There is some evidence that addressing chronic pain early in its course may result in averting the development of ''high-impact'' chronic pain [28] in some individuals; these people report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain.

There are various definitions for chronic pain from, for example, the Centers for Disease Control and Prevention [29] and the National Institutes of Health,[30] and in the Institute of Medicine's (IOM) ''Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research'',[31] and in the World Health Organization International Classification of Disease Edition 11,—most define chronic pain consistently, with some variation, as pain that persists longer than 3 months. The CDC, for example, has defined chronic pain within its 2016 opioid prescribing Guideline as ''pain that typically lasts >3 months or past the time of normal tissue healing, and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.'' For clarity and operational use, we proposed to define chronic pain as ''persistent or recurrent pain lasting longer than 3 months.'' We welcomed comments from the public regarding whether this was an appropriate definition of chronic pain, or whether we should consider some other interval or description to define chronic pain. We were also interested in hearing from commenters about how the chronic nature of the person's pain should be documented in the medical record.

We posited a monthly payment approach may also be more financially straightforward from the standpoint of

[25] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.*

[26] *https://www.cdc.gov/falls/facts.html.*

[27] *https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence.*

[28] *https://www.sciencedirect.com/science/article/pii/S1526590018303584?via%3Dihub.*

[29] *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.*

[30] *https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain.*

[31] *https://www.ncbi.nlm.nih.gov/books/NBK92525/#ch1.s3.*

beneficiaries receiving treatment for chronic pain, particularly with respect to applicable coinsurance, which is generally 20 percent of the payment amount, after the annual Part B deductible amount is met.[32]

Beginning for CY 2023, we proposed to create two HCPCS G-codes to describe monthly CPM services. The codes and descriptors for the proposed G-codes are:

• HCPCS code G3002: *Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)*

• HCPCS code G3003: *Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month. (List separately in addition to code for G3002. When using G3003, 15 minutes must be met or exceeded.)*

We were interested in hearing from commenters regarding our proposed inclusion of ''administration of a validated pain assessment rating scale or tool,'' as an element of the proposed CPM services, and including it within the descriptor of the proposed HCPCS code G3002. We also solicited comment on whether a repository or list of such tools would be helpful to practitioners delivering CPM services.

We proposed to include, as an element of the CPM codes, the development of and/or revisions to a person-centered care plan that included goals, clinical needs, and desired outcomes, as outlined above and maintained by the practitioner furnishing CPM services.

We proposed to include health literacy counseling as an element of the CPM codes, because we believe it will enable beneficiaries with chronic pain to make well-informed decisions about their care, increases pain knowledge, and strengthens self-management skills. Health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.[33] Adequate health literacy may improve the person's capability to take responsibility for their health, including pain-related health issues such as adherence to treatment regimens and medication administration, and have a positive influence on health outcomes, and health disparities. CMS' Network of Quality Improvement and Innovation Contractors have used health literacy counseling to improve health counseling,[34] and health literacy counseling has been used to treat arthritis.[35] We noted in the proposed rule that we were interested in hearing from commenters about how pain and health literacy counseling is or may be effectively used as a service element to help beneficiaries with chronic pain make well-informed decisions about their own care, weigh risks and benefits, make decisions, and take actions that are best for them and their health.

For HCPCS code G3002, we proposed to include an initial face-to-face visit of at least 30 minutes, provided by a physician or other qualified health professional, to a beneficiary who has chronic pain, as defined above, or is being diagnosed with chronic pain that has lasted more than 3 months at the time of the initial visit. After consultation with our medical officers, we believe the management of a new patient with chronic pain would involve an initial face-to-face visit of at least 30 minutes due to the complexity involved with the initial assessment. We believe follow-up or subsequent visits could be non-face to face. HCPCS code G3003 describes an additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (listed separately in addition to G3002). We solicited comment on the appropriateness of the proposed 30-minute duration per calendar month for G3002, and also on the proposed duration and frequency for G3003. We also solicited comment on whether we should consider specifying a longer duration of time for G3002 (for example, one hour—or 45 minutes). Similarly, we solicited comment on whether we should consider specifying a longer duration of time for G3003 (for example, 20-minute increments). We also welcomed comment on our proposal to permit billing of CPM services for beneficiaries who have already been diagnosed with chronic pain, and for people who are being diagnosed with chronic pain during the visit.

We welcomed comments regarding how best the initial visit and subsequent visits should be conducted (for example, in-person, via telehealth, or the use of a telecommunications system, and any implications for additional or different coding). We also considered whether to add the CPM codes to the Medicare Telehealth Services List, based on our review of any information provided through the public comments and our analysis of how these new services may be appropriately furnished to Medicare beneficiaries. We also requested comment regarding whether there are components of the proposed CPM services that do not necessarily require face-to-face interaction with the billing practitioner, such as care that could be provided by auxiliary staff incident to the billing practitioner's services. For any components that could be furnished incident to the services of the billing practitioner, we requested comment on whether these could be appropriately furnished under the general supervision of the billing physician or non-physician practitioner (NPP), for example, administration of a pain rating scale or tool, or elements of care coordination, as we have provided for certain care management services.

We believe that most CPM services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain. As calls for improved pain management have increased in recent years, this has resulted in better education and training of primary care practitioners and heightened awareness of the need for pain care nationally. We believe the codes we proposed for CPM services will create appropriate payment for physicians and other practitioners (beyond primary care practitioners) that reflects the time and resources involved in attending comprehensively to the needs of beneficiaries with chronic pain. As the IOM ''Blueprint'' report noted, even people who need consultation with a pain specialist

[32] *https://www.medicare.gov/what-medicare-covers/what-part-b-covers.*

[33] *https://health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030#:~:text=Health%20literacy%20is%20a%20central,well-being%20of%20all.%E2%80%9D.*

[34] *https://qi.ipro.org/health-equity/health-literacy/.*

[35] *https://www.ahrq.gov/health-literacy/improve/precautions/1stedition/tool3.html.*

should benefit from the sustained involvement of a primary care practitioner who is able to help coordinate care across the full spectrum of health care providers, as such coordination ''helps prevent people from seeking relief from multiple providers and treatment approaches that may leave them frustrated and angry and worse off both physically and mentally, and from falling into a downward spiral of disability, withdrawal, and hopelessness.'' [36] The Blueprint stated that this type of fragmentation hinders the development of a strong, mutually trusting relationship with a single health professional who takes responsibility, and that this established relationship is one of the keys to successful pain treatment. We anticipated that if these proposed codes are finalized, primary care practitioners will employ a variety of person-centered pain management strategies, such as those suggested in the PMTF Report and illustrated in CMS' CPM graphic [37] including medications, therapies, exercise, behavioral health approaches, complementary and integrative health, and community-based care based on the complexity, goals, and characteristics of each person they serve with chronic pain and according to the person-centered plan of care. It is also important to note that, in many parts of the country, people have access only to their primary care practitioner for chronic pain care.[38] We understand, however, the need or desire that some individuals with chronic pain have to be seen on an ongoing basis for CPM by a pain specialist who has received special training and/or certification to meet the needs of the most complex and challenging patients with chronic pain.

Therefore, we proposed to permit billing by another practitioner after HCPCS code G3002 has already been billed in the same calendar month by a different practitioner. In these situations, we anticipate that there could be occasional instances where care of an individual with chronic pain is transferred to a pain specialist or other specialist during the same month they received the CPM services from a primary care practitioner, for ongoing care. In these or other situations (such as when the beneficiary elects to choose a different physician or practitioner to furnish CPM services), we would anticipate G3002 and potentially G3003 could be billed by another practitioner during the same month, for the same beneficiary. We believe that it would be unlikely for G3002 to be billed more than twice per month under such circumstances and proposed placing a limit on the number of times the code could be billed per beneficiary per calendar month, at a maximum of twice per calendar month. We solicited comment on our proposal to permit billing by another practitioner after the G3002 has already been billed in the same month by a different practitioner, and on the number of times the code could be appropriately billed per month, per beneficiary.

We proposed to require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record, as not all Medicare beneficiaries with chronic pain eligible to receive these separately billable CPM services may understand or want to receive these services, and the beneficiary should be aware that they are receiving them. At the initial visit, the beneficiary with chronic pain should be educated regarding what the CPM services are, how often they may generally expect to receive the services, and have an explanation of any cost sharing that may apply in their particular situation. Practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of similar care management services, such as CCM services, and we solicited comment on how best to effectively educate both practitioners and beneficiaries with chronic pain about the existence of, and the benefits and value of, the proposed CPM services. We solicited comment regarding whether the initiating visit is the appropriate time for billing practitioners to obtain beneficiary verbal consent, if consent should be given at each visit, and also if beneficiary consent should be sought by the practitioners with whom CPM billing practitioners coordinate other Medicare services under the CPM plan of care, or even more broadly.

We believe there might be some potential for duplicative payment for services allocated to the same patient concurrent with certain other Medicare care management services, such as CCM or behavioral health integration (BHI) services; however, we believe the proposed CPM codes have features that would mitigate such circumstances, such as the elements of the service that specifically address the beneficiary's pain—for example, the administration of a validated pain rating scale or tool. We welcomed comments regarding what, if any, Medicare services we should consider that could not be billed by the same practitioner for the same patient concurrent with any other Medicare services, to avoid duplication of payment, and help limit financial burden to the Medicare beneficiary with chronic pain. We noted that we would expect to refine these codes as needed through future rulemaking as we receive more information how the codes are being used, and how they are implemented in practice.

To the extent that components of the proposed CPM codes are also components of other care management services, we reiterate our policy against double-counting time and require that the time used in reporting CPM services may not represent time spent in any other reported service. We proposed that the CPM codes could be billed in the same month as a care management service, such as CCM, or BHI. We believe there are circumstances in which it is reasonable and necessary to provide both services in a given month, based on the needs of the Medicare beneficiary with chronic pain, for example, when the beneficiary has both chronic pain, and a mental disorder(s), or multiple chronic conditions. We also proposed that the CPM codes would be able to be billed for the same Medicare patient in the same month as another bundled service such as HCPCS Codes G2086–G2088, which describe bundled payments under the PFS for opioid use disorders. We noted that patient consent would need to be obtained for both of the bundled services such as, for example, CPM and BHI, and all other requirements to report CPM and to report the other service or services would need to be met. We invite comments on these billing proposals and their appropriateness in the context of CPM.

Finally, we questioned commenters whether we should consider creating additional coding and payment to address acute pain. We are interested in information regarding a definition for acute pain, standalone or E/M coding, the specific activities that could be furnished, how we might value and price such a code or service, the settings where care should be provided, the types of practitioners that should furnish acute pain care, if the service or any components should be furnished as ''incident to'' services under the direction of the billing practitioner or by other members of the care team, and other information that might help us in proposing such a code or codes.

[36] *https://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[37] *https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf.*

[38] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

(b) Valuation of Chronic Pain Management Services

Consistent with the valuation methodology for other services under the PFS, proposed HCPCS codes G3002 and G3003 would be valued based on what we believe to be a typical case, and we understand that, based on variability in patient needs, some patients will require more resources, and some fewer. The proposed CPM codes would separately pay for a specified set of CPM elements furnished during a month, including the administration of validated rating scales, establishment and review of a person-centered care plan that includes goals, clinical needs, and desired outcomes, and other elements as described in the proposed code descriptors. To value CPM, we compared the proposed services to codes that involve care management. In doing so, we concluded that the CPM services were similar in work (time and intensity) to that of PCM in that both the PCM codes and proposed CPM codes reflect services that have similar complexities, possible comorbidities, require cognitive time on the part of the practitioner, and may involve coordination of care across multiple practitioners.

For HCPCS code G3002, we developed proposed inputs using a crosswalk to CPT code 99424 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month.*), which is assigned a work RVU of 1.45. Additionally, for G3002 we proposed to use a crosswalk to the direct PE inputs associated with CPT code 99424. We believe that the work and PE described by this crosswalk code is analogous to the services described in G3002, because G3002 includes similar *care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional,* as described in CPT code 99424.

We proposed to value G3003 at a work RVU of 0.50, using a crosswalk to CPT code 99425 (*each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month) (List separately in addition to code for G3002*), which is assigned a work RVU of 1.00. However, the required minimum number of minutes described in G3003 is half of the number of minutes in CPT code 99425. For HCPCS code G3003, we proposed to use a crosswalk to half of the direct PE inputs associated with CPT code 99425. We believe that the work and PE described by this crosswalk code is analogous to the services described in G3003, because G3003 includes similar activities as described in CPT code 99425.

We proposed that G3002 can only be billed when the full 30 minutes of service time has been met or exceeded. Additionally, we proposed that the add-on code (G3003) can only be billed when the full 15 minutes of service time is met or exceeded.

Our proposed valuation of CPM services includes services that are personally performed by a physician (or other appropriate billing practitioner, such as a nurse practitioner (NP) or physician assistant (PA)) described by certain E/M visit codes that apply to a new patient in various settings. Accordingly, we proposed that G3002/G3003 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 99202– 99215 (*Office/outpatient visits new*), since these codes reflect face-to-face services furnished by the physician or other billing practitioner for related, separately billable services that are being furnished to a patient the practitioner has not previously seen. We believe it would be unlikely the practitioner is prepared to address the complex pain needs of a new patient on the same day he or she is seen for a general visit, or a visit where the person is being seen for some other illness or condition. We do not believe that the services included in G3002/G3003 would significantly overlap with CCM services; Transitional Care Management (TCM) services; or BHI services, which have various clinical purposes separate from CPM. We do believe there is likely overlap in the Medicare beneficiary population eligible to receive CCM, TCM, BHI, and the proposed CPM services, but we believe there are distinctions in the nature and extent of the assessments, care coordination, medication management, and care planning for CPM to allow concurrent billing for services that are medically reasonable and necessary, and that it is particularly important to allow for the provision of needed services, including behavioral health services, to beneficiaries with chronic pain. We solicited comment on whether we have appropriately identified the codes Medicare should not pay if furnished during the same day as the proposed CPM codes, and if there are circumstances where multiple care planning codes could be furnished without overlap or other situations, such as where the practitioner is seeing a new patient.

We noted that the proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings. We will consider for future rulemaking separately identifying and paying for CPM services furnished to beneficiaries in any appropriate setting of care, in recognition of the prevalence and burden of pain across all settings of care, and the associated time and service complexity to provide care for chronic pain. We appreciate comments on other settings where CPM services could be provided.

(c) Request for Comment

We believe there could be circumstances in which a beneficiary receiving CPM services needs referrals or recommendations, based on a clinician's assessment, for services or interventions that are not included as elements of the CPM services, such as for community-based care or physical and occupational therapy. We welcomed comments on the care coordination that may occur between relevant practitioners furnishing services, such as complementary and integrative care, and on the community-based care element included in the descriptors for proposed G3002 and G3003.

We also asked commenters to weigh in on how documentation of the performance of the elements of CPM services might best be addressed in medical recordkeeping. We solicited general comment on whether there are any elements of CPM services outlined in this proposal that the public and interested parties believe are not typically furnished in connection with comprehensive chronic pain management, or any proposed elements of the CPM services that should be removed or altered. We solicited comment on whether there are elements

of CPM services that we have not identified and should be added to the code descriptors.

Additionally, we solicited comment on which, if any, CPM elements could be furnished as ''incident to'' services, and whether to add G3002 and G3003 to the list of services for which we allow general supervision as described in our regulation at § 410.26(b)(5). We welcomed comments from the public for future rulemaking regarding what elements of the CPM services could be furnished under general supervision, or direct supervision. For example, facilitation and coordination of any necessary behavioral health treatment, chronic pain related crisis care, and ongoing communication and care coordination between relevant practitioners furnishing care might be appropriate activities to be considered under general supervision.

The proposed CPM codes may involve arrangements where the physician or other health professional might work in collaboration with other health care providers or members of a care team, such as a psychologist, dental practitioner, or social worker, where these individuals might furnish certain elements of the service bundle under the direction of the physician or qualified health practitioner, such as assessments, person-centered care planning, referrals to community-based care, and other activities, as appropriate. We requested comments on if, and how, we should structure the proposed CPM code and payment for these services to account for these types of arrangements that could include team-based care.

We received over 150 unique comments on our proposal from national health care organizations including provider associations, federations, and societies that represent health care professionals; organizations that educate, connect, and advocate for people with pain; State-based health care organizations, medical societies and associations; cancer care centers; health care companies; hospice and palliative care organizations; device manufacturers; pain care providers; and people living with pain and their caregivers. Almost all commenters were supportive of our proposal. We also received several comments mainly from psychologists or psychology associations, requesting we adopt additional coding without medication management in the code descriptor, as medication management in most states is outside the scope of a psychologist's license. The following is a summary of the comments we received and our responses.

Comment: Commenters living with chronic pain and their caregivers shared poignant stories about the importance of the proposed codes. One person observed that in recent years, since the release of the Centers for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids, for people taking opioid medications or for those who were forced to stop taking medications, the relationship between providers and patients has become fraught, tense, and stigmatizing, even risky for physicians and for all these reasons, many clinicians have refused to treat chronic pain patients or have terminated chronic pain patients from their practices, with growing numbers of pain patients unable to find anyone to treat them, even if they do not use opioid medications. The spouse of a person living with chronic pain told of repeated trips to a local hospital seeking emergency treatment that worsened, instead of improved, her care, in part because the couple believed clinicians at the hospital were fearful of prescribing opioids and did not have access to, or ignored, the recommendations of the patient's longtime clinicians, who included several pain specialists. A beneficiary who lives with chronic pain stated that she hoped the change in codes would motivate clinicians to focus more attention on people with pain, as after many years of seeing provider inexperience first-hand, along with the accompanying administrative demands and paperwork pain care demands, she believed having a special billing code will be a ''giant step'' forward for people with pain, potentially allowing more people like her with painful conditions to continue to contribute to society, including through employment. A person living with chronic pain stated he liked what he saw in the code proposal because he hoped it would open the doors to more doctors who would provide pain care, including appropriate medication management, because he thinks doctors are still fearful of Federal and State prescribing guidelines. Another person living with pain stated the CPM services are ''so needed by people like me.''

One commenter noted that they would expect that the amount of pain care required and the cost to Medicare to be large and increasing, especially given the aging American population and the prevalence of age-associated chronic pain conditions in Medicare like arthritis, cancer, and diabetic neuropathy; the same commenter stated that pain management is complex, and there are no existing codes that account for all the tasks required to care for a patient with chronic pain, and that a standalone code will signal to physicians that, when patients have complaints of pain, it is critical to take them seriously. Conversely, another commenter was not supportive of the new codes as they believe that physicians will continue to bill evaluation and management (E/M) codes to avoid adding to their administrative burden.

One commenter requested that we ''pause'' implementation of the codes, further engage with interested parties, and make additional clarifications within the code to address valuation, descriptors, and guidance. Another commenter noted that they do not support including the CPM codes in the applicable list used for accountable care organizations beneficiary assignment, citing that managing chronic pain does not routinely follow the overall health of the patient, and is typically managed by clinicians with specific skills beyond primary care. One commenter questioned if a single bundled code was adequate to address the breadth of conditions that patients may experience, as well as the variety of treatment and management approaches. One commenter urged us to consider that for some people, a visit with a practitioner might focus not just on pain management, but also whole-person care. The same commenter noted that, although they appreciated our efforts to simplify billing requirements for the CCM codes, uptake appears to be low in part due to administrative burden, and they expressed concerns that similar challenges would apply to the CPM codes, which could entail documentation of services rendered in an E/M service. The commenter asked us if we could determine a pathway to make billing more streamlined, perhaps through billing using the G89.xx ICD–10 series. A commenter thanked us for improving access to pain care, including through prevention and treatment for substance use disorders (SUD). A different commentator congratulated us on, through creation of the codes, helping to prevent some individuals from developing SUD. One commenter noted the codes would prompt more practitioners to welcome Medicare beneficiaries with chronic pain into their practices, and encourage practitioners already treating Medicare beneficiaries who have pain to spend the time to help them manage their condition within a trusting, supportive, and ongoing care partnership.

Response: We thank all the commenters who expressed enthusiastic support of the proposed new HCPCS

codes for CPM services, and we appreciate the attention to informing our approach in shaping this policy that we believe will provide improved access to holistic and comprehensive pain management for people with Medicare. A few commenters disagreed with our proposal. One commenter stated that our proposal is not substantially different than existing codes, while another questioned whether one code was sufficient to address the breadth of conditions patients experiencing chronic pain face. We do not agree that there is an existing code that specifically describes the work of the clinician in performing the specific tasks described in the code descriptor for HCPCS code G3002. We anticipate that the CPM codes will be used to address the full range of chronic pain conditions that impact Medicare patients. We look forward to gaining more knowledge through data, and clinician and beneficiary experience as use of the CPM codes becomes more frequent.

Comment: We received a few comments regarding our proposal to define chronic pain as ''persistent or recurrent pain lasting longer than 3 months.'' Most commenters agreed with our proposed definition. We received several suggestions related to the specification of 3 months duration, including one month, 90 days, and the addition of ''expected to last longer'' to our definition. A few others suggested we broaden the definition generally, to ensure that patients with cancer, neuropathic pain, psychogenic pain, and headaches would also benefit from this proposal to create HCPCS codes that describe CPM services, while another commenter congratulated us on using language that it noted was inclusive of all types of pain treatment. One commenter asked us to integrate acute pain and biopsychosocial factors into our definition, and stated that risk indicators of pain are apparent early, potentially limiting robust interventions for the prevention of chronic pain. One commenter opined that our definition of chronic pain was overly broad and did not address the many types of conditions that pain patients may experience. A commenter who agreed with our definition noted that in the International Classification of Disease, 11th edition (ICD–11),[39] chronic pain has its own diagnosis, independent of an underlying disease or condition. Still, another commenter, who also agreed with our definition, noted there are ICD–10 diagnostic codes for chronic pain, the G89.xx series. Another commenter agreed that the proposed definition is largely in line with their understanding, adding more context to include, ''persistent or recurrent pain without a serious progression or exacerbation of an underlying pathologic condition and without tolerability over time.'' Another commenter stated that at a high level, they believe the metric of ''time'' is not the dispositive component to define a chronic pain diagnosis, but the definition should instead take into account a complex series of associated factors like amount of suffering or hindrance of function, and that not all recurrent pain should be considered chronic pain; instead chronic pain as a diagnosis should be utilized for an individual who does not understand how to manage or live their life with their current, recurring, episodic symptoms.

Response: We appreciate all the commenters' suggestions and observations. As we described in the proposed rule, we reviewed definitions from the Centers for Disease Control and Prevention, the National Institutes of Health, the World Health Organization,[40] and in the Institute of Medicine's ''Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.'' For operational ease and consistency with the proposed rule and various sources, we are finalizing as proposed the definition of chronic pain as ''persistent or recurrent pain lasting longer than 3 months.''

Comment: One commenter recommended we focus on improving care for all pain, such as acute pain, as well as pain related to cancer, sickle cell disease, and for people in palliative care, with another commenter also agreeing that additional codes could focus on people with palliative and cancer pain. This commenter noted that increased support for comprehensive acute pain management could also reduce the number of patients who progress from acute to chronic pain. This sentiment was echoed by other commenters, who suggested an additional pain code for acute care that would incorporate massage therapy and other complementary and integrative services for both in-patient and outpatient visits, as is seen in some large health systems. Several other commenters generally supported the inclusion or addition of acute pain management in this or other codes. One commenter suggested that after we gain experience with the use of the codes for chronic pain, we consider their application to acute pain management. A few commenters did not support additional coding and payment for acute pain management, as they believed these circumstances are adequately handled via existing E/M coding and payment.

Response: As we mentioned in the proposed rule, we understand there is some evidence that addressing chronic pain early in its course, such as when the person is experiencing acute pain, may result in averting the development of ''high-impact'' chronic pain in some individuals and that these people report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain. We considered, in the development of this code, whether or not to include acute pain, and elected not to include it in the CPM services descriptor. We will continue to consider how best to approach management of acute pain through coding and payment.

In our proposal, we required an initial face-to-face visit of at least 30 minutes provided by a physician or other qualified health professional with the first 30 minutes personally provided by the physician or other qualified health professional, per calendar month for HCPCS code G3002. We noted that HCPCS codes GYYY1 and GYYY2 were placeholder codes and that the final code number will be HCPCS code G3002 and G3003, respectively. We proposed, for HCPCS code G3003, an additional fifteen minutes of CPM services by a physician or other qualified health professional, per calendar month, and we proposed limiting the application of HCPCS code G3003 to up to three units of an additional 15 minutes of CPM services, per calendar month (listed separately in addition to proposed HCPCS code G3002). We sought comment on both the proposed duration of 30 minutes for HCPCS code G3002, and the duration and the limit on HCPCS code G3003.

Comment: Most commenters agreed that our proposal for 30 minutes for HCPCS code G3002 was reasonable and adequate for the treatment and management of the first visit for a person with chronic pain and that fifteen-minute intervals for subsequent time-based intervals is adequate.

One commenter expressed a concern that neither code allowed for adequate time, and that the codes should allow for at least an hour for the first visit and 45 minutes for subsequent visits, especially to allow for the intensity of clinical time that would be likely

[39] *https://icd.who.int/en.*

[40] *https://painconcern.org.uk/new-classification-for-chronic-pain/#:~:text=Chronic%20primary%20pain%20is%20defined,explained%20by%20another%20chronic%20condition.*

needed to diagnose and treat a new patient. The same commenter urged us, because the myriad of situations that could apply based on the complexity of treating pain overall in the Medicare population, to consider additional flexibilities in the duration of time for the codes based on each person with pain's situation. Another commenter noted that the time required to coordinate with other specialists, referrals, therapies, and trial different treatments is ''considerable'' to create and modify an individual treatment plan for each patient. Another commenter suggested that twice a month billing for proposed HCPCS code G3002 is insufficient for completion of the list of requirements, and recommended that four visits per month be allowed to ensure that the element list is completed. A separate commenter echoed this sentiment, suggesting there be no limitation on the number of times per month this code can be billed, citing the multitude of providers seen by some patients. Another commenter recommended we consider extending the length of visits from 45 minutes (30 minutes for proposed HCPCS code G3002, 15 minutes for proposed G3003) to 60 minutes to account for the complexity of pain care. A commenter noted that 30 minutes was too high a threshold for appointments beyond the initial visit, and recommended that subsequent visits only have a limit of 15 minutes after which billing is allowed. One commenter stated that we should not put any limits on the number of times proposed HCPCS code G3003 can be billed each month. A commenter requested that the frequency and duration of permitted CPM visits be flexible enough to account for the variety of practice types—from primary care to specialized clinics offering intensive and integrated chronic pain management services, and this commenter also noted that patients have different intensities of need, with some requiring longer appointments, or at greater frequency, while some have lower needs, stating that 30 minute and 15 minute durations of HCPCS codes G3002 and G3003 respectively, as well as the frequency, may be too limited to adequately account for the challenging demands of chronic pain management. Another commenter stated that 30 minutes seems reasonable but flexibility is important as chronic pain conditions vary and sometimes more than 30 minutes may be needed, especially for a first visit. Another commenter requested clarification related to the frequency of allowed billing for CPM codes, as some services such as comprehensive palliative care require a wide range of care.

Response: We appreciate the commenters' overall support of our proposal to set the duration of HCPCS code G3002 at 30 minutes, to accommodate both the specified elements of the monthly bundle, and the complex needs of the person with chronic pain, and we are finalizing HCPCS code G3002 for 30 minutes duration. We agree with the commenters who observed that additional flexibilities are needed to account for the numerous situations that could apply to each person with pain's clinical situation, and the factors that might go into the clinician's determination regarding how much time is appropriate to spend treating a person with chronic pain, and also how many and what type of clinicians might need to also furnish care during a particular month. Although we expect that in most instances the person with chronic pain would see one clinician on a regular basis who is performing a lead role in managing that individual's pain, we can also foresee limited circumstances where a beneficiary may need to have their care transferred to a pain specialist, or other specialist in the same month, and the pain specialist or other specialist may also bill HCPCS code G3002 for the same beneficiary, in the same month. There may also be situations where the person with chronic pain needs to see two different clinicians managing their pain on a regular basis, for example, a cancer specialist and a rheumatologist, with both billing the CPM code(s). We would not expect many beneficiaries living with chronic pain would typically be seeing more than one or two physicians or qualified health professionals in a month who might be performing HCPCS code G3002; in part, because of the burden of care described by chronic pain patients and their caregivers, and also because beneficiaries incur cost-sharing expenses for these services and other care they receive—typically 20 percent of the Medicare payment amount after the annual Medicare Part B deductible amount is met.

Based on the comments, especially those that encouraged us to increase billing flexibilities to account for the unique needs of each person with chronic pain, we have reconsidered the proposed limit on billing G3003 to three times per month, and are finalizing in this rule flexibility to bill the second code, for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month, after HCPCS code G3002 has been billed. We will be monitoring use of the codes going forward to understand more about how they are being used.

Comment: One commenter asked if our proposal required the physician to meet with the patient each month or only once in the initial month of the service, as the commenter noted that monthly visits with the physician are not likely to be necessary for some people receiving ongoing chronic pain management. Another commenter stated that a monthly visit may be onerous for cancer patients who are already receiving time-intensive care. A commenter pointed out that it could take year or more of regular visits to develop, coordinate, and revise a treatment plan optimal in managing the patient's chronic pain; the same commenter stated that a patient might drop back to bi-monthly, quarterly, bi-annually, and annual visits so long as pain is being effectively managed. Another commenter requested clarification regarding if all the elements in the descriptor would be required each month.

Response: We agree with the commenters who noted that each person with chronic pain may not need to receive the monthly bundle every month; rather, using a person-centered approach, one which optimizes care according to individual circumstances and preferences, requires variability in how often services are appropriately rendered. Therefore, the CPM services for the HCPCS code G3002 may not be rendered more than once per month by each individual practitioner billing the code for each beneficiary, but could be rendered less than twelve times per year, depending on the specific needs of the person with chronic pain.

Comment: Some commenters requested clarification on our proposal that the first time HCPCS code G3002 is billed that initial visit must be in person, or if subsequent monthly visits must be ''face-to-face,'' or in person. Several commenters recommended that we not make in-person first time visits an absolute requirement, so as to accommodate for mobility difficulties for people living a long-distance from the physician's office. Other commenters recommended that ''face-to-face'' components be available via both video and telecommunication technology to support access. Several commenters stated that we needed to clarify that the code required that only the very first visit be in-person, and that follow-up visits could be delivered in-person, or by telehealth. A different commenter's concern was that HCPCS code G3002 seemingly requires an ''initial'' face-to-face visit of at least 30 minutes, and while the commenter did

not object to one required initial face-to-face visit at the onset of CPM treatment, they thought that CMS potentially requiring an in-person visit monthly is unnecessary, overburdensome, and would exacerbate health care disparities. One commenter noted an initial visit with the patient could be supported by telehealth. Another commenter noted that patients should be seen in the office for the initial visit, at least until they are regulated on their pain medicines. An additional commenter requested clarification as to whether a practitioner could bill these codes both for patients that have an established history of chronic pain, and those that are being diagnosed as having chronic pain for the first time.

Response: We thank the commenters for their comments, but we are finalizing the requirement that the first time HCPCS code G3002 is billed, the physician or qualified health practitioner must see the beneficiary in-person, where both individuals are in a clinical setting such as a primary care practitioner's office or other applicable setting. We believe that an in-person visit at the onset of care will benefit both the clinician's accuracy in administering the elements of the HCPCS code G3002 bundle of services, and help at the beginning of care to foster a successful therapeutic relationship between the clinician and the person with chronic pain. One commenter told us doctor-patient relationships in pain management have become so ''fraught, mistrustful, and corrosive'' that they have led to a crisis, as illustrated by CMS' own Journey Map of the Chronic Pain Experience,[41] which, in their view, accurately demonstrates the current ''dysfunctional and damaging state'' of pain care. These reports support our decision to require that the physician or other qualified health professional meet with the beneficiary in person for the first time. We acknowledge that for some people living with chronic pain who may live far from the clinician's office, or who have issues with transportation, or whose pain is exacerbated by activity, even getting to a clinician in-person for a first visit may be challenging. We are not requiring that each subsequent visit, whether these be monthly or at some other periodicity be held in-person, but rather leaving that determination to the discretion and preference of the clinician and the beneficiary as they are best positioned to together determine how to develop and maintain the care partnership to effectively manage pain.

Comment: A commenter stated that while patients earlier in their journey managing chronic pain may have care primarily coordinated by a primary care practitioner, others progressing to high-impact chronic pain may have their care mainly coordinated via a pain management specialist; this commenter suggested we allow the codes to be billed at a maximum twice per month to account for the difference in specialty primarily managing a patient's care. This commenter also suggested we add pain management specialists to the list of examples of care that a patient might need (for example, physical and occupational therapy, etc.).

Response: We agree with the commenter that it is possible that a beneficiary living with chronic pain might need to see more than one clinician type who is enabled to bill for the CPM services—as the commenter noted, one likely scenario might be a person who sees a primary care practitioner, and a pain specialist (for the purposes of this rule, we are not defining ''pain specialist''). As described in the proposed rule, we believe it is unlikely that most beneficiaries with pain would want, or need to, see more than a few physicians or other qualified health professionals in the same month to manage their pain, and administer the elements of the CPM services for various reasons, including the reasons commenters who urged us to add the CPM services to the telehealth list have flagged. We also believe that the beneficiary would likely object to, or could even by confused by, having large numbers of clinicians managing their chronic pain. Although we are not restricting the numbers of clinicians who can bill HCPCS code G3002, we will be monitoring its use going forward to better understand more about the types of practitioners and patients using the CPM codes and services.

Comment: A few commenters requested clarification as to whether the person being seen for the first time with proposed HCPCS code G3002 had to have already been diagnosed with a chronic pain diagnosis, or a condition that causes chronic pain. One commenter stated we should include both people who both meet the definition of chronic pain on the first visit, and also people who have adequate medication documentation or concerns that would likely attest they have met the definition of chronic pain, to create an equitable care environment.

Response: We are clarifying that the beneficiary, at the first visit, need not have an established history or diagnosis of chronic pain, or be diagnosed with a condition that causes or involves chronic pain; rather, it is the clinician's responsibility to establish, confirm, or reject a chronic pain and/or pain-related diagnosis when the beneficiary first presents for care and the clinician is using HCPCS code G3002.

Comment: Several commenters questioned if clinicians are required to furnish all appropriate elements of the code bundle in each encounter for HCPCS code G3002, including medication management. One commenter stated that we should allow clinicians flexibility for any of the services listed, in any order and over any time period to best manage the person's pain condition(s) and that should allow for omission of certain ones when they are not appropriate or not desired by the patient (for example, medication management, behavioral counseling). Another commenter stated that its stakeholders were concerned that HCPCS code G3002 seems to indicate that all listed services must be completed to bill for the code.

Response: We are clarifying that clinicians will be required to furnish all appropriate elements of the code bundle, but also clarifying that we do not expect that all elements of the code bundle will be appropriate for every patient. Therefore, we can confirm that if medication management is appropriate for a specific patient, then a clinician who bills HCPCS code G3002 will be required to furnish medication management to that patient. As described later in this preamble, we will be finalizing the descriptor of HCPCS code G3002 as follows, with the two modifications shown in italics: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, *and/or* maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, for example, physical therapy and occupational therapy, *complementary and integrative approaches*, and community-based care, as appropriate. We believe that the services enumerated as examples accurately summarize the

[41] *https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf.*

components of some elements of key care for people with Medicare living with pain.

Comment: Many commenters requested that we remove medication management from the code descriptors. One commenter stated it appreciated medication management being included in the code descriptor and that careful evaluation of all medications, including use of American Geriatrics Society Beers Criteria®, should be included as part of the CPM service, urging us to keep the element of medication management in the descriptor finalized for this code.

Response: We continue to believe that medication management is an essential element of pain care, and we are not removing it from the code descriptors for HCPCS codes G3002 and G3003. A 2022 Congressional Budget Office publication [42] indicated nationwide per capita use of prescription drugs has increased in recent years, as has Medicare Part D enrollee use, from an average of 48 prescriptions per year in 2009 to 54 prescriptions per year in 2018. In addition, between 2017–2018, nearly 58 percent of U.S. adults used a dietary supplement [43] in the past 30 days, and the percentage of adults using these supplements increases with age; [44] nutritional supplements are used by some people for the treatment of pain.[45] Although we are not explicitly defining medication management for the purposes of HCPCS codes G3002 and G3003, we believe that medication management would customarily include, as part of this element, a review of prescription drugs, over-the-counter medications, supplements, natural treatments, and/or any other substances the person with chronic pain might be using for any purpose. Medicare's Annual Wellness Visit requires the clinician to collect and document use or exposure to ''medications and supplements, including calcium and vitamins [46].'' Common prescription medications used for pain include acetaminophen, non-steroidal anti-inflammatory drugs, anticonvulsants, antidepressants, musculoskeletal agents, antianxiety medications, and opioids. Americans also use dietary supplements for a range of purposes, including the treatment of pain.[47] [48] Some individuals with pain may also be using substances such as cannabis and other plant-based treatments for pain.[49] [50] Bearing this information in mind, we believe medication management by the eligible physician or qualified health professional would be an applicable element of the HCPCS code G3002 for most beneficiaries with chronic pain.

Comment: One commenter stated that massage therapy, therapeutic exercise programs, and complementary and integrative services (like acupuncture, tai chi, yoga, and mindfulness meditation) should be referenced in the code, even if currently not covered by Medicare, and that clinicians should be allowed to bill for the range of treatments listed in the HHS PMTF Report, even though the Medicare program may not pay for those services. One commenter noted that care coordination could include not just complementary and integrative care, but also prescribing of durable medical equipment. One commenter stated we should try to remove barriers to more ''alternative'' therapies.

Response: The PMTF Report recommends a range of treatments and therapies that could be used for successful pain management including medications, restorative therapies (for example, therapeutic exercise, massage therapy), interventional procedures (for example, nerve blocks, joint injections), behavioral health approaches (for example, cognitive behavioral therapy), and complementary and integrative health approaches. The latter include, as described in the Report, acupuncture, massage and manipulative therapies, mindfulness-based stress reduction, yoga, tai chi, and spirituality. HHS's 2010 National Pain Strategy [51] (NPS) also mentions complementary and integrative care, focusing mostly on access difficulties for patients with chronic pain, including insurance coverage. Since the NPS was published, Medicare has finalized a coverage decision to cover acupuncture for chronic low back pain.[52] NIH's National Center for Complementary and Integrative Health continues to evaluate various approaches,[53] as is the cross-cutting NIH HEAL Initiative® [54]. The HHS Agency for Healthcare Research and Quality has also performed some work in this area.[55]

First, we are clarifying that we are not requiring in the code descriptor that a clinician refer a beneficiary to services; that determination should be made between the clinician and the beneficiary. We understand that clinicians customarily refer beneficiaries, including those who have chronic pain, to a range of treatments based on their individual circumstances, and according to the person-centered plan of care.

Second, based on the commenter's suggestion and on our proposal within the CY 2023 PFS proposed rule, where we solicited comment regarding interest in chronic pain management services and specifically mentioned specialty care coordination such as complementary and integrative pain care; recent coverage in Medicare for acupuncture for chronic low back pain; [56] and evidence that may point to efficacy for some individuals with chronic pain using complementary and integrative approaches, we have elected to revise the code descriptor for HCPCS code G3003 by adding ''complementary and integrative approaches'' to the code descriptor as examples of approaches that a clinician could take in coordinating pain care across a range of treatments and therapies for a beneficiary. However, we are not requiring that a clinician make a referral to such care, nor are we requiring that the clinician only refer Medicare beneficiaries to services currently covered by Medicare. We are finalizing the addition of ''*complementary and integrative approaches*'' to the descriptor for HCPCS code G3003. In context, the addition will read as follows: ''. . . any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, *e.g.,* physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate.''

Comment: Several commenters supported the requirement for the development, implementation, revision, and maintenance of a person-centered

[42] *https://www.cbo.gov/publication/57772#:~:text=Use%20of%20prescription%20drugs%20among,year%E2%80%94a%2013%20percent%20increase.*

[43] *https://ods.od.nih.gov/factsheets/list-all/.*

[44] *https://www.cdc.gov/nchs/products/databriefs/db399.htm#section_3.*

[45] *https://www.nccih.nih.gov/health/providers/digest/nutritional-approaches-for-musculoskeletal-pain-and-inflammation.*

[46] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html.*

[47] *https://ods.od.nih.gov/.*

[48] *https://www.fda.gov/food/dietary-supplements.*

[49] *https://www.cdc.gov/marijuana/health-effects/chronic-pain.html.*

[50] *https://effectivehealthcare.ahrq.gov/products/plant-based-chronic-pain-treatment/living-review.*

[51] *https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf.*

[52] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=295.*

[53] *https://www.nccih.nih.gov/health/providers/digest/mind-and-body-approaches-for-chronic-pain-science.*

[54] *https://heal.nih.gov/funding/awarded.*

[55] *https://www.ahrq.gov/topics/complementary-and-alternative-medicine.html.*

[56] *https://www.medicare.gov/coverage/acupuncture.*

care plan that includes strengths, goals, clinical needs, and desired outcomes by the practitioner furnishing CPM services. A commenter asked that we recognize the role nurses play in person-centered planning. One commenter supported this element of the CPM services, and stated that person-centered care planning is not only key for people living with chronic pain, but also for others living with serious illness, and that the person-centered care plan and specifically these elements in the CPM service should become required for people with serious illness. One commenter expressed concern that current billing codes compensate providers the same regardless of the severity of the beneficiary's condition or time spent with the provider.

Response: We are correcting the code descriptor to more clearly indicate that we do not expect the clinician to develop, implement, revise, and maintain the person-centered care plan, that is, performing each of these activities each time HCPCS codes G3002 or G3003 is billed; rather, the status of the person-centered plan may vary based upon the individual circumstances of the beneficiary with chronic pain. Thus, we are finalizing a revision to the HCPCS code G3002 descriptor to clarify this element as ''the development, implementation, revision, *and/or* maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes''. We do not agree, based on the revisions to proposed concurrent billing policies and revisions in the descriptors that we are finalizing for HCPCS codes G3002 and G3003, as described above and below, that there will be insufficient flexibility to address the severity or breadth of needs that a Medicare beneficiary living with chronic pain might have. We believe that both the ''and/or'' edit that we are finalizing as part of the code descriptor, and the additional flexibilities for payment, discussed below, are sufficient to address the unique needs of each beneficiary with chronic pain.

Comment: Several commenters opined on the inclusion of pain and health literacy counseling, which we included as a proposed element of the HCPCS code G3002 descriptor, to help beneficiaries with chronic pain make well-informed decisions about their own care, weigh risks and benefits, make decisions, and take actions that are best for them.[57] One commenter recommended we instead use the term ''self-care management,'' and noted that this term is more broadly inclusive of health literacy counseling. Another commenter stressed the important role nurses have in ensuring patients are fully informed by educating and advocating on behalf of patients as they navigate the care continuum. Another commenter stressed that the receipt of integrative pain care would involve the practitioner taking into account the ''whole person'' in managing pain, especially important in light of the importance of care coordination coupled with the goals of health literacy. (We note that we recently emphasized the importance of health literacy in our 2022–2032 CMS Framework for Health Equity.[58]) The Framework's fourth priority is to ''advance language access, health literacy, and the provision of culturally-tailored services,'' and states that ''Medicare-enrolled individuals with low health literacy experience increased hospital admissions and visits to emergency departments, as well as higher medical costs and lower access to care.'' Another commenter stated that in their experience, health literacy counseling is most efficiently done through networks of chronic pain support groups led by specially trained individuals who have received training and education by pain leaders, and that it is a fundamental and essential component in learning to cope with chronic pain, which is devastating and challenging. The commenter further observed that we could improve health outcomes by providing funding to non-profit groups that specialize in chronic pain management to help grow these type of educational and skill-based support groups. Another commenter supported this requirement, adding that this should be able to be provided via telehealth to reduce barriers to entry. A commenter noted that health literacy, especially with medication adherence, is valuable to people with chronic pain using multiple medications, as often these patients lack a comprehensive understanding of all their medications, which can deter adherence; if they had better resources to help them understand them, adherence would increase.

Response: We agree that pain and health literacy counseling is an important element of care for people with chronic pain and appreciate the commenters' suggestions about how it can contribute to improved health outcomes. We thank the commenters, and we are finalizing pain and health literacy counseling as an element of the HCPCS code G3002 descriptor, as proposed. As we gain experience with the CPM codes we may consider additional options to increase the availability of pain and health literacy counseling for Medicare beneficiaries.

Comment: Many commenters opined on our proposal to include administration of a validated pain assessment rating scale or tool as an element of code descriptor of HCPCS code G3002. Several commenters noted that pain subjectivity can make pain management a difficult task, and that the use of validated pain assessment tools can illuminate and inform a fuller picture of the person's condition, as well as the person's care plan. One commenter stated that pain scales can be beneficial, but they need to be tailored to each person, and that function and quality of life are also important elements to monitor. The same commenter recommended the use of the National Quality Forum's patient-reported measure, Patients' Experience of Receiving Desired Help for Pain to achieve this. Another commenter stated something similar, indicating that we should explore ways to address the inconsistencies in pain measurement due to influences like geography and cultural norms. Among the many comments related to bias in pain assessment, one commenter urged us to consider the biases of assessment tools when proposing a validated pain scale. One commenter vehemently opposed the inclusion of a validated pain assessment scale citing concerns with pain bias, proprietary systems, and established outcomes beyond such scales, which they noted together create a case to avoid requirements for providers to use scales that have not received widespread support. The commenter also expressed concerns with pain bias that has developed over time in pain scales, especially for women, older adults, and ethnic groups, where the scales were not removed from use even after bias was documented, potentially worsening health equity issues. This commenter continued, stating that there is disagreement over the use of pain scales and that no single scale has been adopted as a common scale, in part because of proprietary issues. A different commenter agreed with the assessments of bias in traditionally marginalized populations, offering that objective pain scales and objective benchmarked pain data be used. This commenter defined benchmarked objective pain data including a pain database on adults, a database on women and pain, an

[57] *https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/health-literacy.*

[58] *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

orthopedic pain database, or an older adult pain database.

Additionally, we received comments related to the ''well-documented bias against historically-disadvantaged groups'' in pain assessment, and suggestions that the best tools for chronic pain also focus on pain interference, impact on function, activities of daily living, emotional and psychological health, and the patient's perception of their own quality of life. Regarding specific tools, one commenter agreed with administration of a validated pain assessment rating scale or tool, and stated that we should not limit the acceptable tools; rather we should enable practitioners to select the most appropriate tool for staff to administer as part of the person-centered CPM care plan, and that a reference repository or list of potential tools would be helpful. The same commenter asked that we not be prescriptive in requiring a particular scale or tool. Another commenter recommended the consideration of the use of outcome and quality-of-life measures as opposed to reductionistic tools that only measure one aspect of pain. A different commenter supported our proposal to use a validated tool, suggesting the PROMIS–8A, but urging us to make a list of validated tools available, and also avoid requiring use of a specific tool. Another commenter expressed concern about unintended consequences of using a pain rating scale or tool for validation and suggested the addition of a measurement that uses objective measures. A commenter noted that a pain scale is a reliable and valid way to understand the extent of how pain is impacting the person, but should not be the sole measure to show improvement. Further, a commenter recommended we undertake more inquiry before mandating the use of any specific tool or registry and assemble a stakeholder group, issue a Request for Information, or use some other means to conduct a landscape analysis of validated tools. One commenter noted that the use of a validated pain assessment tool should be excluded and be available as a separate add-on code. This commenter also noted that such a step would incentivize a multidimensional assessment of physical, social, and emotional functioning.

Response: We recognize that periodic assessment of the experience of pain is an essential element of pain care in the immediate sense and over time, as chronic pain may be enduring as a symptom of disease or a long-term disease in and of itself. We also note that no prescribed set nor single pain assessment measure will be required in the administration of HCPCS code G3002 or G3003, because no particular tool or tool set can assess the complex nature of the experience of pain across all individuals, nor appropriately guide its treatment. We regularly collaborate with other HHS operating divisions including working with the National Institutes of Health (NIH) on the NIH HEAL® Initiative (Helping to End Addiction Long-term), which includes more than 30 large scale pain and substance use disorder programs. The NIH HEAL Initiative and the NIH Pain Consortium pain research agendas engage nearly all NIH Institutes, Centers, and Offices. The ambitious and crosscutting nature of the NIH HEAL Initiative® and trans-agency interactions of the NIH Pain Consortium require engagement from experts across disciplines and sectors and with other HHS operating divisions including CMS. Much of this NIH research effort focuses on preclinical, translational and clinical research aimed to improve pain management.[59] We have been working with NIH to create and disseminate an accessible, curated, and dynamic set of Pain Assessment resources for clinicians seeking instruments to assess their patients' pain and pain-related symptoms (such as sleep disruption, loss of function, and behavioral health). The resources are carefully selected as validated and meaningful tools to inform clinicians and patients in shared decision making as to the most effective pain management plan for each person. Recognizing that while many tools are validated in certain populations, they may need refinement to address cultural sensitivities in populations with health disparities. We will leverage efforts of the NIH HEAL Initiative to continue to include appropriately updated tools for these populations as they evolve. We are finalizing the inclusion of administration of a validated pain rating scale or tool in the HCPCS code G3002 descriptor. We will continue to consider opinions and feedback from clinicians and people with pain as to the use of The Pain Assessment Resource and more generally, validated screening tools, and collaborate with our NIH operating division partners to leverage their work in this area and ensure that the Pain Assessment Resource is comprehensive, inclusive across disciplines, and up to date over time. A link to the resource is available at *https://www.painconsortium.nih.gov/resource-library/resources-pain-assessment*.

[59] *https://heal.nih.gov/about.*

Comment: We received numerous comments on components of the proposed CPM services that do not necessarily require a ''face-to-face'' or in-person visit with the practitioner, such as care that could be provided by auxiliary staff ''incident to'' the services of the physician or other qualified health care practitioner. A few commenters requested clarification on which specific aspects of the code could be furnished without face-to-face care. We also received many comments requesting a general supervision requirement, rather than a direct supervision requirement, with commenters citing provider shortages as barriers to care. Another commenter suggested that the initial visit would not have to be face-to-face so long as an in-person visit occurred shortly after the CPM initiation, and prior to the prescribing of controlled substance medications for pain. One commenter stated that other clinical staff in the practice should be able to follow up and interact with patients. Another commenter stated that relevant components that could be non-face-to-face could include questions about medication and improvements related to medication, social determinants of health, or history of substance use disorders, or crime, as well as coordination of any necessary behavioral health treatment, and pain and health literacy counseling. A commenter stated that most components of the proposed CPM services do not require face-to-face interaction with the billing practitioner such as overall treatment management, medication management, pain and health literacy counseling, and care management which can provided by clinical staff incident-to a billing practitioner under general supervision, and that these providers' ability to furnish care has proved to increase access to medically necessary care, and helped relieve some of the burden for billing practitioners while still ensuring patients are receiving high-quality care. A commenter noted that registered nurse care managers could provide CPM services as incident to services, under the general supervision of a physician or other qualified health professional. Another commenter stated that the definition provided of ''provided by a physician or other qualified health care professional'' was limiting, and suggested that we use, ''clinical staff time directed by a physician or other qualified health care professional.'' Another commenter requested that CMS consider creating separate billing codes to reflect time spent by physicians and

clinical staff as is done in the chronic care management (CCM) code.

Response: We agree with the commenters and believe that certain elements of the proposed bundle, such as care planning or care coordination with other health care professionals, would not likely require face-to-face care. These might include activities such as telephone calls, medical records review, and coordination and information exchange with other health care providers. We are also not requiring that subsequent visits for which a physician or other qualified health professional bills HCPCS code G3002 or G3003 be for services that were provided to a beneficiary face-to-face. However, the initial visit for HCPCS code G3002 must be a face-to-face visit.

Comment: A few commenters applauded our efforts to support team-based care for Medicare beneficiaries with chronic pain. One commenter stated that chronic pain management may involve arrangements with psychologists as part of team-based care. Another commenter stated that since there is no disease-modifying or curative therapy for chronic pain, best managing chronic pain requires multi-modal interventions and coordination across a patient's care team, and coordinating care with other practitioners and providers such as integrative medicine, physical therapists, psychiatry, and hospital programs.

Response: We agree with the commenters about team-based care, which leads to better outcomes for beneficiaries, and better experience for staff, and improves all aspects of care delivery. Team-based care positively effects the person's care experience, such as office visit cycle time, care access, preventive screening, self-management, goal setting and action planning, and medication management. Team-based care also improves process and workflows, helping to ensure staff are working at the top of their capabilities, and sharing in accountability.[60]

Comment: A few commenters requested that the structure of the CPM codes include payment for the time interdisciplinary providers spend in consultation with one another. Additionally, this commenter noted concern that requesting coordination with ''relevant providers'' was not specific enough, and would not require inclusion of the range of services available to treat chronic pain. One commenter stated that we should ensure that reimbursement is revenue neutral, to continue to encourage practitioners to treat chronic pain.

Response: We are not requiring in the code elements that the clinician billing CPM codes coordinate and communicate with other relevant practitioners, as these actions would vary based on the beneficiary with chronic pain's circumstances. Nor is the list of services we have used as examples meant to be inclusive of every type of care a person with chronic pain could require in the course of individualized treatment for chronic pain. We do expect that communication and care coordination between providers of all types would be of benefit to the beneficiary with pain and we leave the extent of that communication and coordination to the discretion of the physician or qualified health professional billing the CPM codes, as appropriate.

Comment: Several commenters requested that we recognize CPM services for all practitioners who may bill E/M visits, including oncologists. One commenter noted we had stated the new codes can be billed by a ''physician or other qualified health care professional'' and agreed that physicians, including primary care physicians, board certified pain management specialists, neurologists, anesthesiologists, board-certified headache specialists, rheumatologists, osteopaths, and other physician specialists that focus on pain conditions should be able to bill the new CPM codes; the commenter asked us to clarify what types of practitioners can bill for proposed HCPCS code G3002 and G3003. A commenter noted that we stated our anticipation that the CPM codes would most frequently be billed by primary care providers. This commenter specified that cancer specialists also spend considerable time managing acute and chronic pain, with this sentiment being echoed by providers of palliative and hospice care, as well as nurse anesthetists, all concerned and asking for clarification regarding whether they ''counted'' as approved providers. A commenter requested more support and increased access for innovative alternative treatment to opioids (ALTO) programs, which have been shown in a few states to reduce opioid prescriptions in emergency department settings. One commenter stated that, if we identify specialties expected to furnish the CPM services, geriatrics should be included. Two commenters recommended that Rural Health Centers and Federally Qualified Health Centers be allowed separate payment for these codes. One commenter requested that the code be inclusive of the broad range of providers that treat pain, as each patient should be able to access the provider best suited to primarily manage their pain. A commenter stated that, while we stated we believe primary care providers might most often use the codes, cancer specialists spend considerable time managing both acute and chronic pain associated with cancer, and we should explicitly state that CPM services can be billed by any clinician with E/M services in their scope, including oncologists and pain management specialists. Two commenters stated we should make rehabilitation therapists eligible to bill the code, and, if they are part of the care team, they should share in the reimbursement proportionally among practitioners rendering care. One commenter asked that we include marriage and family therapists as providers who can render CPM services. A commenter recommended HCPCS code G3002 be billable by other Medicare providers like doctors of chiropractic. Another commenter encouraged us to include massage therapists under Medicare Part C in coding and billing changes to capture services that are provided as part of complementary and integrative pain care.

Response: We appreciate the commenters' thoughts about the broad range of provider types that might furnish care that effectively addresses the many aspects of chronic pain, and note that we are not limiting the types of physician specialties, or the types of qualified health professionals, who can furnish CPM services, as long as they can furnish all of the service elements of HCPCS code G3002, including prescribing medication as needed, within their scope of practice in the State in which the services are furnished.

Comment: Several commenters urged us to consider the contributions of interdisciplinary teams including physical and occupational therapists, social workers, massage therapists, pharmacists, and athletic trainers when creating rules for incident to billing. Two commenters requested that CMS use the term, ''clinical staff'' as is used in other codes to ensure inclusion of different provider types. One commenter noted that members of the interdisciplinary team are needed to provide person-centered, holistic pain management and that incident to billing will support team-based care, and that we should consider separate billing for physician time versus other clinical staff time; another commenter also made this request. A different commenter noted

[60] *https://innovation.cms.gov/files/x/tcpi-changepkgmod-nextsteps.pdf.*

that limitations on ''incident to'' billing has been limiting for the creation of collaborative, interdisciplinary teams. A commenter asked us to address ''incident to'' with greater clarity, to explain if the CPM services could be provided in a domiciliary or home setting, which is not the same as a provider's office or clinic, including under general supervision. One commenter noted that component activities of CPM services can be appropriately provided as ''incident to'' physician services, as well as by hospital staff under the Medicare Part B outpatient benefits. The commenter further stated that since staff who implement CPM care plan services are either office or facility-based, payment for the services should be recognized under both the PFS and the Outpatient Hospital Prospective Payment System. One commenter stated that clinicians such as social workers, pharmacists, and chaplains could be very helpful to address aspects of chronic pain through incident to billing. Another commenter recommended CMS focus on a simpler way to capture and reimburse for CPM services. For example, CMS might explore whether E/M codes billed with an ICD–10 diagnosis code for chronic pain from the G89.xx series, in which a person-centered plan of care for pain is documented, could be eligible for monthly billing of a G3003-type code (for example, each 15 minutes of CPM care plan services implementing an individualized CPM plan inclusive of staff monitoring patient's adherence and response to the plan, coordinating services and communicating with other practitioners and providers). This G3003-type code would acknowledge and pay for the component activities of CPM care plan services that are appropriately provided ''incident to'' physician services by practitioner-employed office staff or by hospital staff under the outpatient hospital benefits.

Response: We note that this rule generally addresses payment for physicians' services under the PFS. Comments regarding other payment systems not addressed in the proposed rule are outside the scope of this rulemaking. The billing practitioner should report the place of service for the location where they would ordinarily provide face-to-face chronic pain management services to the beneficiary. We thank commenters for their feedback and may consider further development of the CPM codes to recognize components that could be furnished by auxiliary personnel incident to the services of the billing practitioner, and components that could be primarily performed by clinical staff, in the future. We note that auxiliary personnel is defined at § 410.26(a)(1) as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We did not propose to change this definition of auxiliary personnel in the proposed rule, and therefore, the comments asking CMS to modify the definition of auxiliary services are outside the scope of this rulemaking. Additionally, we note that all requirements for services furnished incident to a physician's (or practitioner's) professional services listed at § 410.26 continue to apply. We will keep the commenters' concerns in mind when considering any further development of the CPM codes in the future.

Comment: Many commenters asked us to clarify if the proposed CPM services would be available for billing/reporting in conjunction with remote patient monitoring (CPT code 99091), remote physiologic monitoring (CPT codes 99453, 99454, 9457, 99458), or remote therapeutic monitoring (CPT codes 98975, 98976, 98977, 98980, 98981 and as proposed GRTM1/2/3/4 codes. One commenter also requested clarification surrounding what virtual presence/remote supervision is permitted, who can order these services, what documentation is required, and whether billing is permitted for individual services in addition to the management components of CPM. A commenter noted that patients with chronic pain may also benefit from remote therapy monitoring to monitor their pain levels, medication adherence, and response to prescribed therapy regimens.

Response: HCPCS codes G3002 and G3003, and the services describing remote patient monitoring, remote physiologic monitoring, and remote therapeutic monitoring, are distinct types of services, although there may be some overlap in eligible patient populations. There may be some circumstances where it is reasonable and necessary to provide both services in a given month. Thus, HCPCS codes G3002 and G3003, could be billed for the same patient in the same month as the Remote Physiologic Monitoring (RPM) or Remote Therapeutic Monitoring (RTM) services. All applicable requirements for the individual codes must be met, per the elements of each individual code, for both types of remote monitoring and CPM services. Additionally, the time and effort cannot be counted more than once when billing CPM codes concurrently with RPM or RTM. Billing practitioners should remember that cost sharing applies to each service independently. If all requirements to report each service are met, without time or effort being counted more than once, then CPM and RPM or RTM may be billed.

Comment: Several commenters stated they were concerned about low payment, and other payment issues related to the proposed CPM codes, which we had valued in our proposal based on our conclusion that the CPM services were similar in work (time and intensity) to that of Principal Care Management (PCM) service. One commenter observed that in order for physicians to be willing to treat chronic pain patients, especially primary care physicians, we need to make physician payments for the new CPM codes higher than primary care and PCM visits to avoid lower payment for CPM than for a standard follow-up clinical visit for primary care (CPT code 99214 for 30 min clinical visit). The commenter was very concerned that unless we considered raising these rates before the new CPM codes go into effect, physicians will not use them to accomplish the intended improvements in pain care that Medicare patients so desperately need, and that the use of other codes not specific to pain will impair our ability to accurately track data regarding chronic pain, and care outcomes, in the Medicare program. Another commenter had similar concerns, recommending that the valuation of the new codes be on par with current office and outpatient E/M codes. A different commenter noted that it had significant concerns with our proposal to disallow use of the codes on the same day as a ''general'' visit like an E/M visit where the person is being seen for a separate illness or condition, and that this would be a grave mistake that would hamper the delivery of truly integrative pain care. This commenter also added that this move would exacerbate disparities at a time when CMS is working to promote health

equity, urging us to allow same day E/M billing. Another commenter requested clarification regarding the interaction with other service codes to ensure that this code enhances rather than inhibits physician encounters. A different commenter stated that people living with chronic pain are likely to have at least one or more comorbidities that are being treated along with their pain, and often these health concerns are, in fact, addressed by one singular practitioner on the same day. The same commenter noted that requiring people to be seen on different days that they come for other health care services will significantly reduce numbers of people with pain who are willing, or able, to receive CPM services, including people who are older adults, disabled, homeless, lack reliable/affordable transportation, cannot take time off work, and/or are unable to secure child care—among other issues. The commenter stated mandating repeated in-person visits would be arduous for disabled people already poorly served by public transportation, a problem that characterizes many smaller cities, suburbs, and rural communities. Another commenter stated that our proposed code valuation will prohibit use of the codes or make them go unused, as they pay less than CPT code 99214, or result in less payment, causing providers to reconsider the number of pain patients they care for. Additionally, the commenter expressed fears that for providers already wary of rendering care to people with chronic pain, the valuation of the codes would further disincentivize them from treating these patients, not only paying less, but requiring more work. The commenter described a ''worst case'' scenario where if the codes became ''required'' for people receiving CPM services (for example, use of a 99xxx code was deemed fraudulent) it anticipated that many clinicians would cease seeing patients with chronic pain because of the low valuation, and required services that appear ''extraordinarily laborious.'' This commenter included several real life scenarios from clinicians working at the front lines of pain; stating that if we really wish to support the use of CPM, the valuation should be *at least* (emphasis added) comparable to CPT code 99213 or 99214, but *to truly incentivize* (emphasis added) adoption and utilization of CPM services, we should consider significantly increased reimbursement to allow CPM services to grow sufficiently to meet anticipated demand. A different commenter noted primary care providers will be disinclined to prescribe opioids due to this payment rule. The commenter expressed concern that these patients will then have to find pain management clinics, which are not present in all communities. A commenter stated a similar opinion, discussing that primary care providers are afraid of prescribing opioids and that patients are suffering as a result. Another commenter noted that they would like the code to differentiate between a patient who is now meeting the threshold for chronic pain from those patients with a previous diagnosis of chronic pain, who is simply seeing a new provider. This commenter noted that a person is an expert in their own condition, and sharing all of that information with a new provider is often very time-consuming, whereas someone with new chronic pain may not have as much information to share. This commenter recommended ''substantial'' time for both scenarios. One commenter requested clarity on the interaction between the E/M and CPM codes to avoid any inadvertent misuse by providers, and recommended that CMS consider creating a modifier to attach to the CPM codes to prevent double payments. Another commenter was concerned that the proposed CPM codes could lead to an underutilization of important non-opioid pain management options because providers are not clear on the rules around the use of these codes. One commenter opined that there should not be any concurrent billing restrictions imposed on CPM services, which would force patients to pick between certain services and care. Another commenter noted that the current valuation and payment are disproportionate to the work required of HCPCS code G3002, and noted that this code more closely aligns with what is included in a level 4 or 5 E/M service. A different commenter echoed previous statements regarding concern that the valuation of HCPCS codes G3002 (formerly GYYY1) and G3003 (formerly GYYY2) and RVUs will create disincentives to care for patients with chronic pain. The commenter suggested separating HCPCS code G3002 into two codes: one code for face-to-face that is valued higher than a standard E/M visit, and a second for coordination undertaken by the physician or other qualified healthcare professional outside of face-to-face care (similar to CCM and PCM codes). Another commenter suggested two add-on codes for HCPCS code G3003 because these patients can be complex, and may require intense coordination. An additional commenter suggested adding a GYYY3 and GYYY4 code. HCPCS code G3002 (formerly GYYY1) would remain and HCPCS code G3003 (formerly GYYY2) would be half the resource inputs of G3002. GYYY3 would be a new code for subsequent visits after the initial visit with a 15-minute threshold instead of a 30-minute threshold, and GYYY4 would be another new code for administration of the validated pain measurement as an add-on for HCPCS codes G3002 or G3003. One commenter stated that the code should be treated as an E/M and fall into the category as a visit, billed in FFS clinics and related to RHCs and FQHCs paid for as per the current methodology. The commentator suggested using a payment ''crosswalk'' of 99213 and 99214 tied to proposed HCPCS codes G3002 and G3003, including a modifier of 30–40 percent to compensate providers adequately for the labor involved in CPM services. One commenter stated that it believed clinicians billing for CPM services would face substantial decreases in work RVUs generated relative to current reimbursement compared to outpatient E/M codes and is unclear on how both codes could be billed. Another commenter stated that they believed the reimbursement proposed is inappropriately low, and urged us to adjust the proposed RVUs of 1.45 for HCPCS code G3002 and 0.5 for HCPCS code G3003 in the final rule. This commenter noted the work intended in this code will require significant time investment by physicians, qualified health professionals, and clinical staff. The same commenter noted HCPCS code G3002 should be crosswalked with CPT code 99414 at 1.92 work RVUs and HCPCS code G3003 be crosswalked with CPT code 99212 at 0.7 work RVUs. Another commenter stated we are undervaluing HCPCS code G3002 by crosswalking it to CPT code 99424, which has 1.45 RVUs. A similar 30-minute new patient office visit (CPT code 99203) is valued at 1.6 RVUs. This commenter also stated that an established patient visit (CPT code 99214) is valued at 1.92 RVUs. This commenter recommended CPT codes 99495 and 99496 for better crosswalks. Another commenter requested clarification on whether it is permissible for the same practitioner to bill a service like interventional pain management during the same month the clinician bills for the CPM services. Another commenter noted that E/M codes 99214 and 99213 already allow for time-based, face to face encounters with providers, have similar or greater work RVUs, and less limitations and requirements as compared to those specified in the code

descriptors for G3002 and G3003. This commenter recommends increasing the time allotment to 45 and 20 minutes for HCPCS codes G3002 and G3003, respectfully. The same commenter also expressed concern that providers would be less likely to utilize the CPM codes in favor of those they are already using and allowing for an increase in time allotment would correct this issue, according to this commenter.

Response: It is not our intent to either underpay, or create incentives for clinicians to use other codes that would constrain the use of the new codes. However, in the absence of experience with these new codes, we must base our projections reasonably on our experience with existing codes that we believe bear some relationship to the new proposed codes, such as the PCM code. Therefore, in light of the crosswalk to CPT codes 99424 and 99425, we are finalizing as proposed the work RVUs of 1.45 for HCPCS code G3002 and 0.5 for HCPCS code G3003. We will monitor use of the CPM codes to better determine if the payment rates and billing flexibilities are appropriate. In the proposed rule, we outlined our concerns about duplicate, or overlap billing in situations where the eligible clinician might bill certain E/M codes on the same day the CPM service(s) are rendered. Based on the commenters' concerns, we have reconsidered our approach to billing CPM services. We believe that, due to the complexities of pain treatment, there could be beneficiaries seeing a clinician for the first time, or in a subsequent visit, who could also need to be seen by the clinician for the CPM service(s) on the same day, or for a subsequent visit. The code sets for E/M services are organized into various categories and levels; the more complex the visit, the higher level of the code the clinician would bill within the appropriate category. Clinicians must make certain that the codes selected are appropriate for the services furnished, and that they fulfill the requirements to bill an E/M service.[61] Many Medicare beneficiaries have multiple chronic conditions,[62] and many of these conditions could involve chronic pain. We believe it is reasonable to assume that in many instances, the clinician could be spending time with the Medicare patient discussing health and wellness related to a variety of conditions that person may be experiencing, or expect to experience, and that interaction might not have a focus on the chronic pain aspects of the person's care. Additionally, if the person with pain has made the effort—which could be considerable, as commenters have noted, to get to an appointment with a clinician, it makes sense from a burden standpoint—allowing for the burden on both the clinician, and the person with Medicare, to permit billing for both the E/M service, and the CPM service(s) on the same day. Therefore, if all requirements to report each service are met, without time or effort being counted more than once, then both E/M and CPM may be billed on the same day.

Comment: Two commenters requested that we revisit existing guidance and regulations to allow pharmacies to bill Medicare for opioid-based compounded drugs. Another commenter urged CMS to reconsider the issue of reimbursement for medication used in intrathecal pumps. One of these commenters also requested that the compounded medications delivered to the physician's office for insertion into an implanted pump be reimbursed as an incident-to drug or Durable Medical Equipment, depending on the billing entity.

Response: We appreciate the commenters' thoughts about compounded drugs and reimbursement for medication used in intrathecal pumps; however, these comments are out of the scope of our proposals for CPM services.

Comment: Many commenters asked us to add CPM services to the Medicare Telehealth Services List. One commenter asked that we enable the CPM codes, in addition to being rendered through telehealth, to be furnished through audio-only technology. We address these comments in section II.D.1.c. of this final rule, Other Services Proposed for Addition to the Medicare Telehealth Services List.

Comment: One commenter suggested we include screening services in the CPM bundle to identify, reduce, and prevent hazardous or harmful alcohol and drug use, which the commenter characterized as common in people with SUD in residential treatment settings living with chronic pain. An additional commenter echoed the request for screening to identify, reduce, and prevent hazardous or harmful alcohol and drug use generally. This commenter also encouraged the inclusion of ordering of tests and Durable Medical Equipment, as well as consultations with other providers and communication with pharmacies be included. One commenter suggested the inclusion of nutrition screening and nutrition therapy in the code descriptions, as people with chronic pain often have complex dietetic and nutritional needs. Another provider group recommended that the term ''prognosis'' be added to the ''diagnosis'' in the bundle description as an option.

Response: As outlined in the proposed rule and in the CPM code descriptors, we expect clinicians to facilitate and coordinate any necessary behavioral health treatment, and other relevant care associated with HCPCS codes G3002 and G3003, such as complementary and integrative approaches and/or community-based care. This includes, as described in the CMS Behavioral Health Strategy,[63] multiple elements including access to prevention and treatment services for SUD, mental health services, crisis intervention and pain care to enable care that is well-coordinated and effectively integrated. Under the Strategy, we have defined behavioral health as ''encompassing a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental disorders and substance use disorders.'' ''Whole-person care'' is defined as ''the whole of a beneficiary's needs including physical health, behavioral health, long-term services and supports (home and community-based services, and institutional care), and health-related social needs.''

Comment: One commenter suggested we ensure that the proposed CPM codes are reimbursable in the beneficiary's home, and all other settings where primary care, mental health care, and SUD care can occur. Another commenter recommended inclusion of residential treatment facilities, long term care facilities, and homes as settings in which billing can occur.

Response: We appreciate the commenter's suggestion that we ensure that the proposed CPM codes are payable for services delivered in the beneficiary's home, and all other settings where primary care, mental health care, and SUD care can occur. We note that CPM is priced in both facility and non-facility settings, and we are not limiting the place of service for CPM, other than as discussed above (the initial visit must be in-person). The billing practitioner should report the place of service for the location where they would ordinarily provide face-to-face chronic pain management services to the beneficiary

Comment: Several commenters stated that the elements of the proposed CPM codes favor prescriptions by medical

[61] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/eval-mgmt-serv-guide-icn006764.pdf.*

[62] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook_Charts.*

[63] *cms.gov/cms-behavioral-health-strategy.*

providers, instead of prioritizing non-pharmacological strategies for pain management, including those developed by psychologists, that may be safe and effective for many patients. One commenter further stated that the creation of additional bundled codes that do not include medication management will allow for greater flexibility in treatment and allow psychologists to provide pain management services and practice to the top of their license when participating in team-based comprehensive chronic pain treatment. Another commenter suggested that physical and occupational therapists should be able to bill the codes, stating that these practitioners' practice integrates an understanding of a patient's or client's prescription and non-prescription regimen with consideration of its impact on health, function, movement, and disability, and that it is within the physical therapist's professional scope of practice to administer and store medication to facilitate outcomes of physical therapist patient and client management. The same commenter asked that we require, in the code descriptor, that physicians and other non-physician practitioners must refer appropriate chronic pain patients to physical and/or occupational therapy prior to being reimbursed for the codes. A few commenters requested that CMS create a code for providers who do not bill for E/M codes. One commenter stated that physical therapists and psychologists are not qualified to perform all the necessary services we have outlined, such as thorough pain assessments and diagnoses, medication management, crisis care, etc. and suggested we establish a path whereby non-physician professionals can bill a chronic pain code for services that are part of an overall treatment plan. Two commenters suggested that education be provided to physician providers to increase the consultation of physical and occupational therapists, also stating that physical therapists are significantly underutilized in community and rural settings.

Response: We acknowledge and support the important work of psychologists and occupational and physical therapists in the care of people with Medicare, including beneficiaries with chronic pain. We believe that this code describes a distinct PFS service that is reasonable and necessary in the diagnosis and treatment of the person with chronic pain, and that medication management, as described in the preamble text above, is a key element of such care and of the proposed HCPCS code G3002; therefore, we are including it as a code element.

We understand that cognitive behavior therapy (CBT), as one example, is a common treatment provided by psychologists, including to people with chronic pain.[64] [65] [66] Medicare covers psychotherapy, as well as other services that support mental health and wellness.[67] Chronic pain can be linked, in some people, to mental health conditions, such as anxiety and depression.[68] Psychotherapy is billed with Current Procedural Terminology (CPT) codes [69] that reflect the amount of time spent with the patient, and family may or may not be present during these therapy sessions. To bill these CPT codes, the psychotherapist must provide a mental health diagnosis using an International Classification of Diseases (ICD) code and/or Diagnostic and Statistical Manual (DSM) code.

While clinical psychologists (CPs) do not have prescription authority in all States and are therefore, not authorized to bill the Medicare program for any of the CPT codes that include medication management components, there are CPT codes that CPs can bill for treating Medicare patients who are diagnosed with chronic pain. Hence, the Health and Behavior Assessment and Intervention (HBAI) range of CPT codes are intended to be used for psychological assessment and treatment, when the primary diagnosis is a medical condition, such as chronic pain.

This family of codes was revised in 2020, when a new set of codes to describe these HBAI treatment services went into effect.[70] Health behavior assessment under these HBAI services is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation and adherence to medical treatment. Health behavior interventions under these HBAI services are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions. The HBAI codes apply to services that address psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. Use of HBAI codes requires a physical health diagnosis (ICD–10) to be the primary diagnosis. The HBAI codes capture services related to physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health-related risky behaviors, and adjustment to physical illness. The HBAI codes and the Psychotherapy codes cannot be billed contemporaneously. We believe HBAI codes are well-suited to the provision of CBT, as appropriate, to people with chronic pain when the person does not have a concurrent mental disorder.

For HCPCS codes G3002 and G3003, we are finalizing the codes for use by physicians and other qualified health professionals. However, we will consider if there is a benefit to modifying these codes and/or creating new codes that can potentially support broader chronic pain management by other practitioner types, including those who may not be prescribers in the scope of practice in the State in which they practice and are an important part of the care team for beneficiaries with chronic pain, in future rulemaking, such as clinical psychologists, or doctors of chiropractic. We do not agree that clinicians should be required to make referrals to occupational and physical therapists; although, as we stated in the proposed rule, and in the code descriptor, we do expect that there will be ''ongoing communication and care coordination between relevant practitioners furnishing care, for example physical therapy and occupational therapy . . . as appropriate.''

Comment: Several commenters opined on our proposal to require verbal consent at the initiating visit, or at the initiating visit and subsequent visits, to help make sure that people with Medicare living with chronic pain want the services, are aware they may need them, and that they also receive an explanation of any cost sharing that may apply in their particular situation. All commenters were supportive of our proposal. One commenter stated that, although it supported requiring consent, it noted that consent should be obtained at the third visit, so patients could be given an opportunity to work with the

[64] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[65] *https://www.va.gov/painmanagement/docs/cbt-cp_therapist_manual.pdf.*

[66] *https://www.nih.gov/news-events/nih-research-matters/meditation-cognitive-behavioral-therapy-ease-low-back-pain.*

[67] *https://www.cms.gov/files/document/mln1986542-medicare-mental-health.pdf.*

[68] *https://health.gov/healthypeople/objectives-and-data/browse-objectives/chronic-pain.*

[69] *https://www.ama-assn.org/practice-management/cpt.*

[70] *https://www.apaservices.org/practice/reimbursement/health-codes/health-behavior.*

physician a few times, but at the first visit the physician should still be required to educate patients regarding CPM services, explain their frequency/purpose/value, and any cost-sharing that may apply, so patients can better understand the model which is different according to the commenter from the disjointed, fragmented, solitary struggle for effective pain care that the vast majority of pain patients presently experience, and that in this manner, patients would have an opportunity to understand CPM services better. The commenter also stated consent should be discussed, including any costs with family/unpaid caregivers. The same commenter stated we need not require consent at each visit, and suggested that we should support practitioners referred by the CPM billing practitioner to also seek the patient's consent, to emphasize in part that they are working as a team. A different commenter stated that in implementing the new codes, we should establish requirements similar to CCM services, for example, requiring that providers document that all components of the service are met and that informed consent, inclusive of cost-sharing, has been obtained. Another commenter urged us to allow consent to be obtained and documented by members of the care team in addition to the physician/qualified health profession. One commenter believes that verbal consent should be obtained upon enrollment (at the first visit) and not at every visit, which would create inefficiencies. The spouse of a person living with longtime chronic pain observed that ''patient consent, consultation should always be a part of primary care as patients are typically ignored, especially in pain management.'' A commenter stated that consent, for some people with dementia or other cognitive health issues, might have to be obtained through a legal representative outside of the face to face initiating visit.

Response: We are appreciative of the comments regarding consent, as we believe the person with chronic pain should be educated regarding what the CPM services are, how often they may be generally expected to receive the services at this initial visit, and receive an explanation of any cost sharing that may apply in their particular situation; this is an important element of person-centered care and self-determination. We disagree with the commenter who suggested we obtain verbal consent after the first visit. Similar to how the Medicare Chronic Care Management service is administered, we believe the physician or qualified health care practitioner should get the person's consent for services before the practitioner bills for them. This helps to ensure that beneficiaries are engaged and are aware of their treatment and cost sharing responsibilities, and helps prevent duplicate billing. If the beneficiary does not provide consent or if other conditions for payment are not met, the practitioner cannot bill Medicare. As outlined in this preamble, referrals may be made to providers who are not rendering a Medicare covered service(s), or who may not be enrolled in Medicare, such as acupuncturists, massage therapists, psychiatrists, dieticians, dentists, and providers of community-based services, which could include companies that make environmental modifications, adult day health programs, direct support workers, and others, and we do not believe that requiring consent from providers who are not billing for the CPM codes is necessary or practicable. We agree that providers should document in the record that the beneficiary has given consent for the services, although we are not requiring that the clinician document that ''each element'' of the code has been delivered, since that would vary based upon the person's needs. We are thankful for the commenter who noted that consent, for some beneficiaries, may have to be obtained from a legally responsible person, such as for people with chronic pain who have dementia, an intellectual or developmental disability, or any other type of cognitive disorder; those arrangements vary under State law.

Comment: One commenter recommended that we focus and support continued communication and care coordination for the CPM services, which it stated has been a long-time struggle for chronic pain care, but an essential element, especially in underserved communities.

Response: We agree that care coordination and communication between all clinicians and other providers furnishing care to beneficiaries living with chronic pain is an essential element, including for people with pain living in underserved communities.

Comment: A few commenters stated that payers and providers should look at quality care and meaningful improvements in function and quality of life (beyond use of a validated pain rating scale or tool). One commenter stressed the importance of utilization and outcome measures that can assess efficacy and cost-effectiveness such as hospitalizations, emergency department and urgent care visits, specialist utilization and procedures, number of prescription medications, and other health care data. Another appreciated our interest in growing the available data related to the prevalence and impact of chronic pain in the Medicare population, and requested that once we collect data, this data be deidentified and made available to the public to assist interested parties in the development and refinement of programs. Another commenter requested that we provide a mechanism for quality outcomes measurement based on the provided service to shed light on pain experienced by the Medicare population, what works best, and what provides improved health outcomes, in part to reduce the need for specialty care and hospitalization. One commenter noted the importance of medication adherence, and data regarding medication adherence specific to chronic pain, including to avoid unnecessary hospitalizations, adverse events, and deaths.

Response: We agree with the commenters that quality and data collection are foundational components to delivering value as part of the overall care journey, and help ensure optimal care and best outcomes for people of all ages and backgrounds, and across service delivery systems/settings, and payer types, as described in our CMS National Quality Strategy.[71] We are aware that there are scant measures that examine chronic pain and medication adherence for chronic pain, and trust that government and interested parties will continue to explore options in measure development, testing, and endorsement to improve measurement in chronic pain care. However, because we did not make any proposals regarding the link between quality and CPM codes, these comments are out of the scope of our proposed rule.

Comment: Several commenters wanted to ensure that use of the CPM codes would not limit or interfere with the beneficiary's access to other medical or pharmacy benefits.

Response: We appreciate the comment and can confirm that its use will not interfere with other medically necessary Medicare benefits.

Comment: Many commenters requested more specifics related to the administrative requirements and potential burdens the use of the CPM codes would place on providers. Commenters urged CMS to work to ensure the documentation requirements not be overly burdensome. This was echoed by a commenter with chronic

[71] *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

pain who noted that physicians seem ''overwhelmed with today's paperwork and administrative demands.''

Response: In 2020, we established our Office of Burden Reduction and Health Informatics,[72] to unify our efforts to reduce regulatory and administrative burden, and advance interoperability and national standards. We are continuing to engage beneficiaries and the clinical community to better understand their experiences, form solutions, and infuse CMS with a customer-focused mindset. We will be interested to get feedback from clinicians about burden, once the CPM codes are implemented in practice.

Comment: A few commenters recommended CMS reduce potentially prohibitive payment methods, including prior authorization and cost sharing to improve access to chronic pain management. These commenters also suggested increasing access for non-opioid methods of pain management, such as physical therapy and behavioral health care. Another commenter also requested further clarification of cost sharing requirements, as many people with chronic pain have disabilities, with concern about limited access to pain management.

Response: The various interventions described in the PMTF Report's pain management ''Toolbox'' attest that individualized care consists of diagnostic evaluation that results in an integrative, person-centered care plan that includes all necessary treatment options, that we hope clinicians will consider when they treat Medicare beneficiaries with chronic pain. Regarding cost-sharing, as described above, standard Part B cost-sharing will apply to the CPM services. In some instances, people who are low income or disabled and are dually eligible Medicare and Medicaid beneficiaries, for example, will have different cost-sharing from beneficiaries who are enrolled in Medicare, only. We emphasize that the CPM codes do not require prior authorization.

Comment: One commenter expressed concern and confusion over our use of the word ''bundle'' in the proposed rule, which they interpreted as payment that contemplated paying other involved providers in an episode of care environment. The commenter further stated that payment-based ''bundling'' is already a fast-growing and promising form of pain care that should be correctly labeled.

Response: We apologize for any confusion by our use of the word ''bundle.'' The proposed CPM codes are not bundles as the commenter contemplates, but rather codes similar to the CCM codes, or the code for Cognitive Assessment and Care Planning Services, 99483, that denote the elements of the code itself. By ''bundle,'' we were just referring to all of the elements contained within the CPM code descriptors.

Comment: One commenter stated that caregivers and trusted family members are also part of the team providing support to people with chronic pain, and recommended including these individuals in the CPM services, which it noted is especially important for people who have communication or cognitive issues. Another commenter stated that caregiver participation for these individuals is especially important as they are often directly affected by the person's pain and can help in making its perception better, or worse.

Response: We agree that the role of caregivers is of critical importance across Medicare as caregivers provide a broad range of mostly unpaid assistance with diverse health-related activities provided by a friend, family member, partner, or neighbor to a care recipient. The caregiver has a significant personal relationship with the care recipient, and care may be episodic, daily, occasional, or of short or long duration. Caregivers assist in basic personal care activities such as eating and bathing; household management activities, such as shopping and meal preparation; and other activities, such as managing medications, attending medical encounters, and coordinating financial and other activities, such as handling insurance and paying bills. Caregivers may also be involved in managing complex health care and assistive technology activities at home and in navigating care transitions between settings of care. We are pointing out that Medicare makes payment for CPT code 96161 (*Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*). However, as noted in the descriptors for HCPCS codes G3002 and G3003, CPM services must be furnished by a physician or other qualified health practitioner.

Comment: One commenter stated that in implementing the CPM services, it is important for CMS to take a balanced approach between administrative burden and program integrity, and that use of the codes should be considered along with potential risk of ''bad actors'' to inappropriately use them. The same commenter indicated that we should prevent multiple group practices from concurrently billing for this service for the same patient during the same time period as this would eliminate duplicative services and payment. A different commenter echoed that sentiment, concerned with ''doctor shopping,'' leading to billing denials and driving up provider costs. Another commenter viewed this problem differently, discussing that some patients will travel for answers, or based on the availability of chronic pain providers in their areas, may need to see their primary care provider first, then may see other providers. This commenter was concerned that providers would not specifically know when this code was billed by previous providers, risking rejection even after services were provided. This commenter recommended eliminating the limits on monthly billing.

Response: As with implementation of any new billing code, we will be monitoring its use going forward, not just for data and other purposes, but also for program integrity reasons. For HCPCS code G3002 and G3003, we would not generally expect multiple group practices to be concurrently billing for a service that is to be rendered once per month, per practitioner, per beneficiary. As noted previously, we will be gathering data on the clinicians billing for and patients receiving the services described by these CPM codes, and we may consider making changes to these codes in future rulemaking, if necessary.

Comment: One commenter asked us to consider whether or not our proposal to create new codes for CPM is the best course, or if we should reconsider and expand the CCM codes. Another commenter elaborated on issues with the CCM codes, stating these are confusing to clinicians, involve administrative and documentation burden, which discourages uptake, and that it hopes this scenario will not develop with the CPM codes.

Response: We appreciate the comments about CCM vs. CPM; we did consider differences in the CCM codes, which we explained in the proposed rule, and believe the best course is to finalize the CPM codes and monitor their use in practice.

Comment: One commenter stated that evidence shows that many people with chronic pain, especially people from communities of color, have low trust in the health care system, based on previous discrimination and follow up. Another commenter stated that it is very important we improve pain management for members of racial and ethnic minorities, given both the rising

[72] *https://www.cms.gov/About-CMS/OBRHI.*

rates of drug overdose deaths among these populations and disparities in the identification and effective management of pain.

Response: As we outlined in the proposed rule, we are aware of disparities in chronic pain care and seek to address these disparities in part through finalization of the CPM codes.

Comment: A commenter asked that we consider a ''MedLearn'' article or Educational Transmittal to help providers understand more about the CPM services including who can bill, documentation, potential restrictions with other codes, etc. Several other commenters suggested provider communication such as a Medicare Learning Network article or similar blog post to summarize comments and the final rule. Another commenter suggested that we convene all essential stakeholders in public meetings, organized by the Agency, to hear stakeholder input about the best way to move forward to encourage rather than limit non-opioid pain management.

Response: We appreciate these suggestions from the commenters and are considering how best we can educate providers about use of the new codes, working with our HHS operating division partners.

Comment: A few commenters stated that CPM services should be able to be billed concurrently with CCM, Behavioral Health Integration, or Primary Care Management. Another commenter noted that CPM services might disincentivize the provision of CPM services to the most complex patients in part because neurologists routinely bill certain codes for safety purposes, and the CPM proposal, which prohibited same day billing of certain other codes, would impair care.

Response: We thank the commenters for sharing their feedback. As noted in the CY 2023 PFS proposed rule, we believe there are distinctions in the nature and extent of the assessments, care coordination, medication management, and care planning for CPM to allow concurrent billing for services that are medically reasonable and necessary, and that it is particularly important to allow for the provision of needed services, including behavioral health services to beneficiaries with chronic pain. Therefore, if all requirements to report each service are met then CPM may be billed in the same month as CCM, TCM, and BHI services. We reiterate that the time spent in providing CPM services may not represent time spent in providing any other reported service.

Comment: A commenter questioned how the CPM codes relate to the proposal in the CY 2023 OPPS proposed rule that would add the Facet Joint Interventions service category to the prior authorization list. This commenter noted that it seems incongruous for CMS to be encouraging chronic pain management with this CPM code while discouraging it in another.

Response: We thank the commenter for the comment; however, the discussion of the new prior authorization proposal in the CY 2023 OPPS proposed rule is beyond the scope of this CY 2023 PFS rule.

To further assist clinicians and interested parties in understanding more about how we anticipate the CPM services might be used, members of our clinical team have prepared the following scenarios to illustrate how the codes might be used in practice.

- *Scenario 1:* An individual clinician sees a new patient who is seeking to establish care (for example, a general internist sees a patient who is new to her practice and has a history of chronic pain). The internist/clinician would need to review the patient's history, including current and prior medications and treatments tried, and perform an examination to ascertain the source of the patient's symptoms as well as an initial functional assessment and develop a care management plan as part of the visit).

++ This scenario would also likely involve some aspect of medication management, may include referrals to behavioral health clinicians, substance use disorder, and/or pain management specialists, and would most certainly involve scheduling a follow-up appointment with the internist, which could occur in 1–2 weeks or in several months (or somewhere in between) depending on the needs of the patient.

++ While other clinicians are involved either through referrals or to support other elements of the CPM services, it is expected that generally only one or two clinicians would bill HCPCS code G3002/G3003, asserting that they are providing the CPM services.

- *Scenario 2:* An individual clinician sees an established patient who is well known and has a stable care plan and on maintenance medications (that is, a family physician sees a patient for routine care to update the care management plan and perform a functional assessment to ensure that the treatment plan is still supporting the patient's goals of care).

++ As we stated above, it would be unusual for no medications or supplements to be involved in the majority of cases of the management of chronic pain. This may or may not mean the patient is on a chronic opioid or other medication, and medication management is an almost universal component of chronic pain management care—even for very stable patients.

++ Medication management does not only involve management of medications that the patient is currently taking, but the ability to recognize when a new medication or over the counter treatment should be considered as an adjunct to other treatment, to discuss that recommendation in the context of shared decision-making and to initiate the pharmacotherapeutic plan of care.

++ Coordination of care (be it the person's behavioral health treatment or pain management care in general) is critical, and we mention in the proposed rule language that coordination is expected ''as an element of the CPM codes, the development of and/or revisions to a person-centered care plan that includes goals, clinical needs, and desired outcomes, as outlined above and maintained by the practitioner furnishing CPM services.'' However, not all psychologists are trained or authorized to coordinate such care as a primary care clinician is trained, as we have explained.

- *Scenario 3:* An individual clinician provides care to a patient with multiple chronic conditions (for example, a family physician sees a patient with a history of chronic low back pain, obesity, diabetes, and chronic renal insufficiency and routinely must manage multiple concerns at the same visit).

++ This clinician would likely perform routine functional assessments of this patient, medication management, ongoing clinical assessments of their diabetes and kidney function, and discussion of what their options are when it comes to managing their pain in the context of these other conditions. As such, without knowing the history of this patient's conditions, their current medications, past treatments that have been successful or failures, the clinician cannot properly manage this patient's chronic pain (for example. changes in medication must be made in the context of this patients' kidney function). Additionally, the clinician may wish to offer the patient non-pharmacologic options for the treatment of their chronic low back pain, which may include referrals to chiropractic, acupuncture, physical therapy, massage, cognitive behavioral therapy or other integrative or complementary/integrative treatments, all of which would be reasonable discussions to take place in the context of billing HCPCS codes G3002 and G3003, as appropriate.

• *Scenario 4:* One individual clinician transfers care of a patient to another individual clinician in the course of the month (for example, a family physician refers to a pain management specialist who then takes over the pain care aspects of a patient with chronic pain).

++ This situation could necessitate two different practitioners billing HCPCS code G3002 during that first month; the lead clinician could change to someone else on an infrequent and limited basis,

In summary, we are finalizing code descriptors for HCPCS codes G3002 and G3003, with two modifications to HCPCS code G3002 shown in italics, below.

HCPCS code G3002 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)*)

HCPCS code G3003 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month. (List separately in addition to code for G3002. When using G3003, 15 minutes must be met or exceeded.)*)

In response to public comments, we are finalizing our proposed policies pertaining to HCPCS codes G3002 and G3003, with a few modifications, as follows:

• We are defining chronic pain as persistent or recurrent pain lasting longer than 3 months, as proposed;

• We are requiring that the first time HCPCS code G3002 is billed, the physician or qualified health practitioner must see the beneficiary in-person. Both individuals must be in a clinical setting such as a primary care practitioner's office or other applicable setting, as proposed;

• A physician or other qualified health practitioner may bill HCPCS code G3003, for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month, after HCPCS code G3002 has been billed, as revised;

• A work RVU of 1.45 for HCPCS code G3002 and a work RVU of 0.5 for HCPCS code G3003, as proposed;

• That any of the CPM in-person components included in HCPCS codes G3002 and G3003 may be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries, as revised;

• That HCPCS codes G3002 and G3003 may be furnished and billed by physicians and other qualified health professionals, as proposed; and

• That both E/M and CPM may be billed on the same day if all requirements to report each service are met, and time spent providing CPM services does not represent time spent for providing any other reported service, as proposed.

In response to comments expressing lack of clarity about certain proposed policies pertaining to HCPCS codes G3002 and G3003, we are clarifying in this final rule that:

• The beneficiary, at the first visit, need not have an established history or diagnosis of chronic pain, or be diagnosed with a condition that causes or involves chronic pain; but that rather, it is the clinician's responsibility to establish, confirm, or reject a chronic pain and/or pain-related diagnosis when the beneficiary first presents for care and the clinician first reports HCPCS code G3002;

• That clinicians will be required to furnish all appropriate elements of the code bundle, but that we do not expect that all elements of the code bundle will be appropriate for every patient;

• That we are not requiring in the code descriptor that a clinician refer a beneficiary to other services; that determination should be made between the clinician and the beneficiary; and finally

• That CPM services would be available for billing/reporting in conjunction with remote patient monitoring, remote physiologic monitoring, or remote therapeutic monitoring if all requirements to report each service are met, and time spent providing CPM services does not represent time spent for any other furnished and billed service.

(34) Revisions to the ''Incident to'' Physicians' Services Regulation for Behavioral Health Services

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we created an exception to our ''incident to'' regulation at § 410.26(b)(5) under which ''incident to'' services generally must be furnished under direct supervision. Specifically, we finalized a policy to require general, rather than direct, supervision when chronic care management services are furnished incident to the billing physician's or NPP's services outside of the practice's normal business hours by clinical staff. In the CY 2017 PFS final rule (81 FR 80255), we finalized a revision to our regulation under § 410.26(b)(5) to require a general, rather than direct, level of supervision for designated care management services, and established that we would designate care management services through notice and comment rulemaking.

We understand that circumstances related to the PHE for COVID–19 have likely contributed to an increase in the demand for behavioral health services while also exacerbating existing barriers to beneficiaries' access to needed behavioral health services. For example, the American Psychological Association (APA) conducted a survey in 2020 and a follow-up survey in 2021 to better understand the impact of the COVID–19 pandemic on mental health treatment and the work of practicing psychologists. In the 2021 follow-up survey, many psychologists reported increases in the demand for treatment of anxiety and depression. They reported the greatest increases in treating anxiety disorders (84 percent, up from 74 percent), depressive disorders (72 percent, up from 60 percent), and trauma- and stress-related disorders (62 percent, up from 50 percent). Other diagnoses with large increases included sleep-wake disorders, obsessive-compulsive and related disorders, and substance-related and addictive disorders.[73]

Additionally, according to HRSA's National Center for Health Workforce Analysis, by 2025, shortages are projected nationally for a variety of behavioral health practitioners, including psychiatrists; clinical, counseling, and school psychologists; mental health and substance use social workers; school counselors; and

[73] *https://www.apa.org/pubs/reports/practitioner/covid-19-2021.*

marriage and family therapists.[74] Currently, there is no separate benefit category under the statute that recognizes the professional services of licensed professional counselors (LPCs) and Licensed Marriage and Family Therapists (LMFTs). Therefore, payment for the services of LPCs and LMFTs can only be made under the PFS indirectly when an LPC or LMFT performs services as auxiliary personnel incident to, the services, and under the direct supervision, of the billing physician or other practitioner. According to the American Counseling Association, there are more than 140,000 licensed professional counselors (LPCs) in the U.S., and the Medicare program's reimbursement for mental health treatment services delivered by this professional group could address provider shortages.[75] Additionally, according to the U.S. Bureau of Labor Statistics, there were approximately 54,800 Marriage and Family Therapists (MFTs) as of May 2021.[76]

In the 2022 CMS Behavioral Health Strategy,[77] CMS included a goal to improve access to and quality of mental health care services. In light of the current needs among Medicare beneficiaries for improved access to behavioral health services, and the existing workforce shortages impeding access to needed treatment for behavioral health, we have considered regulatory revisions that may help to reduce existing barriers and make greater use of the services of LPCs and LMFTs. We noted that CMS does not have authority to create a statutory benefit category for practitioner types. Therefore, we proposed to amend the direct supervision requirement under our ''incident to'' regulation at § 410.26 to allow behavioral health services to be furnished under the general supervision of a physician or NPP when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. We are limiting the scope of this proposal to behavioral health services at this time due to increased needs for behavioral health treatment and workforce shortages in this field. We believe that this proposed change will facilitate utilization and extend the reach of behavioral health services. We believe that any risk associated with this proposed change would be minimal, since the auxiliary personnel providing the services would need to meet all of the applicable requirements to provide incident to services, including any applicable licensure requirements imposed by the State in which the services are being furnished, as described in § 410.26(a)(1).

We received a high volume of public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they applaud CMS' proposed revisions to the ''Incident to'' Physicians' Services regulation for behavioral health services. Commenters stated that this proposal will help expand access to, and coordination of mental health services in rural and underserved areas where masters' level practitioners represent a substantial segment of the mental health providers in the area and doctoral-level clinicians such as psychologists are few, and for some patients a long distance away. Further, allowing the supervision of auxiliary staff such as licensed professional counselors (LPCs) and marriage and family therapists (MFTs) without requiring a continuous, direct physical presence would enable more patients to receive services. Commenters also described that these provisions will better engage the full panoply of behavioral health care providers in meeting the needs of Medicare beneficiaries, while further promoting beneficiary choice to select the type of behavioral health provider that best suits their mental health needs. Many commenters also noted that these proposed revisions are essential in light of the fact that the COVID–19 pandemic has exacerbated rates of depression, loneliness, and suicide among the elderly population.

Several commenters did not fully support changing the supervisory requirements from ''direct'' to ''general'' because they noted that most LPCs and LMFTs possess enough professional knowledge and training on mental health and addiction to not be under any level of supervision by a physician or NPP and requested that CMS add a separate benefit category for LPCs and LMFTs, whom the commenters state comprise 40 percent of the behavioral health workforce, in order to increase access to behavioral health services for Medicare beneficiaries. However, many commenters noted that they recognize that without Congressional action, CMS's ability to expand Medicare beneficiaries' access to LPCs and LMFTs is limited and stated they support all steps CMS can take to increase beneficiary access to these practitioners within its regulatory authority.

A few commenters noted that many mental health counselors practice in settings where they are not employed by or working directly with physicians or NPPs and would not be able to take advantage of this flexibility. Other commenters noted that the proposal to allow LPCs and LMFTs to furnish behavioral health services under general supervision is an important step to more effectively deploy behavioral health professionals to practice at the top of their license, stating that LPCs could be well positioned to treat patients for conditions including depression and anxiety, thereby creating greater capacity for clinical psychologists and other providers with more advanced training to treat patients with conditions that require more complex care. Commenters also described that with this new flexibility, primary care practices may be able to leverage a broader range of behavioral health professionals in the delivery of team-based integrated primary care, and therefore, design their workflows in ways to better address the needs of their patients.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to amend the direct supervision requirement under our ''incident to'' regulation at § 410.26 to allow behavioral health services to be furnished under the general supervision of a physician or NPP when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP.

Comment: Many commenters requested that CMS specify which services are considered ''behavioral health services,'' and would be eligible to be furnished under general supervision under our proposal. A few commenters urged CMS to define ''behavioral health services'' under the broadest terms possible for the purposes of this provision.

Response: We do not define behavioral health services by HCPCS codes; we did not propose to do so, and we believe individual practitioners are in the best position to determine whether particular treatments or diagnostic services are behavioral health services. However, we generally understand a behavioral health service to be any service furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders (SUD). We note that in the CY 2022 PFS final rule (86 FR 65061), we stated that SUD services

[74] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[75] *https://www.counseling.org/government-affairs/federal-issues/medicare-reimbursement.*

[76] *https://www.bls.gov/oes/current/oes211013.htm.*

[77] *https://www.cms.gov/cms-behavioral-health-strategy.*

are considered mental health services for the purposes of the expanded definition of ''interactive telecommunications system.'' Additionally, in the CY 2010 PFS final rule (74 FR 61787), we referenced that the outpatient mental health treatment limitation, which was phased out as of 2014, applied to outpatient treatment of a mental, psychoneurotic, or personality disorders, identified under the International Classification of Diseases (ICD) diagnosis code range 290–319. These are the types of behavioral health services that would be eligible to be furnished by auxiliary personnel under the general supervision of a physician or certain other nonphysician practitioners who are authorized under their statutory benefit category to have integral, although incidental, services provided incident to their own professional services. Services could include, but are not limited to services such as psychotherapy, Screening, Brief Intervention, and Referral to Treatment (SBIRT) services, psychiatric diagnostic evaluations, and other services furnished primarily for the treatment or diagnosis of mental health or SUD disorders.

Comment: Many commenters sought clarification regarding which types of clinicians may serve as auxiliary personnel under this policy. A few commenters pointed out that terminology for clinicians who furnish behavioral health care varies across states and requested that CMS include all independently licensed providers in each state. One commenter noted an example, that Washington State does not have an LPC credential, but the equivalent independent license in Washington is a Licensed Mental Health Counselor, or LMHC, and noted that states that have alternative titles for comparable credentials would benefit greatly by being able to use these clinicians to furnish services under general supervision for Medicare beneficiaries and requested that CMS consider expanding this proposal to include all those providers with comparable state-issued licenses. Some commenters encouraged inclusion of other mid-level clinicians who provide behavioral health treatment services, such as certified addictions counselors. Other commenters pointed out a range of clinicians that participate in furnishing behavioral health treatment, including occupational therapists, psychiatric pharmacists, and peer support specialists. Another commenter pointed out that physician assistants are qualified to help address workforce shortages and access to behavioral health treatment. Many commenters also highlighted the importance of peer support services, which commenters stated are designed to value lived experience and to empower an individual to direct their own recovery with dignity, noting that integrating peer support services in clinical settings increases engagement in care and improves both physical and mental outcomes, and requested clarification as to whether peer support specialists could be considered auxiliary personnel. A few commenters noted that under Medicare's partial hospitalization program, CMS defaults to State licensure laws on which providers are eligible to provide care, and therefore, encouraged CMS to adopt, for the purposes of this provision, deference to State licensure laws where the care is taking place.

Response: We note that the definition of auxiliary personnel at § 410.26(a)(1) defines auxiliary personnel as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We note that we did not propose any changes to the existing regulatory definition of auxiliary personnel in § 410.26, and therefore, we are not making any changes to this definition in this rule. All requirements for services furnished incident to a physician's or NPP's professional services listed at § 410.26 continue to apply. Many of the clinician types mentioned by commenters could satisfy this definition.

Comment: Several commenters requested that CMS create a mechanism for licensed psychologists to bill Medicare for the services furnished by advanced psychology trainees under a licensed psychologist's supervision, noting this is allowed by many State Medicaid programs. The commenters stated that clinical psychology interns have 1,000 to 2,000 hours of clinical experience prior to beginning their internship, but under current Medicare rules, they are not able to independently bill Medicare, which leaves psychology training programs without a steady source of funding and prevents trainees from gaining valuable experience working with older patients and patients with disabilities. Additionally, several commenters requested that CMS include behavioral health providers who are in the process of seeking full licensure, such as associate marriage and family therapists and State licensed associate counselors, as auxiliary personnel. The commenters noted that these are individuals who have met their state's graduate education and exam requirements but have not yet met the supervised experience requirement.

Response: We thank the commenters for their feedback; however, we note that these comments are outside of the scope of our proposed change to the required level of supervision for behavioral health services furnished incident to a physician, NPP, or CP, because we did not propose any changes to Medicare payment rules regarding interns or postdoctoral students.

Comment: A few commenters stated they opposed the expansion of NPPs scope of practice beyond their State license, education, and training. One commenter stated that while they recognize the important services these practitioners provide on the care team, Medicare patients—most of whom have multiple chronic conditions, in addition to complex behavioral health issues—should have access to primary care and specialty physician services. They stated they believe that NPPs should be under the direct supervision of a licensed physician and work within the care team. Several commenters urged CMS to defer to State laws and leave the scope of practice to the State legislatures and State licensing boards. Another commenter noted that scope of practice is determined by one's licensure in the State and supervision can ensure safe delivery of that care. One commenter encouraged CMS to conduct data collection and research on the care provided by LPCs and LMFTs prior to expanding the policy to other providers to ensure patients are receiving the best quality care to meet their needs. A few commenters stated they oppose any supervisory changes that undermine the oversight of physician-led health care teams. One commenter expressed concern that under general supervision, the supervising clinician usually provides oversight to a larger number of non-medical behavioral health clinicians, which creates an obstacle to providing immediate feedback when needed and suggested that guardrails are needed to ensure that appropriate psychiatric consultation is available.

Response: The change to the level of supervision for ''incident to'' behavioral health services from direct to general does not alter the longstanding regulatory definition of auxiliary personnel. Accordingly, any individual who qualifies as auxiliary personnel under the ''incident to'' regulations at § 410.26, which requires services to be furnished in accordance with applicable State law, will continue to qualify as such, regardless of the required level of supervision assigned to the services. The definition of general supervision requires the services to be furnished under the physician's (or other practitioner's) overall direction and control. These requirements must be met for the physician or practitioner to bill for the behavioral health service. In the case where State law and scope of practice are silent about whether an individual serving in the capacity of auxiliary personnel is licensed/authorized to provide a given behavioral health service, the supervision level for the provision of the behavioral health service will default to the standard direct supervision requirement for ''incident to'' services. Additionally, in order for payment to be made under Medicare Part B for the services and supplies incident to the services of a physician or other practitioner, the service must be an integral, though incidental, part of the service of the physician or practitioner in the course of diagnosis or treatment of an injury or illness, in accordance with § 410.26(b). For this to be met, we would expect there to be a course of treatment established by the physician or practitioner and in which the physician or practitioner is actively participating and managing.

Comment: Several commenters expressed support for CMS allowing behavioral health services to be furnished under general supervision in the RHC and FQHC settings as well, and a few commenters encouraged CMS to utilize its regulatory authority to amend the FQHC ''incident to'' regulations and FQHC mental health visit to include an encounter performed by an LPC and LMFT to generate a billable visit in Medicare to better align with Medicaid.

Response: We appreciate these suggestions from the commenters. We note that for CY 2023, the proposed change to the level of supervision for ''incident to'' behavioral health services from direct to general was applicable only to services payable under the PFS, which means services furnished in the RHC and FQHC settings were not addressed in the relevant proposal in the CY 2023 PFS proposed rule (87 FR 46062 through 46068). We may consider changes to the regulations regarding services furnished at RHCs and FQHCs in the future. Additionally, we note that the types of practitioners' services that can be considered RHC and FQHC services are specified in section 1861(aa)(1) and (3) of the Act, respectively, and do not include the services of LPCs and LMFTs.

Comment: One commenter suggested that CMS require a claims modifier when services are billed ''incident to'' which could indicate the type of personnel who performed the service (for example, LPC, LMFT, clinical psychologist, clinical social worker). The commenter stated that because this proposal would relax the supervision policy for behavioral health services billed as ''incident to'' services, transparency is necessary to understand the impacts of this change, evaluate the quality of behavioral health care provided, monitor the use of services, and inform future improvements.

Response: We thank the commenter for this suggestion. We may consider a claims modifier for billing ''incident to'' services broadly for future rulemaking.

Comment: Several commenters raised potential impacts for beneficiaries who are dually eligible for Medicare and Medicaid. A few commenters urged CMS to clarify that LPCs may be reimbursed by the Medicaid program for services they provide to dually-eligible Medicare beneficiaries, without documentation of a Medicare claim denial or, alternatively, create a protocol to provide such a denial so that the Medicaid program will process the claim.

Response: We thank commenters for this information and feedback, but we note that this rule focuses on supervision, not which party will be reimbursed for furnishing behavioral health services. We note that this policy is limited to the change in the required level of supervision for behavioral health services furnished by auxiliary personnel incident to the services of a physician or NPP, and therefore, we do not anticipate that this policy would have an effect on the processing of crossover claims for beneficiaries who are dually eligible for Medicare and Medicaid.

(35) New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

In the CY 2017 PFS final rule (81 FR 80230), we established G-codes to describe monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99492–99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078). Additionally, we created a fourth G-code to describe services furnished using other models of BHI in the primary care setting, which was replaced by CPT code 99484 in the CY 2018 PFS final rule (82 FR 53077 and 53078).

We stated in the CY 2017 PFS final rule (81 FR 80236) that we recognized that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care. We finalized a code set to pay accurately for care furnished using this specific model of care, given its widespread adoption and recognized effectiveness. However, we stated we recognized that there are primary care practices that are incurring, or may incur, resource costs inherent to treatment of patients with similar conditions based on BHI models of care other than the psychiatric CoCM that may benefit beneficiaries with behavioral health conditions, and therefore, finalized a General BHI code which may be used to report a range of models of BHI services, and that we expected this code to be refined over time as we receive more information about other BHI models in use.

In the CY 2018 PFS final rule (82 FR 53078), we stated that we had received inquiries from interested parties about whether professionals who were not eligible to report the approved initiating visit codes for BHI services to Medicare might nonetheless serve as a primary hub for BHI services. For example, interested parties have suggested that a CP might serve as the primary practitioner that integrates medical care and psychiatric expertise. For purposes of future rulemaking, we sought comment on the circumstances under which this model of care is happening and whether additional coding would be needed to accurately describe and value other models of care. A few commenters suggested that CMS create separate codes to describe behavioral health care management services that could be billed by CPs and NPPs who are not authorized to bill Medicare for E/M services. One commenter suggested that CMS include psychiatric diagnostic evaluation services that can be furnished and billed by CPs as eligible initiating visits. Commenters also

described other models of care that are in use, including the STAR–VA model and a model used in outpatient health care settings where a clinical social worker (CSW) not only furnishes psychiatric care but also assists with psychosocial aspects of medical care.

In the CY 2017 PFS final rule (81 FR 80239), we stated that we had received a few comments suggesting that in addition to the qualifying E/M services (or an AWV or IPPE), the initiating visit services for BHI should include in-depth psychological evaluations delivered by a CP including CPT codes 90791, 96116 or 96118, which include care plan development. In this final rule, we established that the same services that qualify as the initiating visit for CCM would also qualify as initiating services for BHI, which do not include in-depth psychological evaluation by a CP and which were not, in their entirety, within the scope of CPs' practice, and therefore, CPs would not be able to report the General BHI code directly (although a psychiatrist may be able to do so) (81 FR 80239).

In the 2022 CMS Behavioral Health Strategy,[78] we included a goal to improve access to and quality of mental health care services, and included an objective to ''increase detection, effective management and/or recovery of mental health conditions through coordination and integration between primary and specialty care providers.'' As previously noted in this proposed rule, we understand that circumstances related to the COVID–19 PHE have likely contributed to an increase in the demand for behavioral health services while also exacerbating existing barriers in beneficiaries' access to needed behavioral health services. In light of the feedback we have received and considering the increased needs for mental health services, we proposed to create a new G code describing General BHI performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration. Specifically, we proposed to create HCPCS code GBHI1 *(Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)* We proposed to value this service under the proposed HCPCS code GBHI1 based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484 *(Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team),* because the services described by GBHI1 closely mirror those described by CPT code 99484. Therefore, we believe that this crosswalk is an appropriate valuation of the level, time, and intensity of the proposed service described by HCPCS code GBHI1. CPs are authorized under their statutory benefit category at section 1861(ii) of the Act to furnish ''qualified psychologist services'' to include ''such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.'' Additionally, the statutory benefit category for CSWs at Section 1861(hh)(2) of the Act defines ''clinical social worker services'' as ''services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.'' Based on the authorizations under the CP and CSW statutory benefit categories, CPs are authorized to furnish and bill for services that are provided by clinical staff incident to their professional services when the ''incident to'' requirements specified in § 410.26 of our regulations are met, and would be authorized to do the same when furnishing services described by proposed HCPCS code GBHI1, whereas CSWs would only be able to bill Medicare for services they furnish directly and personally. The proposed work value for HCPCS code GBHI1 is 0.61 (based on a direct crosswalk to CPT code 99484). We solicited comment on whether this proposed value accurately reflects the resource costs involved in furnishing these models of care, or whether additional coding may be needed, for example, separate coding for CPs and CSWs. We also solicited comment on the proposed requirements for billing GBHI1, including any applicable ''incident to'' requirements, and the role and responsibilities of CSWs and CPs.

In the CY 2017 PFS final rule (81 FR 80239), we finalized the requirement of an initiating visit for the BHI codes for new patients or beneficiaries not seen within a year of commencement of BHI services. We stated that the initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the billing practitioner's professional services), ensure the billing practitioner assesses the beneficiary prior to initiating care management processes, and provide an opportunity to obtain beneficiary consent. We noted that the existing eligible initiating visit codes are not, in their entirety, within the scope of the CP's practice. Given that, we proposed to allow a psychiatric diagnostic evaluation (CPT code 90791) to serve as the initiating visit for GBHI1. We welcome comment on whether we should consider additional codes to qualify as the initiating visit.

In the CY 2017 PFS final rule (81 FR 80235), we established that CCM and BHI services could be billed during the same month for the same beneficiary if all the requirements to bill each service are separately met. We are also proposing that HCPCS code GBHI1 could be billed during the same month as CCM and TCM services, provided

[78] *https://www.cms.gov/cms-behavioral-health-strategy.*

that all requirements to report each service are met and time and effort are not counted more than once. The patient consent requirements would apply to each service independently.

In the CY 2017 PFS final rule (81 FR 80235), we established that the BHI services may be furnished incident to the billing professional's services under general supervision because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) to have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. We believe this is also the case for the service described by GBHI1. Therefore, consistent with other care management codes paid under the PFS, we proposed to add HCPCS code GBHI1 to the list of designated care management services for which we allow general supervision.

We received public comments on new coding and payment for general behavioral health integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs). The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposed coding and payment for BHI that would recognize psychologists' role in integrated care. The commenters expressed support for recognizing multiple evidence-based models of integrated care, stating this allows psychologists the flexibility required to support the behavioral health needs of the broader community. Other commenters noted that by providing access to behavioral health and health behavior services within primary care settings, BHI services can be particularly helpful in addressing treatment disparities affecting members of racial and ethnic minorities, and those living in underserved and vulnerable communities with inadequate access to mental and behavioral health specialists. A few commenters stated this proposal will provide additional flexibility to primary care practices to design their workflows to best suit the needs of beneficiaries and the care team's capacities. Commenters noted that the establishment of this code will also help to recognize psychologists' role in integrated care and allow psychologists the flexibility required to support the behavioral health needs of the broader community. Other commenters pointed out that a potential advantage of the proposed service code is that HCPCS code GBHI1 appropriately adds additional autonomy to CP and CSW clinical practice, which has the potential to improve job satisfaction and retention. Additionally, commenters stated that allowing for reimbursement of measurement-based care, interprofessional coordination, and care management services may incentivize more CPs and CSWs to participate in the Medicare behavioral health clinician network, which would in turn increase patient access to care management services and behavioral health treatment driven by validated outcome measurements. Commenters also expressed support for allowing these services to be furnished under general supervision.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing this code as proposed. We note that the code GBHI1 was a placeholder code and that the final code number will be HCPCS code G0323 (*Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*)

Additionally, we are finalizing our proposal to add HCPCS code G0323 to the list of designated care management services for which we allow general supervision.

Comment: Several commenters stated they agreed with CMS that CPT code 90791 (psychiatric diagnostic evaluation) could appropriately serve as the initiating visit, noting that psychologists and social workers are not able to bill E/M services. A few commenters also requested that CPT code 96156, health behavior assessment and reassessment, also serve as an allowable initiating visit for the newly proposed BHI code. Another commenter urged CMS to broaden the types of visits that can serve as an initiating visit for HCPCS code GBHI1, stating that a visit with a primary care provider or social worker would also be appropriate initial visit types and that limiting the initiating visit to a psychiatric diagnostic evaluation undermines CMS' intent to expand access to wraparound services for individuals receiving mental health services.

Response: We appreciate the commenters suggestion about considering other CPT codes such as 96156 (health behavior assessment, or reassessment), as well as E/M visit codes in addition to CPT code 90791 (psychiatric diagnostic evaluation) to serve as the initiating visit for GBHI1. However, when considering that CPs and CSWs cannot bill the program for E/M visits because they are not licensed by the States to furnish such services and, that the range of health behavior assessment and intervention codes are for billing primarily for physical illnesses rather than psychiatric illnesses, we believe that 90791 is the best option that aligns with the services that CPs and CSWs are authorized to furnish under State law and scope of practice. Accordingly, recognizing a code for which CPs and CSWs can bill as an initiating visit for HCPCS code G0323 offers them greater access and opportunity to furnish integrated care management services.

Comment: A few commenters expressed concern about the medical management of patients in models of care without psychiatric involvement and suggested that the ability to receive immediate advice on prescribing from a psychiatrist or child psychiatrist, as is the case in the existing evidence-based psychiatric CoCM model, should be a mandatory element in all other collaborative care models to ensure patient safety and high-quality patient care. A commenter also pointed to the existing interprofessional consultation codes (CPT codes 99446–99449, 99451–99452) and urged CMS to emphasize the importance of consultative relationships between psychiatrists, primary care physicians, clinical psychologists, and clinical social workers in order to ensure high-quality care.

Response: We thank the commenters for this feedback. In the CY 2017 PFS final rule (81 FR 80236 through 80238), we noted that we created the General BHI code in order to allow payment for models of integrated care other than the psychiatric collaborative care (CoCM) code. We agree with the comment regarding the importance of consultative relationships between various members of the care team, including psychiatrists, primary care physicians, clinical psychologists, and clinical social workers.

Comment: Many commenters supported the proposed valuation based on a crosswalk to CPT code 99484. A few commenters opposed the proposed valuation, stating that CPT code 99484 describes clinical staff time and is valued assuming the service is performed by a behavioral health care manager and that those assumptions do not accurately reflect the cost when the service is performed by a clinical psychologist or clinical social worker. Another commenter stated they do not believe this proposed value accurately reflects the resource costs involved in furnishing these models of care as the amount of time needed to complete the required elements will take far longer than 20 minutes per month and there is a substantial amount of work that occurs outside of the office. The commenter urged CMS to consider a code that permits multiple billable units of 20 minutes per unit per month capped at 10 units per month to better acknowledge the amount of time it takes to adequately perform the required elements, as well as the critical effort that occurs outside the office visit.

Response: We thank the commenters for this feedback. After consideration of the comments, for CY 2023, we are finalizing the value of HCPCS code G0323 as proposed, however we may consider changes in how this code is valued for future rulemaking. We note that the commenter's suggestion regarding codes that permit multiple billable units of 20 minutes per unit per month is outside of the scope of the proposal.

Comment: A few commenters requested that CMS clarify whether HCPCS code GBHI1 may be billed in conjunction with codes describing remote monitoring services. The commenter stated they support the new code but sought clarification on whether HCPCS code GBHI1 could be billed in conjunction with the following services: remote patient monitoring (CPT code 99091), remote physiologic monitoring (CPT codes 99453, 99454, 99457, 99458), or remote therapeutic monitoring (CPT codes 98975, 98976, 98977, 98980, 98981 and as proposed GRTM1/2/3/4) codes.

Response: HCPCS code G0323, and the services describing remote patient monitoring, remote physiologic monitoring, and remote therapeutic monitoring, are distinct types of services, although there may be some overlap in eligible patient populations. There may be some circumstances where it is reasonable and necessary to provide both services in a given month. The BHI codes, including HCPCS code G0323, could be billed for the same patient in the same month as the RPM or RTM services. All applicable requirements for the individual codes must be met, including obtaining informed consent from the beneficiary, for both the remote monitoring and BHI. In this circumstance, appropriate billing in a given month means that time and effort cannot be counted more than once when using BHI codes with RPM or RTM. Billing practitioners should remember that cost sharing applies to each service independently. If all requirements to report each service are met, without time or effort being counted more than once, both may be billed.

Comment: Several commenters requested that CMS clarify that providers of peer support services (also known as peer support specialists and peer recovery specialists) may bill as part of behavioral health integration codes including the new GBHI1 code and collaborative care codes.

Response: While there is no statutory benefit category under Medicare law that authorizes direct billing and payment to peer support specialists for their professional services under the Medicare Part B program, it may be possible for peer support specialists to provide their services in an ''incident to'' capacity. That is, if a peer support specialist meets the definition of auxiliary personnel as defined under the ''incident to'' regulations at § 410.26, then they could be eligible to provide behavioral health services within their scope of practice in accordance with State law under the supervision of a physician or certain nonphysician practitioners.

Comment: One commenter suggested that CMS should consider use of telehealth visits to meet the initiating visit criteria as this would serve to increase access in alignment with CMS' stated goal. Another commenter encouraged CMS to monitor utilization of the code if finalized and noted that the type of work described is resource intensive and needs to be valued accordingly. Another commenter stated they supported the proposed crosswalk, but it was unclear to them whether the current valuation is accurate, stating that CPT code 99484 will be reviewed by the RUC at their September 2022 meeting.

Response: We may consider these commenters' suggestions for future rulemaking. Additionally, we intend to monitor utilization of this code and any subsequent changes to the valuation of CPT code 99484 in order to determine whether we may need to re-visit the valuation through future rulemaking.

Comment: One commenter encouraged CMS to consider broadening the scope of services in this code to include coordination of social care. The commenter stated that the behavioral health care manager will be more successful in getting individuals successfully engaged in treatment if they are able to attend to basic resources and social needs by referring to relevant social services and programs and that counting minutes spent coordinating mental health treatment but not minutes spent helping address other concerns is burdensome for clinicians and does not make sense clinically when it is all part of a typical evidence-based clinical social work interventions that result from a comprehensive psychosocial assessment and collaborative planning process to work toward the overarching goal (in this case, improved behavioral health).

Response: We appreciate the commenters suggested consideration of making payment for coordination of social services. We did not propose to include coordination of social care in HCPCS code G0323, so for this reason we will not be finalizing such a change. As we continue to consider ways to expand access to behavioral health services, we may consider this for future rulemaking.

Comment: A few commenters stated they support additional coding to promote integration and recommended that CMS develop a bundled payment for behavioral health services that would include wraparound services and could be used in value-based payment arrangements.

Response: We appreciate these suggestions. While they are out of scope for this proposed rule, we may consider additional coding to promote integration and payment through future rulemaking.

(36) Request for Information: Medicare Part B Payment for Services Involving Community Health Workers (CHWs)

The American Public Health Association (APHA) defines a community health worker as a ''frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery.'' Community Health Workers are classified as a workforce category by the Department of Labor. The Community Health Worker Core

Consensus Project (C3) lists the following ten roles of CHWs: [79]

- Cultural mediation among individuals, communities, and health and social service systems.
- Providing culturally appropriate health education and information.
- Care coordination, case management, and system navigation.
- Providing coaching and social support.
- Advocating for individuals and communities.
- Building individual and community capacity.
- Providing direct service.
- Implementing individual and community assessments.
- Conducting outreach.
- Participating in evaluation and research.

Findings from randomized controlled trials indicate that particular CHW interventions reduce chronic disease disparities in low income, racial and ethnic minority communities, such as type 2 diabetes, hypertension, HIV/AIDS, and obesity.[80] [81] [82] [83] [84] We are also interested in better addressing the social needs of beneficiaries; for example, in the FY 2023 IPPS/LTCH proposed rule, we proposed new measures under the Hospital Inpatient Quality Reporting Program pertaining to assessing social determinants of health. The CHW skillset may position this workforce to address these social needs. In light of the significant benefits that services involving CHWs can potentially offer the health of Medicare beneficiaries, including a reduction in health disparities, we are interested in learning more about how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. For example, physicians and other eligible practitioners are able to report care management services and behavioral health integration services based on tasks personally provided by clinical staff under their supervision. Some of the elements of the comprehensive care plans referenced in the description of care management services include medication management, community/social services ordered, and coordination with other agencies, which are also some of the services personally provided by CHWs.

Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We are interested in learning whether and how CHWs, as auxiliary personnel of physicians and hospitals, may provide reasonable and necessary services to Medicare beneficiaries under the appropriate supervision of health care professionals that are responsible more broadly for medical care, including behavioral health care. We are also looking to understand whether and how services involving CHWs are accounted for under the existing CCM codes or other care management or behavioral health integration services, including whether the employment and supervision arrangements ordinarily adopted within the industry would meet the requirements that allow for billing by supervising professionals or providers, including RHCs and FQHCs. For example, do CHWs tend to be employees of physicians or of the same entities that employ physicians? Are physicians or other medical professionals supervising their interaction with patients in a manner consistent with direct supervision—for example, immediate availability in the same location?

We noted that CHWs are employed in a number of sectors, including local government, community-based organizations, and social services sectors. Therefore, the health care providers working with CHWs may have established nontraditional relationships with these organizations outside of the health sector. We are interested in learning how payments between health care provider organizations, and community-based organizations, local governments, and social service organizations, account for the costs of services provided by CHWs, and how health care provider organizations ensure that the funding amount is sufficient to cover the costs of the full range of CHW services. We also solicited comment on whether and to what extent CHW services are provided in association with preventive services, including those covered by Medicare.

Physicians and certain other health care practitioners are authorized to bill Medicare for services furnished incident to their professional services by auxiliary personnel. Our regulation at § 410.26 requires that auxiliary personnel who perform services incident to the services of the billing physician or other practitioner must be acting under the supervision of the billing practitioner, and must meet any applicable requirements, including licensure, imposed by the State in which the services are furnished. We understand that there is wide variation in State standards for CHWs. In addition, the training that CHWs receive is typically provided by employers but varies widely in terms of its breadth and scope.[85] We are trying to understand how CHWs might also be recognized as auxiliary personnel in the Medicare context, and are therefore interested in learning how States may have determined whether and under what circumstances CHWs have the necessary qualifications to perform services that would improve the health of Medicare beneficiaries and others being treated by supervising professionals or providers.

We received several public comments in response to our request for information about Medicare Part B Payment for Services Involving Community Health Workers (CHWs). We appreciate the thoughtful feedback submitted by the public on this matter and may consider these comments in future rulemaking.

(37) Recognition of the Nurse Portfolio Credentialing Commission (NPCC)

The Medicare program established qualifications under regulations at § 410.75 for NPs and, under § 410.76 for clinical nurse specialists (CNS). Both the NP and CNS qualification regulations require that NPs and CNSs be certified as a NP or a CNS by a

[79] St John, J.A., Mayfield-Johnson, S.L., & Hernández-Gordon, W.D. (2021). Introduction: Why Community Health Workers (CHWs)? In *Promoting the Health of the Community* (pp. 3–10). Springer, Cham.

[80] Kangovi S, Mitra N, Grande D, Huo H, Smith RA, Long JA. Community Health Worker Support for Disadvantaged Patients With Multiple Chronic Diseases: A Randomized Clinical Trial. *Am J Public Health*. 2017;107(10):1660–1667. doi:10.2105/AJPH.2017.303985.

[81] Cooper L.A., Roter D. L., Carson K. A., et al. A randomized trial to improve patient-centered care and hypertension control in underserved primary care patients. J Gen Intern Med. 2011;26(11):1297–1304.

[82] Spencer MS, Rosland AM, Kieffer EC, Sinco BR, Valerio M, Palmisano G, et al. Effectiveness of a community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial. Am J Public Health. 2011 Dec;101(12):2253–60.

[83] Brown LD, Vasquez D, Lopez DI, Portillo EM. Addressing Hispanic Obesity Disparities Using a Community Health Worker Model Grounded in Motivational Interviewing. Am J Health Promot. 2022;36(2):259–268.

[84] Kenya, S., Jones, J., Arheart, K. *et al.* Using Community Health Workers to Improve Clinical Outcomes Among People Living with HIV: A Randomized Controlled Trial. *AIDS Behav* 17, 2927–2934 (2013).

[85] Fasting, D., Mayfield-Johnson, S.L., St. John, J.A., & Hernández-Gordon, W.D. (2021). In Promoting the Health of the Community (pp. 43–52). Springer, Cham.

recognized national certifying body that has established standards for NPs and/or CNSs, and that a listed certifying body must be approved by the Secretary. An identical list of Medicare recognized and approved national certifying bodies for NPs and CNSs is included under Chapter 15, section 200 and 210 of the Medicare Benefit Policy Manual, pub. 100–02.

The organizations listed under program manual instructions as recognized national certifying bodies for NPs and CNSs are as follows:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

The Nurse Portfolio Credentialing Commission (NPCC) has requested to have its organization added to the lists of recognized national certifying bodies for NPs and CNSs who specialize in clinical genetics/genomics and are awarded the Advanced Clinical Genomics Nurse (ACGN) credential. The NPCC's request to CMS describes the NPCC as a non-profit organization, established in 2018 by genetics/genomics nurse leaders as the only organization that now offers new credentials to advanced practice registered nurses (APRNs) who specialize in genetics/genomics, a nursing specialty recognized by the American Nurses Association.

Additionally, the NPCC's letter states that its organization evolved directly from the American Nurses Credentialing Center (a listed, CMS-recognized national certifying body) and the Genetic Nursing Credentialing Commission, which are the organizations that awarded new genetics/genomics nursing credentials from 2001 to 2018. However, as of 2019, the American Nurses Credentialing Center (ANCC) stopped offering new credentialing to genetics nurses and instead offers only renewal credentialing to nurses who specialize in genetics. Since 2019, the NPCC has awarded the ACGN credential to 32 APRNs from 17 States.

Now, with the NPCC being the only organization that offers new credentialing to nurses in genetics, the NPCC is concerned that the absence of its organization from the current list of recognized national certifying bodies appropriate for NPs and CNSs presents a barrier and a disadvantage for newly credentialed APRNs. Specifically, the NPCC is concerned that newly NPCC credentialed NPs and CNSs seeking enrollment under Medicare would be denied on the basis that they do not meet Medicare's certification requirement unless the NPCC is listed as a recognized national certifying body appropriate for NPs and CNSs who specialize in genetics/genomics. The website for the NPCC is available at *https://www.nurseportfolio.org*.

When considering previous requests to add other organizations to the list of recognized national certifying bodies for NPs and CNSs, we stated that it is not our intention to be overly restrictive in our program requirements and consequently prevent qualified NPs and CNSs who specialize in areas of medicine other than those certified by the ANCC from participating in the Medicare program as NPs or CNSs and from rendering care to patients in need of specialized services (see 71 FR 69707). Accordingly, we proposed to add the NPCC organization to the list of recognized national certifying bodies in manual instructions for NPs at section 200 and CNSs at section 210 of the Medicare Benefit Policy Manual, pub. 100–02. We requested public comments on this proposal.

The following is a summary of the public comments received on our proposal concerning the NPCC, along with our response to these comments.

Comment: One commenter stated that its organization is concerned that the addition of the NPCC to the list of recognized national certifying bodies for NPs and CNSs would create confusion between the national certifying bodies for NPs and CNSs that are already listed under program manual instructions and, the NPCC. The commenter described the NPCC as a type of credentialing organization that provides an additional credential in advanced clinical genomics to demonstrate expertise in a specific specialty area to already certified and licensed NPs and CNSs. Therefore, the commenter asserted that since the list of recognized national certifying bodies in program manual instructions lists the organizations that provide the certification necessary to practice under Medicare as a NP or a CNS in accordance with Medicare regulations, it does not support adding the NPCC, which offers a specialty credential that goes beyond the requisite qualification requirements for NPs and CNSs.

Response: We appreciate the commenters concern about creating confusion by adding the NPCC to the list of recognized national certifying bodies for NPs and CNSs. When establishing this list of recognized national certifying bodies for NPs and CNSs, we were cautious about being overly restrictive in our program requirements and consequently preventing qualified NPs and CNSs who specialize in areas of medicine other than those certified by the American Nurses Credentialing Corporation (ANCC) from participating in the Medicare program as NPs or CNSs and from rendering care to patients in need of specialized services. Accordingly, the current list recognizes organizations that certify NPs and CNSs with specialties in obstetrics, gynecology, neonatal nursing, pediatrics, oncology, hospice and palliative care. It is our intent to exercise this same caution when considering additional prospects given the current severe shortage of health care professionals such as NPs and CNSs available to render care to patients, particularly those who are certified and furnish specialized services. Since the ANCC no longer offers new credentialing to genetics nurses, the NPCC is the only organization that offers new credentialing for this nurse specialty. Therefore, our consideration to recognize and list the NPCC is to prevent the potential for such genetics nurses from being denied enrollment in the Medicare program.

Comment: Another commenter stated that CMS should recognize the NPCC as a national certifying body for NPs and CNSs.

Response: We appreciate the support of our proposal. After considering the public comments on the NPCC proposal, we are finalizing our proposal to recognize and add the NPCC to the list of national certifying bodies that is housed in our program manual instructions in the Medicare Benefit Policy Manual, pub. 100–02, at Chapter 15, section 200 for NPs and, 210 for CNSs.

(38) Request for Information: Medicare Potentially Underutilized Services

Medicare provides payment for many kinds of services that support beneficiaries in promoting health and well-being and that may also, in some cases, reduce unnecessary spending within the health care system by decreasing the need for more expensive kinds of care. Some examples of these services may include patient

educational services, like Diabetes Self-Management Training or preventive services, like the Annual Wellness Visit.

We solicited comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by Medicare beneficiaries. We also solicited regarding how we might best mitigate some of these obstacles, including for example, through examining conditions of payment or payment rates for these services or by prioritizing beneficiary and provider education investments.

We discussed that ''high value'' health services have been described as those ''services that provide the best possible health outcomes at the lowest possible cost.'' [86] The American College of Physicians states that high value services seek ''to improve health, avoid harms, and eliminate wasteful practices.'' [87] However, we described that we believe that some high value Medicare services may be potentially underutilized by beneficiaries. In some cases, limited use of these kinds of services occurs disproportionately in underserved communities.

Disparities in health and healthcare persist despite decades of research and widespread efforts to improve health outcomes in the United States.[88] Certain populations, including groups experiencing racial disparity, people with disabilities, individuals dually eligible for Medicare and Medicaid, and those living in rural and underserved areas are more likely to experience challenges accessing healthcare services, lower quality of care, and below average health outcomes when compared to the general population.[89] [90] [91] Many known factors impede efficient and equitable healthcare, including workforce challenges, transportation issues, healthcare costs, language barriers, a lack of health literacy, and confusion about health insurance coverage and processes.[92] Additional factors include social determinants of health and community-level burdens that contribute to the exacerbation of health disparities. For example, disparities in cancer screening and treatment across racial and ethnic groups have been well documented. Research demonstrates that minority populations are less likely to receive cancer screening tests than their white counterparts and, consequently, are more likely to be diagnosed with late-stage cancer.[93] Additionally, racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests that would serve to confirm cancer diagnoses.[94] We are committed to building solutions that will help close gaps in healthcare quality, access, and outcomes.[95]

We noted that we are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[96] Health equity as defined by CMS [97] means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. More information regarding CMS's Strategic Plan for health equity is available in the CMS Strategic Plan Pillar: Health Equity Fact Sheet: *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

In light of the concerns regarding the potential underutilization of high value health services, particularly among potentially underserved communities, we are committed to promoting these high value services within the Medicare program. In concert with the CMS strategy to advance health equity in addressing health disparities that underlie our health system, we stated that we seek to engage with interested parties and solicit comment regarding ways to identify and improve access to high value, potentially underutilized services by Medicare beneficiaries.

We solicited comment on how to best define and identify high value, potentially underutilized health services. We also stated that we are also looking to understand what existing services within current Medicare benefits may represent high value, potentially underutilized services, such as:

- Preventive Services;
- Annual Wellness Visits;
- Diabetes Management Training;
- Screening for Diabetes;
- Referral to appropriate education/prevention/training services
- Immunizations/vaccinations
- Cancer screenings
- Cardiac rehabilitation services
- Intensive Behavioral Therapy for obesity
- Opioid treatment programs
- Complex/Chronic Care Management
- Cognitive Assessment & Care
- Behavioral Health Integration Services

[86] ''Michigan Program on Value Enhancement.'' Institute for Healthcare Policy & Innovation (28 Apr. 2022). *https://ihpi.umich.edu/featured-work/michigan-program-value-enhancement.*

[87] High value care. ACP. (n.d.). (May 9, 2022). *https://www.acponline.org/clinical-information/high-value-care.*

[88] Office of Minority Health. (2021, January, page 3). *Paving the Way to Equity: A Progress Report.* Centers for Medicaid and Medicare Services. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[89] Agency for Health Care Research and Quality (AHRQ). (2021, June). *2019 National Healthcare Quality and Disparities Report.* AHRQ. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr19/index.html.*

[90] Executive Order No. 13985, 86 FR 7009 (2021, January 20). *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.* For the purposes of this RFI, we are using the definitions of equity and underserved communities established in Executive Order 13985, ''The term 'equity' means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' The term ''underserved communities'' refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

[91] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human. Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based. Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[92] Lahr, M., Henning-Smith, C., Rahman, A., Hernandez, A. (2021, January). *Barriers to Health Care Access for Rural Medicare Beneficiaries: Recommendations from Rural Health Clinics.* University of Minnesota Rural Health Research Center. *https://rhrc.umn.edu/wp-content/uploads/2021/01/UMN–RHC-Access-to-Care-PB_1.20.pdf.*

[93] Agency for Healthcare Research and Quality [AHRQ], 2004; National Institutes of Health/National Cancer Institute [NIH/NCI], 2001). Racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests needed to confirm cancer diagnoses (Battaglia et al., 2007; Ries et al., 2003.

[94] Battaglia et al., 2007; Ries et al., 2003.

[95] Office of Minority Health. (2021, January). *Paving the Way to Equity: A Progress Report.* Centers for Medicaid and Medicare Services. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[96] *https://www.cms.gov/pillar/health-equity.*

[97] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

Other examples of Medicare preventive services are available at the following website: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html*.

We invited the public to submit information about specific obstacles to accessing these services and how specific potential policy, payment or procedural changes could reduce potential obstacles and facilitate better access to high value health services. Specifically, we solicited new and innovative ideas that may help broaden perspectives about potential solutions. Ideas may include, but are not limited to:

- Educational or marketing strategies (informed by beneficiary input) to promote awareness of available programs and resources that advance the utilization of ''high value'' services;
- Aligning of Medicare and other payer coding, payment and documentation requirements, and processes related to ''high value'' services;
- Recommendations from States and other interested parties regarding how to best raise awareness of underutilized services, with special consideration for the dual-eligible population;
- Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance the utilization of ''high value'' services; and
- New recommendations regarding when and how CMS issues regulations and policies related to ''high value'' services and how CMS can advance rules and policies for beneficiaries, clinicians, and providers.

We stated that we are interested in learning about how CMS might best promote high value care and health equity, address concerns regarding health disparities, and increase access to high value services, which could improve the health of Medicare beneficiaries. We also noted that comments received in response to this RFI may be used to identify potential opportunities for improvement to and refinement of existing Medicare FFS and MA programs.

We received numerous comments on our request for information about Medicare Potentially Underutilized Services. We appreciate the thoughtful feedback submitted by the public on this important issue and plan to consider these suggestions for possible future rulemaking and program refinement.

(39) Change in Procedure Status for Family Psychotherapy

The CPT codes that describe family psychotherapy are payable under Medicare, but are currently assigned a restricted status indicator in the Medicare Physician Fee Schedule payment files. The codes describing family psychotherapy with the patient present are CPT code 90847 (Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes) and CPT code 90849 (Multiple-family group psychotherapy). We noted that CPT code 90846 (Family psychotherapy (without the patient present), 50 minutes) describes family psychotherapy without the patient present. In past rulemaking, we have discussed that Medicare has generally taken the stance that coverage is limited to items and services that are for the diagnosis and treatment of the individual beneficiary.

During the COVID–19 pandemic, the number of adults reporting adverse behavioral health conditions has increased sharply, with higher rates of depression, substance use, and self-reported suicidal thoughts observed in racial and ethnic minority groups.[98] We are seeking to ensure that appropriate care is furnished to Medicare beneficiaries and noted that CPT codes 90847 and 90849 are payable under Medicare. Accordingly, we proposed to update our payment files to remove the restricted (''R'') procedure status indicator for CPT codes 90847 and 90849 and assigning these codes an active (''A'') procedure status indicator.

We noted that there are national coverage determinations (NCDs) addressing family psychotherapy described by CPT codes 90847 and 90849 describing the settings of care in which these services are covered, documentation requirements and other guidelines.[99] The Medicare National Coverage Determinations (NCD) Manual, Pub. 100–03, section 70.1, titled ''Consultations with a Beneficiary's Family and Associates'' states that ''family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition.'' [100] The change to the ''A'' status indicator for these subject CPT codes does not alter the policy under the applicable coverage determinations for these codes.

We received public comments on the change in procedure status for family psychotherapy. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal to change the procedure status indicator for the family therapy codes (90847, 90849) from R (restricted) status to A (active) status. A few commenters stated that this change will remove a barrier to care, while some noted that there remain national coverage determinations carrying documentation requirements and guidelines that the MACs can consider and ultimately use to restrict coverage. One commenter stated they believed that CPT code 90846 should also not be restricted, as this is an important service particularly for adolescents, families of substance use disorder patients, and families attempting to manage behavioral manifestations of dementia.

Response: In response to the comment requesting that the procedure status for CPT code 90846, which describes psychotherapy without the patient present, be updated to an active status, we thank the commenter for this feedback and may consider changes to the procedure status for CPT code 90846 in the future. After consideration of the comments, we are finalizing our updates to the procedure status indicators for CPT codes 90847 and 90849—both will be assigned an A for active status, effective January 1, 2023.

(40) Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment, Furnished by Intensive Outpatient Programs (IOPs)

There are a range of services described by existing coding under the PFS that can be billed for treatment of mental health conditions, including SUDs, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, we have increased the coding and payment mechanisms for substance use treatment services paid under the PFS. For example, in the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD) (HCPCS codes G2086–G2088). In the CY 2021 PFS final rule, we finalized expanding the bundled payments described by HCPCS codes G2086–

[98] *https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm*.

[99] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57065&ver=10&keyword=&keywordType=starts&areaId=all&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=90847&hcpcsEndCode=90847&sortBy=title&bc=1*.

[100] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=16&ncdver=1*.

G2088 to be inclusive of all SUDs (85 FR 84642 and 84643).

Additionally, in the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing bundled payments for episodes of care for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). Medicare also covers services furnished by inpatient psychiatric facilities and partial hospitalization programs (PHP). PHP services can be furnished by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHPs are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in § 1861(ff) of the Social Security Act (the Act). According to the Medicare Benefit Policy Manual, Chapter 6, Section 70.3, the treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation. PHPs work best as part of a community continuum of mental health services which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support.

We understand that in some cases, people that do not require a level of care for mental health needs that meets the standards for PHP services, nonetheless require intensive services on an outpatient basis. We are interested in whether or not the current coding and payment mechanisms under the PFS adequately account for intensive outpatient services that are part of a continuum of care in the treatment. For example, according to SAMHSA's *Advisory on Clinical Issues in Intensive Outpatient Treatment for Substance Use Disorders,* IOP programs for substance use disorders (SUDs) offer services to clients seeking primary treatment; step-down care from inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. IOP treatment includes a prearranged schedule of core services for example, individual counseling, group therapy, family psychoeducation, and case management) for a minimum of 9 hours per week for adults or 6 hours per week for adolescents. The 2019 National Survey of Substance Abuse Treatment Services reports that 46 percent of SUD treatment facilities offer IOP treatment.[101]

We solicited comment on whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or substance use disorder treatment, including and especially SUDs, for Medicare beneficiaries. We are particularly interested in the extent to which any potential gaps would best be addressed by the creation of new codes, revision of particular billing rules for some kinds of care in specific settings, or whether the valuation of particular codes (existing or new) needs to be addressed in order to better reflect the relative resource costs involved in furnishing intensive outpatient mental health services. We are also interested in additional, detailed information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform our ability to ensure that Medicare beneficiaries have access to this care.

We received several public comments in response to our comment solicitation on intensive outpatient mental health treatment, including SUD treatment, furnished by IOPs. We appreciate the feedback submitted by the public on this matter, including support for providing care along the full continuum of behavioral health services, the settings of care in which IOP services are typically furnished, the service elements that are typically included in IOP treatment, and potential options for valuation of such services, and may consider these comments in future rulemaking.

(41) Comment Solicitation on Payment for Behavioral Health Services Under the PFS

As discussed throughout this final rule, we are committed to ensuring that beneficiaries have access to needed services for mental and behavioral health. Through the CMS Behavioral Health Strategy, CMS seeks to remove barriers to care and services, and to adopt a data-informed approach to evaluate our behavioral health programs and policies. We strive to support a person's whole emotional and mental well-being and promote person-centered behavioral health care.[102]

As part of our review of our payment policies and systems, we understand that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to PE. In the CY 2018 PFS final rule (82 FR 52999), we discussed that some interested parties had suggested that for codes in which direct PE inputs for a service are very low, the methodology for allocating indirect PE does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. We stated that primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders, are among the services most affected by our methodology.

We solicited comment on how we can best ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS.

We received several public comments in response to our comment solicitation on payment for behavioral health services under the PFS. We appreciate the feedback submitted by the public on this matter and may consider these comments in future rulemaking.

(42) Payment for Interstitial Device Remote Monitoring (HCPCS Code G2066)

We received comments regarding payment changes for cardiovascular remote monitoring services described by HCPCS code G2066. We note that we did not make any proposal to change the payment rate of HCPCS code G2066, we are not finalizing any changes to the payment rate for HCPCS code G2066, and that these comments are out of the scope of our proposed rule. However, after considering the comments, we acknowledge the concerns raised by interested parties regarding price transparency and payment stability for certain contractor priced services.

We believe it is important for interested parties to continue to engage with their local MAC to address these concerns about price transparency and payment stability for contractor priced services. Ideally, these interactions would support dialogue that address the specific concern about lack of transparency, through the sharing of applicable and requested information, which in turn supports the MACs payment decision process. We believe that to the extent such requested information is shared, MACs would be

[101] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep20-02-01-021.pdf.*

[102] *https://www.cms.gov/cms-behavioral-health-strategy.*

willing to engage in a discussion about the information, including how their review of the information relates to their payment decisions. This ongoing dialogue would also allow the MACs to make determinations about how to effectuate their payments decision to address the concerns about payment stability, that is, the requested information and engagements would provide a better understanding of the impact of payment changes on interested parties, and inform MAC consideration for allowing interested party adjustment to any payment changes through advance communication, or use of transition periods.

(43) Radiation Oncology Model

On August 29, 2022, CMS finalized delaying the current start date of the Radiation Oncology Model (ROM) to a date to be determined through future rulemaking. In the CY 2020 PFS final rule (84 FR 62797), we finalized that, in the interest of payment stability, we would continue to maintain current coding for radiation treatment services, including HCPCS G-codes with their current work RVUs and direct PE inputs, given the introduction of the RO Model, and to prevent disruption in beneficiary access to radiation treatment services. While we did not make any proposals for payment for these radiation treatment services under the PFS for CY 2023, we note that we are reviewing our current coding and payment policies for the radiation therapy services, including whether we should adopt the revised CPT coding that was established in CY 2015 to allow for coding and payment consistency, considering the fact that CMS finalized delaying the current start date of the ROM earlier this year. Any such changes would be addressed in future rulemaking.

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TABLE 16: CY 2023 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	NEW	7.05	7.05	Yes
15851	Removal of sutures or staples requiring anesthesia (ie, general anesthesia, moderate sedation)	0.86	1.10	1.10	No
15853	Removal of sutures or staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00	No
15854	Removal of sutures and staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00	No
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	22.09	20.42	22.09	No
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace	5.22	5.22	5.22	No
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	27.75	24.83	26.80	No
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment	8.16	7.30	7.96	No
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	27.13	27.13	27.13	No
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	NEW	C	C	No
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level	7.03	7.03	7.03	No
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level	2.34	2.34	2.34	No
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment	17.48	17.13	17.13	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	19.60	19.60	19.60	No
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	2.80	2.80	2.80	No
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling	NEW	2.44	2.44	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
33900	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, unilateral	NEW	11.03	11.03	No
33901	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, bilateral	NEW	14.50	14.50	No
33902	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, unilateral	NEW	14.00	14.00	No
33903	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, bilateral	NEW	16.50	16.50	No
33904	Percutaneous pulmonary artery revascularization by stent placement, each additional vessel or separate lesion, normal or abnormal connections	NEW	5.53	5.53	No
36836	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	NEW	7.20	7.20	No
36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	NEW	9.30	9.30	No
42975	Drug induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing, flexible, diagnostic	1.90	1.58	1.58	No
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	2.09	2.09	2.09	No
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon	NEW	3.11	3.11	No
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)	NEW	2.80	2.80	No
49436	Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter	2.72	2.72	2.72	No
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	5.96	5.96	No
49592	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	8.46	8.46	No
49593	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or	NEW	10.26	10.26	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible				
49594	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	NEW	13.46	13.46	No
49595	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	13.94	13.94	No
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	18.67	18.67	Yes
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	7.42	7.42	No
49614	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	10.25	10.25	No
49615	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	NEW	11.46	11.46	No
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	NEW	15.55	15.55	Yes
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	16.03	16.03	Yes
49618	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	22.67	22.67	Yes

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible	NEW	13.70	13.70	Yes
49622	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated	NEW	17.06	17.06	Yes
49623	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic)	NEW	2.61	3.75	No
50080	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (eg, stone[s] up to 2 cm in single location of kidney or renal pelvis, nonbranching stones)	15.74	12.11	12.41	No
50081	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (eg, stone[s] > 2 cm, branching stones, stones in multiple locations, ureter stones, complicated anatomy)	23.50	20.61	20.91	No
55821	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages	15.76	15.18	15.18	No
55831	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal	17.19	15.60	15.60	No
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	26.80	22.46	22.46	No
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	NEW	19.53	19.53	No
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical	16.20	14.91	14.91	No
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	13.18	12.00	12.00	No
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar	3.15	3.86	3.86	No
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg,	4.25	4.25	4.25	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment				
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment	3.19	3.78	3.78	No
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, including imaging guidance, when performed	1.35	1.35	1.50	No
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.48	1.65	1.80	No
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve, including imaging guidance, when performed	1.27	1.31	1.31	No
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, including imaging guidance, when performed	1.00	1.28	1.39	No
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.36	1.64	1.75	No
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, including imaging guidance, when performed	1.10	1.34	1.34	No
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.41	1.68	1.68	No
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor	8.69	6.68	6.68	No
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex	9.77	9.03	9.03	No
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor	8.80	7.91	7.91	No
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex	9.77	9.46	9.46	No
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor	5.93	6.36	6.36	No
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex	7.13	7.38	7.38	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	8.50	8.50	No
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	9.97	9.97	No
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	10.25	10.25	No
73580	Radiologic examination, knee, arthrography, radiological supervision and interpretation	0.54	0.59	0.59	No
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation	0.79	0.79	0.79	No
76881	Ultrasound, complete joint (ie, joint space and peri-articular soft-tissue structures), real-time with image documentation	0.63	0.54	0.90	No
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation	0.49	0.59	0.69	No
76883	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	NEW	0.99	1.21	No
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation	0.67	0.67	0.67	No
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)	0.54	0.54	0.54	No
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.60	0.60	No
90460	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered	0.17	0.24	0.24	No
90461	90461 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered	0.15	0.18	0.18	No
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	0.17	0.17	0.17	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)	0.15	0.15	0.15	No
90473	Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)	0.17	0.17	0.17	No
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)	0.15	0.15	0.15	No
92065	Orthoptic training; performed by a physician or other qualified health care professional	0.37	0.71	0.71	No
92066	Orthoptic training; under supervision of a physician or other qualified health care professional	NEW	0.00	0.00	No
92284	Diagnostic dark adaptation examination with interpretation and report	0.24	0.00	0.00	Yes
92287	Anterior segment imaging with interpretation and report; with fluorescein angiography	0.81	0.40	0.40	No
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	C	0.50	0.50	No
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	0.00	0.00	0.00	No
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	C	0.00	0.00	No
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	0.50	0.50	0.50	No
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	C	0.55	0.55	No
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	0.00	0.00	0.00	No
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	C	0.00	0.00	No
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	0.55	0.55	0.55	No
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization	1.11	1.00	1.00	No
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used	1.13	1.03	1.03	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	for bypass to one or more coronary arteries during congenital heart catheterization				
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography	0.86	0.50	0.50	No
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography	0.86	0.50	0.50	No
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography	0.97	0.70	0.70	No
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure)	0.88	0.88	0.88	No
93569	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral	NEW	0.63	0.78	No
93573	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral	NEW	1.30	1.30	No
93574	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization	NEW	1.44	1.44	No
93575	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, during cardiac catheterization for congenital heart defects, each distinct vessel	NEW	1.92	1.92	No
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	14.75	13.80	15.00	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	19.75	16.90	18.10	No
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia	5.50	5.50	5.50	No
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed	19.77	15.80	17.00	No
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	5.50	5.50	5.50	No
95919	Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral	NEW	0.18	0.18	No
96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	NEW	N	N	No
96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes	NEW	N	N	No
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days	NEW	C	C	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	1.92	1.63	1.63	No
99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.	2.61	2.60	2.60	No
99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.	3.86	3.50	3.50	No
99231	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.	0.76	1.00	1.00	No
99232	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded	1.39	1.59	1.59	No
99233	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.	2.00	2.40	2.40	No
99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	2.56	2.00	2.00	No
99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.	3.24	3.24	3.24	No
99236	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or	4.20	4.30	4.30	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.				
99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter	1.28	1.50	1.50	No
99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter	1.90	2.15	2.15	No
99242	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	I	I	I	No
99243	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	I	I	I	No
99244	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	I	I	I	No
99245	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.	I	I	I	No
99252	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.	I	I	I	No
99253	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	I	I	I	No
99254	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	I	I	I	No
99255	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 80 minutes must be met or exceeded.	I	I	I	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional	0.48	0.25	0.25	No
99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making	0.93	0.93	0.93	No
99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making	1.60	1.60	1.60	No
99284	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making	2.74	2.74	2.74	No
99285	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making	4.00	4.00	4.00	No
99304	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.	1.64	1.50	1.50	No
99305	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.	2.35	2.50	2.50	No
99306	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	3.06	3.50	3.50	No
99307	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.	0.76	0.70	0.70	No
99308	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	1.16	1.30	1.30	No
99309	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.55	1.92	1.92	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
99310	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	2.35	2.80	2.80	No
99315	Nursing facility discharge management; 30 minutes or less total time on the date of the encounter	1.28	1.50	1.50	No
99316	Nursing facility discharge management; more than 30 minutes total time on the date of the encounter	1.90	2.50	2.50	No
99341	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	1.01	1.00	1.00	No
99342	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.52	1.65	1.65	No
99344	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	3.38	2.87	2.87	No
99345	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.	4.09	3.88	3.88	No
99347	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	1.00	0.90	0.90	No
99348	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.56	1.50	1.50	No
99349	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	2.33	2.44	2.44	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
99350	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	3.28	3.60	3.60	No
99358	Prolonged evaluation and management service before and/or after direct patient care; first hour	2.10	I	I	No
99359	Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes	1.00	I	I	No
99415	Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour	0.00	0.00	0.00	No
99416	Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes	0.00	0.00	0.00	No
99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time	I	I	I	No
99418	Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time	NEW	I	I	No
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination, Medical decision making of moderate or high complexity,	3.80	3.84	3.84	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity, Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]), Medication reconciliation and review for high-risk medications, Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s), Evaluation of safety (eg, home), including motor vehicle operation, Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks, Development, updating or revision, or review of an Advance Care Plan, Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 60 minutes of total time is spent on the date of the encounter.				
G0316	Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	0.61	0.61	No
G0317	Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	0.61	0.61	No
G0318	Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	0.61	0.61	No
G0323	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling	NEW	0.61	0.61	No

HCPCS	Descriptor	CY 2022 Work RVU	Proposed CY 2023 Work RVU	Final CY 2023 Work RVU	CMS Work Time Refinement
	and/or psychiatric consultation; and continuity of care with a designated member of the care team.				
G3002	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, complementary and integrative care approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)	NEW	1.45	1.45	No
G3003	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month. (List separately in addition to code for G3002. When using G3003 15 minutes must be met or exceeded.)	NEW	0.50	0.50	No

TABLE 17: CY 2023 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
15778	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms	5	3	L1: Refined time to standard for this clinical labor task	-0.91
15778	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	7	3	L1: Refined time to standard for this clinical labor task	-1.82
15778	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	4	3	L1: Refined time to standard for this clinical labor task	-0.46
15778	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	4	3	L1: Refined time to standard for this clinical labor task	-0.46
43290	Egd flx trnsorl dplmnt balo	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and referral forms	5	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.91
43290	Egd flx trnsorl dplmnt balo	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	15	10	G1: See preamble text	-2.28
43291	Egd flx trnsorl rmvl balo	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	10	2	L1: Refined time to standard for this clinical labor task	-3.64
49436	Embedded ip cath exit-site	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.37
49591	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Conduct patient communications	6	3	L1: Refined time to standard for this clinical labor task	-1.37
49591	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49591	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49591	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49591	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49592	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49592	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49592	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49592	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49593	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49593	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49593	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49593	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49594	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and	8	5	L1: Refined time to standard for	-1.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					equipment in facility			this clinical labor task	
49594	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49594	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49594	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49595	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49595	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49595	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49595	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49596	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49596	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49596	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49596	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49613	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Conduct patient communications	6	3	L1: Refined time to standard for this clinical labor task	-1.37
49613	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49613	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49613	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49613	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49614	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49614	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49614	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49614	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49615	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49615	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49615	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls	7	3	L1: Refined time to standard for	-1.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and prescription			this clinical labor task	
49615	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49616	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49616	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49616	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49616	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49617	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49617	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49617	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49617	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49618	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49618	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49618	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49618	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49621	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49621	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49621	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49621	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49622	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49622	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49622	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49622	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
63020	Neck spine disk surgery	EQ168	light, exam	F		125	0	E10: Equipment removed; not typically used for this procedure	-0.41
63030	Low back disk surgery	EQ168	light, exam	F		125	0	E10: Equipment removed;	-0.41

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								not typically used for this procedure	
90460	Im admin 1st/only component	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
90460	Im admin 1st/only component	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.20
90471	Immunization admin	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
90471	Immunization admin	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.20
90472	Immunization admin each add	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
90472	Immunization admin each add	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
90473	Immune admin oral/nasal	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
90473	Immune admin oral/nasal	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.20
90474	Immune admin oral/nasal addl	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
90474	Immune admin oral/nasal addl	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.08
99341	Home/res vst new sf mdm 15	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80
99342	Home/res vst new low mdm 30	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80
99344	Home/res vst new mod mdm 60	SJ053	swab-pad, alcohol	NF		2	0	G1: See preamble text	-0.08
99344	Home/res vst new mod mdm 60	SJ061	tongue depressor	NF		1	0	G1: See preamble text	-0.03
99344	Home/res vst new mod mdm 60	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80

TABLE 18: CY 2023 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
43291	Egd flx trnsorl rmvl balo	EQ235	suction machine (Gomco)	NF		53	45	E15: Refined equipment time to conform to changes in clinical labor time	-0.07
43291	Egd flx trnsorl rmvl balo	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		53	45	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
43291	Egd flx trnsorl rmvl balo	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	NF		80	72	E15: Refined equipment time to conform to changes in clinical labor time	-1.58
49436	Embedded ip cath exit-site	EF014	light, surgical	NF		70	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
49436	Embedded ip cath exit-site	EF015	mayo stand	NF		43	40	E15: Refined equipment time to conform to changes in clinical labor time	0.00
49436	Embedded ip cath exit-site	EF031	table, power	NF		70	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
49436	Embedded ip cath exit-site	EQ137	instrument pack, basic ($500-$1499)	NF		49	46	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

TABLE 19: CY 2023 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
0446T, 0448T	implantable interstitial glucose sensor	SD334	$1,500.00	$3,000.00	100%	6	97
88108, 88112, 88120, 88121, 88173, 88182, 88184, 88185	centrifuge tube	SL024	$0.08	$0.26	225%	1	2,631,215
88120, 88121, 88366, 88374, 88377	ThermoBrite	EP088	$4,625.07	$5,250.16	14%	3	259,145
88182, 88184, 88185	flow cytometer	EP014	$192,000.00	$205,774.80	7%	1	1,991,567
88184, 88185	lysing reagent (FACS)	SL089	$3.645	$5.53	52%	10	1,990,922
88302, 88304, 88305, 88307, 88309, 88355, 88362, G0416	embedding paraffin	SL061	$5.30	$9.38	77%	1	12,572,274
88302, 88304, 88305, 88307, 88309, G0416	Clarifier	SL469	$0.005	$0.007	40%	1	12,572,163
88364, 88365, 88367, 88368, 88369, 88373	Universal Detection Kit	SA117	$4.00	$6.05	51%	1	70,414
92230, 92235, 92242, 92287	fluorescein inj (5ml uou)	SH033	$38.02	$49.13	29%	6	362,071
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$200.15	$260.35	30%	21	428,031
93792, G0248, G0249	INR analysis and reporting system w-software	EQ312	$19,325.00	$69,621.00	260%	5	1,051,950

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
G2082	Esketamine (56 mg vial)	SH109	$590.02	$683.67	16%	1	1,268
G2083	Esketamine (84 mg vial)	SH110	$885.02	$1,025.50	16%	1	6,764
56 codes	towel, paper (Bounty) (per sheet)	SK082	$0.007	$0.015	114%	1	-
58 codes	cover slip, glass	SL030	$0.079	$0.114	44%	1	-
No codes	3C patch system	SD343	$625.00	$678.57	9%	1	-

TABLE 20: CY 2023 New Invoices

CPT/ HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
30469	VivAer Stylus	SD352	1,950.00	7	50
30469	Aerin Console Set	EQ405	4,995.00	4	50
36836	Ellipsys Vascular Access Catheter	SD351	6,000.00	1	91
36836	Ellipsys EndoAVF generator	EQ404	3,000.00	1	91
36837	Wavelinq EndoAVF catheters	SD350	7,000.00	1	73
36837	Wavelinq EndoAVF generator	EQ403	18,580.00	1	73
43290	ORBERA Intragastric Balloon System (balloon, placement catheter and connection tube with 3-way valve and saline bag spike)	SD348	1,850.00	8	1,075
43291	Needle aspirator and grasper	SD349	94.00	7	9
49436	dressing, 1in, 7mm hole, w-CHG (eg, Biopatch)	SG099	9.37	1	115
49436	peritoneal dialysis catheter locking titanium adapter	SD353	169.74	1	115
49436	peritoneal dialysis catheter transfer set	SD354	47.17	1	115
49436	peritoneal dialysis catheter mini-cap for transfer set	SD355	0.35	1	115
92065, 92066	Pro Vision Therapy Starter System Model VTSSP	ER122	2,229.95	1	26,730
92065, 92066	Sanet Vision Integrator display/software	ER123	8,245.00	1	26,730
92284	Dark Adaptometer	ER124	29,925.00	1	40,710
95919	Pupillometer Kit	ER125	8,995.00	1	2,110
96202	2 inch 3 ring binder w/set of 8 dividers	SK134	7.91	1	-

TABLE 21: CY 2023 No PE Refinements

HCPCS	Description
15851	Removal sutr/staple req anes
15853	Removal sutr/stapl xreq anes
15854	Removal sutr&stapl xreq anes
22630	Lumbar spine fusion
22632	Spine fusion extra segment
22633	Lumbar spine fusion combined
22634	Spine fusion extra segment
22857	Tot disc arthrp 1ntrspc lmbr
22869	Insj stablj dev w/o dcmprn
22870	Insj stablj dev w/o dcmprn
27446	Revision of knee joint
27447	Total knee arthroplasty
30468	Rpr nsl vlv collapse w/implt
30469	Rpr nsl vlv collapse w/rmdlg
36836	Prq av fstl crtj uxtr 1 acs
36837	Prq av fstl crt uxtr sep acs
42975	Dise eval slp do brth flx dx
43235	Egd diagnostic brush wash
50080	Perq nl/pl lithotrp smpl<2cm
50081	Perq nl/pl lithotrp cplx>2cm
55821	Removal of prostate
55831	Removal of prostate
55866	Laparo radical prostatectomy
55867	Laps surg prst8ect smpl stot
63035	Spinal disk surgery add-on
63052	Lam facetc&frmt arthrd lum 1
63053	Lam factc&frmt arthrd lum ea
64415	Njx aa&/strd brch plxs img
64416	Njx aa&/strd brch pl nfs img
64417	Njx aa&/strd ax nerve img
64445	Njx aa&/strd sciatic nrv img
64446	Njx aa&/strd sc nrv nfs img
64447	Njx aa&/strd femoral nrv img
64448	Njx aa&/strd fem nrv nfs img
69714	Impltj oi implt skl perq esp
69716	Impl oi implt sk tc esp<100
69717	Rplcmt oi implt skl prq esp
69719	Rplcm oi implt sk tc esp<100
69726	Rmv ntr oi implt skl prq esp
69727	Rmv ntr oi imp sk tc esp<100
69728	Rmv ntr oi imp sk tc esp≥100
69729	Impl oi implt sk tc esp≥100
69730	Rplcm oi implt sk tc esp≥100
73580	Contrast x-ray of knee joint
76377	3d render w/intrp postproces
76881	Us xtr non-vasc complete
76882	Us lmtd jt/fcl evl nvasc xtr
76883	Us nrv&acc strux 1xtr compre
76942	Echo guide for biopsy
77002	Needle localization by xray
77003	Fluoroguide for spine inject
90461	Im admin each addl component
92065	Orthop traing pfrmd phys/qhp
92066	Orthop traing supvj phys/qhp

HCPCS	Description
92284	Dx dark adaptation exam i&r
92287	Internal eye photography
95919	Quan puplmtry phy/qhp uni/bi
96202	Mlt fam grp bhv train 1st 60
96203	Mlt fam grp bhv train ea add
99221	1st hosp ip/obs sf/low 40
99222	1st hosp ip/obs moderate 55
99223	1st hosp ip/obs high 75
99231	Sbsq hosp ip/obs sf/low 25
99232	Sbsq hosp ip/obs moderate 35
99233	Sbsq hosp ip/obs high 50
99234	Hosp ip/obs sm dt sf/low 45
99235	Hosp ip/obs same date mod 70
99236	Hosp ip/obs same date hi 85
99238	Hosp ip/obs dschrg mgmt 30/<
99239	Hosp ip/obs dschrg mgmt >30
99242	Off/op consltj new/est sf 20
99243	Off/op cnsltj new/est low 30
99244	Off/op cnsltj new/est mod 40
99245	Off/op consltj new/est hi 55
99304	1st nf care sf/low mdm 25
99305	1st nf care moderate mdm 35
99306	1st nf care high mdm 45
99307	Sbsq nf care sf mdm 10
99308	Sbsq nf care low mdm 15
99309	Sbsq nf care moderate mdm 30
99310	Sbsq nf care high mdm 45
99315	Nursing fac discharge day
99316	Nursing fac discharge day
99345	Home/res vst new high mdm 75
99347	Home/res vst est sf mdm 20
99348	Home/res vst est low mdm 30
99349	Home/res vst est mod mdm 40
99350	Home/res vst est high mdm 60
99358	Prolong service w/o contact
99359	Prolong serv w/o contact add
99415	Prolong clincl staff svc
99416	Prolong clincl staff svc add
99417	Prolng op e/m each 15 min
99483	Assmt & care pln pt cog imp

BILLING CODE 4150–28–C

F. Evaluation and Management (E/M) Visits

1. Background

Over the past several years, we have engaged in a multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits, so that they better reflect the current practice of medicine, are less administratively complex, and are paid more accurately under the PFS. This work is critical to help reduce practitioner burnout in general, especially in light of the COVID–19 pandemic. In a step-wise approach, the AMA CPT Editorial Panel revised the office/outpatient (O/O) E/M visit code family first. Effective January 1, 2021, the CPT Editorial Panel redefined the O/O E/M visits, such that visit level is selected based on the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM) as redefined in the CPT E/M Guidelines. Additionally, effective January 1, 2021, history of present illness (History) and a physical exam are no longer used to select the O/O E/M visit level. (See 85 FR 84549). Also, effective January 1, 2021, the CPT Editorial Panel revised the O/O E/M visit descriptor times and the CPT E/M Guidelines.

We generally adopted these revised codes and changes in CPT code selection and documentation guidance for payment purposes under the PFS effective January 1, 2021 (84 FR 62844 through 62859). While we accepted the revised CPT codes and approach for the O/O E/M visits, we did not accept the revisions for prolonged O/O services, because we were concerned that they could have resulted in overpayment, were administratively complex, and would have impacted our ability to tell how much total time was spent with the patient (see 84 FR 62849 through 62850,

and 85 FR 84572 through 84575). We created G2212 for reporting of prolonged O/O E/M services. Finally, the AMA RUC resurveyed the O/O E/M visits, and we generally accepted the RUC recommendations, which reflected increased service times (84 FR 62851 through 62854). This resulted in increased values for the O/O E/M codes beginning in CY 2021. Also, we created add-on code G2211 (*office/outpatient E/M visit complexity*) that can be reported in conjunction with O/O E/M visits to better account for resources associated with primary care or care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition(s). (84 FR 62854 through 62856). The Consolidated Appropriations Act, 2021 imposed a moratorium on Medicare payment for these services by prohibiting CMS from making payment under the physician fee schedule for HCPCS code G2211 before January 1, 2024. See our fact sheet available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet [103] (*cms.gov*).

For CY 2023, the AMA CPT Editorial Panel has revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. Hereafter in this final rule, we refer to these other E/M visit code families as ''Other E/M'' visits or CPT codes, as relevant. Effective January 1, 2023, the CPT Editorial Panel has redefined the Other E/M visits so that they parallel the O/O E/M visits, where visit level will be selected based on the amount of practitioner time spent with the patient or the level of MDM as redefined in the CPT E/M Guidelines. As for the O/O E/M visits, a medically appropriate history and/or physical exam will be a required element of the services, but will no longer impact the Other E/M visit level. The CPT Editorial Panel also revised the service times within the descriptors, the associated prolonged service codes, and the CPT E/M Guidelines for the Other E/M CPT codes. The CPT Editorial Panel also consolidated a considerable number of the Other E/M CPT codes, with inpatient and observation visits being combined into a single code set, and home and domiciliary visits being combined into a single code set. Currently there are approximately 75 Other E/M CPT codes, and in 2023 there will be approximately 50 Other E/M CPT codes. The CPT Editorial Panel created one new CPT code for prolonged inpatient services by physicians and other qualified healthcare professionals on the date of the E/M visit. Finally, the RUC has resurveyed the Other E/M visits and associated prolonged service codes, and provided revaluation recommendations to CMS.

In total, E/M visits comprise approximately 40 percent of all allowed charges under the PFS. The subset of Other E/M visits comprises approximately 20 percent of all allowed charges. Accordingly, our final policies for the Other E/M visits will have a significant impact on relative resource valuation under the PFS, which could potentially impact patient care more broadly. In this section of our final rule, we provide our final policies addressing coding and revaluation of Other E/M visits for CY 2023. We also finalize a technical correction to the placement of our regulation text for split (or shared) visits, and, as we further consider feedback from interested parties, we delay implementation of our policy to define the substantive portion of a split (or shared) visit at § 415.140 based on the amount of time spent by the billing practitioner until January 1, 2024. Finally, we provide clarification and finalize a technical correction regarding how time is reported for split (or shared) critical care visits.

2. Overview of Policy Proposals

In our proposed rule, we proposed to generally adopt the revised CPT E/M Guidelines for Other E/M visits, which are available online at *www.ama-assn.org/cpt-evaluation-management*. We proposed to adopt the general CPT framework for Other E/M visits, such that practitioner time or MDM would be used to select the E/M visit level. This includes the listing of qualifying activities by the physician or NPP that count toward the time spent when time is used required to select the visit level. A medically appropriate history and/or examination would be required, but history and physical exam would no longer be used to select visit level. We would not adopt the general CPT rule [104] where a billable unit of time is considered to have been attained when the midpoint is passed (for example, we would not consider a service with a time descriptor of 30 minutes to have been satisfied if only 15 minutes of time had been spent furnishing that service). We similarly interpreted this rule for O/O E/M visits, when time is used to select visit level. For example, we required the full time within the CPT code descriptors to be met in order to select an O/O E/M visit level using time, rather than half of the descriptor time (84 FR 62848 through 62851). Also, we do not interpret the CPT E/M Guidelines as adopting this general CPT rule regarding the midpoint of time.

We proposed to adopt the revised CPT codes and descriptors for Other E/M visits, except where specified otherwise. Under our proposed policies, we would adopt the new CPT codes and descriptors for Other E/M visits except for prolonged services, for which we proposed Medicare-specific coding. For administrative simplicity and payment accuracy purposes, and to enable us to determine how much time was spent with the patient using claims data, prolonged Other E/M services would be reported under one of three proposed G codes (one for each family for which prolonged services apply, namely inpatient/observation visits, nursing facility visits, and home or residence visits). This would be consistent with our previously finalized approach to prolonged O/O E/M services.

We proposed to adopt the CPT E/M Guidelines regarding MDM for E/M services. The CPT Editorial Panel revised the CPT E/M guidelines for levels of MDM, and we proposed to adopt them as revised.

In addition, as we noted in the Medicare Claims Processing Manual ((pub 100–04) chapter 26, section 10.8), our longstanding taxonomy for PFS services will continue to apply, where, for payment purposes, physicians and NPPs are not classified as having the same specialty, and the PFS does not recognize subspecialties. However, we are continuing to consider whether we could better align this payment taxonomy with clinical practice, where we might consider NPPs as working in the same specialty as the physicians with whom they work, and/or recognize subspecialties.

Regarding valuation of the Other E/M CPT codes, the RUC recommended direct work RVU comparisons for many Other E/M CPT codes to those currently assigned to O/O E/M CPT codes. In some cases, there were assumptions that patient needs were inherently more complex or work was more intense for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) when compared to the office settings. This direct comparison to the O/O visit codes may not be appropriate or accurate, given that practitioners furnishing visits in the

[103] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

[104] Introduction to 2022 CPT Codebook, p.xviii.

office setting face particular uncertainties in their estimates of illness and treatment courses, and the office settings have fewer resources close at hand. For example, compared to fully-staffed institutional settings, office settings generally have smaller, ancillary staff complements (such as pharmacists, registered nurses, social workers, and other paraprofessionals) who provide specialized advice and services, spend time coordinating with other practitioners for review and evaluation of medical records and test results, educate patients, manage medications, and assess and help address social determinants of health. Additionally, those practicing in institutional settings generally have ready availability of diagnostic equipment (for example, imaging and other advanced services), allowing for more immediate access to clinical information and reducing the amount of time needed to manage a given case. This access is critical for positive health outcomes, to treat or prevent acute exacerbations of chronic conditions and timely manage patients to prevent deterioration and improve outcomes. The challenge of coordinating and gathering these types of care and information in the office setting may add additional time and complexity to the case management. Further, some of the Other E/M CPT code families are being merged into lower complexity settings, such as CPT codes for observation services migrating into the inpatient visit CPT codes.

The values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with a policy that would have provided separate payment for the new add-on code G2211. This add-on code describes the complexity inherent to E/M visits associated with primary care and other similar types of care (specifically, E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition, regardless of the specialty of the billing professional) (see 85 FR 84569 through 84572). Section 113 of the Consolidated Appropriations Act, 2021 delayed Medicare payment for G2211 until at least January 1, 2024 (see the following Fact Sheet available on our website at Physician Fee Schedule [105] (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet (*cms.gov*). To the extent we proposed to adopt the RUC-recommended values for Other E/M visits beginning for CY 2023, we do not agree with the RUC that the current visit payment structure among and between care settings fully accounts for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values, since separate payment is not yet made for G2211.

We note that we received a few comments that mentioned the commenters believe the CPT rule for midpoint of time applies to the CPT E/M Guidelines and other CPT reporting instructions, and recommended we do the same. We reiterate that we have not interpreted the CPT reporting instructions this way, and they will not apply for PFS reporting of E/M visits. To avoid payment variation and standardize reporting, it would be helpful if CPT would explicitly clarify in the CPT E/M Guidelines that the midpoint rule for reporting of timed services does not apply.

We also received a few comments questioning whether we were formally proposing a change in taxonomy for NPPs to recognize clinical categories for them or subspecialties for E/M visit reporting, and are recommending such. We are continuing to consider these issues, and wanted to call attention to the differences between the CPT reporting instructions and the PFS reporting rules. We would need more time and rulemaking to develop taxonomy changes and systems changes, and are not finalizing any changes in our policies at this time.

3. Hospital Inpatient or Observation Care (CPT Codes 99218–99236)

a. Coding Changes and Visit Selection for Hospital Inpatient or Observation Care Services

The CPT Editorial Panel deleted seven observation care codes and revised nine codes effective January 1, 2023, to create a single set of codes for inpatient and observation care. (Note that the CPT Editorial Panel also made changes to codes for inpatient and observation discharge, which will be discussed in section II.F.4. of this final rule.) The CPT Editorial Panel also changed the code descriptors to allow level of service to be based on total time or MDM, as well as updating associated reporting instructions and CPT E/M Guidelines.

The CPT Editorial Panel deleted the six codes that were used to report observation care visits: three initial observation care codes, CPT codes 99218 *(Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; a detailed or comprehensive examination; and medical decision making that is straightforward or of low complexity). Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit),* 99219 *(Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity). Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit),* and 99220 *(Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit);* and three subsequent observation care codes, CPT codes 99224 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; problem focused examination; medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified*

[105] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit), 99225 *(Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit),* and 99226 *(Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit).*

The CPT Editorial Panel also revised the six hospital inpatient care codes. The revisions allow these codes to be reported for hospital inpatient or observation care services and allow the codes to be selected by the billing practitioner based on either MDM or time. In addition, the CPT Editorial Panel changed the name of the ''Hospital Inpatient Care'' code family to ''Hospital and Observation Care,'' and the new code family includes three initial hospital or observation care codes: CPT codes 99221 *(Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded),* 99222 *(Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded),* and *99223 (Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded);* and three subsequent inpatient or observation care codes, CPT codes 99231 *(Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded),* 99232 *(Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded),* and 99233 *(Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded).*

The CPT Editorial Panel also revised the three codes under ''Observation or Inpatient Care Services (including Admission and Discharge)'' (frequently referred to as ''same-day discharge'' codes). Billing practitioners could already use these codes to bill for patients in inpatient or observation status, but the CPT Editorial Panel revised the codes to allow the billing practitioner to select the code level based either on MDM or time. The same-day discharge codes were renamed as ''Hospital Inpatient or Observation Care (Admission and Discharge)'': CPT codes 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded),* 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded),* and 99236 *(Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded).*

We proposed to adopt the revised CPT codes 99221 through 99223 and 99231 through 99236. We highlighted that the CPT code descriptors specify that, when selecting the code level based on time, the indicated increment of time must be ''met or exceeded.'' We proposed that, when a practitioner selects CPT codes 99221 through 99223 and 99231 through 99236 based on time, the number of minutes specified in the descriptor for the relevant CPT code must be ''met or exceeded.'' We noted that we did not propose to adopt the 2023 CPT Codebook instructions regarding the application of prolonged codes to CPT codes 99223, 99233, and 99236. (2023 CPT Codebook, p. 15–17). Please refer to the additional discussion of prolonged codes in section II.F.3.f. below.

We also noted that the descriptors for CPT codes 99221 through 99223 and 99231 through 99236 specify that the time counted toward the code is ''per day.'' We proposed to adopt the 2023 CPT Codebook instruction that ''per day,'' also referred to as ''date of encounter,'' means the ''calendar date.'' (2023 CPT Codebook, p. 15.) We also proposed to adopt the 2023 CPT Codebook instruction that when using MDM or time for code selection, a continuous service that spans the transition of 2 calendar dates is a single service and is reported on one date, which is the date the encounter begins. If the service is continuous before and through midnight, all the time may be applied to the reported date of the service, that is, the calendar date the encounter began. (2023 CPT Codebook, p.15.) We noted that nothing in this proposal was intended to conflict with our proposed retention of the ''8 to 24-

hour rule,'' discussed in the next section.

Finally, we proposed to retain our policy that a billing practitioner shall bill only one of the hospital inpatient or observation care codes for an initial visit, a subsequent visit, or inpatient or observation care (including admission and discharge), as appropriate, once per calendar date. We proposed that the practitioner would select a code that reflects all of the practitioner's services provided during the date of the service, as provided in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.B.[106] We discussed additional policies relating to a single billing practitioner providing services to a single beneficiary on the same day in section II.F.3.d. below.

Comment: Many commenters supported our proposal to adopt both the CPT's consolidation of the Hospital Inpatient and Observation Care services and the updates to the code descriptors. Commenters noted that the descriptor revisions, which will allow practitioners to bill by time or MDM, will simplify the documentation requirements for these codes and reduce administrative burden for practitioners. These commenters also maintained that the change allowing visit level selection using time or MDM will promote consistency across E/M code families, as these changes parallel the recent changes to the O/O E/M visit codes (specifically, allowing visits to be selected based on time or MDM, and eliminating the requirements that a certain number of ''components'' must be completed). Several commenters specifically indicated that they found the revisions to the O/O E/M descriptors in CY 2021 to be positive in terms of reducing administrative burden, and supported similar changes to the Hospital Inpatient and Observation Care descriptors. Several commenters noted it may reduce situations in which practitioners and their coders must distinguish between hospital inpatient and observation status for correct billing.

However, one commenter raised concerns about the proposed changes to the Hospital Inpatient and Observation Care descriptors, particularly that the level of visit will be based on time or MDM only. The commenter expressed concern that the new guidelines will discourage physicians from performing a comprehensive history and physical exam. The commenter suggested that hospital quality issues could arise if E/M documentation does not include the information needed for billing services under the Inpatient Prospective Payment System or document information in accordance with hospital Conditions of Participation (such as 42 CFR 482.22(c)(5)(i), which requires completion and documentation of a history and physical exam for each hospital patient within a specified timeframe of admission).

Response: We appreciate commenters' feedback. We refer readers to the discussion of our multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits in section II.F.1. above. We note that, per the new CPT code descriptors, a medically appropriate history and/or examination will be required, but will no longer be used to select visit level. We do not believe the revised CPT descriptors are in conflict with hospital documentation requirements outside of the PFS. Practitioners working in hospitals should continue to be aware of the documentation needed to meet requirements for other payment systems or CoPs, in addition to the documentation required to bill Hospital Inpatient and Observation Care codes under the PFS.

Comment: While not opposing our proposal to adopt the consolidation of the two code families, two commenters requested a delay in implementation of the revised coding. One commenter requested a 90-day delay in implementation to allow for updates to their electronic billing system (to update both the time changes in the descriptors and the removal of the observation code set.). Similarly, another commenter expressed concern about the overall ability of emergency physician practices to adapt to E/M changes for CY 2023, specifically changes to documentation guidelines and, restructured observation care codes, and a continued discrepancy between CPT and PFS coding for critical care services that took effect in CY 2022. This commenter was also concerned about hospital staffing shortages impacting implementation of changes to the observation codes. This commenter stated that many changes to the observation codes and billing rules are complicated and will take time to fully incorporate into workflows; and that CMS should consider delaying or phasing in some of the changes to the observation codes and billing requirements.

Response: We appreciate commenters' feedback. CPT has finalized its consolidation of and changes to the Hospital Inpatient and Observation Care code families effective January 1, 2023. This means, effective January 1, 2023, the observation care codes (CPT codes 99217–99220 and 99224–99227) will no longer be valid, and the revised codes (CPT codes 99221–99223, 99231–99236) will be in effect; this is a deadline set by CPT that CMS cannot influence. If we were to retain the observation coding or the CY 2022 descriptors even temporarily past January 1, 2023, we would have to create G-codes to replace the deleted or altered CPT codes. In this instance, creating G-codes would not alleviate commenters' concerns about having to update electronic billing systems. In addition, we would have to delay revaluation, since the RUC-recommended values are based on a survey of the codes as revised by CPT for CY 2023.

As discussed throughout this section, it is our intention that, aside from the actual CPT codes selected and the changes to descriptor times, the billing policies for Hospital Inpatient and Observation Care will remain largely the same, unless otherwise specified.

Comment: One commenter, while not opposing our proposal to adopt the revised CPT descriptors for the Hospital Inpatient and Observation Care codes, expressed dissatisfaction with some aspects of the revised coding (particularly CPT's guidelines for determining MDM).

Response: We appreciate this commenter's feedback. We proposed to adopt the CPT guidelines for determining MDM levels, and we understand that the specialty societies contributed to their revision for 2023 through the AMA Workgroup and CPT processes. Suggestions for additional revisions can be made to the AMA/CPT, and we will consider any future changes to the MDM guidelines for future rulemaking.

Comment: One commenter interpreted our proposal to adopt the consolidation of the Hospital Inpatient and Observation Care code as an acknowledgment that there is no difference in the physician work or resources required for patients who have been admitted to a hospital versus patients seen in observation status. The commenter suggested that the consolidation of the code families is evidence that we should discontinue the application of our ''23-hour rule.''

Response: At this time, we do not intend to discontinue our ''23-hour

[106] The manual states, ''A/B MACs (B) pay a physician for only one hospital visit per day for the same patient, whether the problems seen during the encounters are related or not. The inpatient hospital visit descriptors contain the phrase ''per day'' which means that the code and the payment established for the code represent all services provided on that date. The physician should select a code that reflects all services provided during the date of the service.''

rule'' (which is discussed in greater detail in the CY 2011 PFS final rule at 75 FR 73226); such consideration would be out of scope for this section of the rule, which pertains specifically to revisions, policies, and valuations of the Hospital Inpatient and Observation Care code sets. However, as discussed further in section II.F.3.b. below, in light of the consolidation of the Hospital Inpatient and Observation Care code sets, we will review whether, and if so, how our policies relating to hospital inpatient and observation services (including the ''23-hour rule'') interact and look forward to further engagement with the public.

Comment: Several commenters requested clarification of our proposal to align with the CPT guidance that a continuous service that spans the transition of 2 calendar dates is a single service and is reported on the date the service began. The commenters indicated they were unclear what ''continuous'' means in this context.

Response: We note that this instruction comes from the CPT Codebook, and we direct commenters to the CPT for additional clarification, if needed.

After consideration of public comments, we are finalizing the updates to the Hospital Inpatient and Observation Care code descriptors and the other policies articulated in this section as proposed.

b. ''8 to 24-Hour Rule'' for Hospital Inpatient or Observation Care

We proposed to retain what is known as the ''8 to 24-hour rule'' regarding payment of admission, discharge, or same-day admission/*discharge* codes, depending on the length of stay and whether the patient was discharged on a different calendar date *than* they were admitted (refer to the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, sections 30.6.8.B and 30.6.9.1.C.). As we discussed in the CY 2001 PFS final rule (65 FR 65376), the ''8 to 24-hour rule'' was designed to avoid unintended incentives to keep a patient in the hospital past midnight during a stay lasting less than 24 hours. When this policy was memorialized in the CY 2001 PFS final rule, it was applied to both the initial inpatient hospital care codes (CPT codes 99221 through 99223) and the initial observation care codes (CPT codes 99218 through 99220) which CPT has deleted for 2023. The policy we proposed at 87 FR 45990 appeared as follows:

- If the beneficiary receives less than 8 hours of hospital inpatient or observation services, the practitioner may not bill for the same-day admission/discharge codes or hospital inpatient and observation discharge day management services (to be described by CPT codes 99234–6 and 99238 and 99239, respectively). If a patient receives less than 8 hours of hospital inpatient or observation services, we proposed that the practitioner would bill only initial inpatient or observation care (described by CPT codes 99221, 99222, or 99223, as appropriate).
- If a beneficiary receives hospital inpatient or observation services for a minimum of 8 hours but less than 24 hours, we proposed that the practitioner would bill CPT codes 99234, 99235, or 99236, as appropriate. (These codes, commonly referred to as ''same-day discharge'' codes, describe hospital inpatient or observation care that includes both admission and discharge as part of a single service.)
- If a beneficiary is admitted for hospital inpatient care or begins observation and is then discharged after more than 24 hours, we proposed that the practitioner could bill an initial hospital inpatient or observation care code (CPT codes 99221 through 99223) for the date of admission, and a hospital discharge day management service (CPT code 99238 or 99239) on the date of discharge.

We wish to correct the policy as it was proposed in 87 FR 45990 and retract the examples we provided illustrating that policy as it appeared. It was our intention to synthesize the policy (which appears in several places in the Medicare Claims Processing Manual, as cited above), and to reiterate that it would remain in effect even after the consolidation of the Hospital Inpatient and Observation Care codes. When we summarized the policy, the references to discharge ''on the same calendar date'' or ''on a different calendar date'' were removed from parts of the policy in error. We apologize for this confusion.

We intended to retain the billing policy for Hospital Inpatient codes as it is reflected in the Medicare Claims Processing Manual, Chapter 12, section 30.6.9.1.C, which states:

''When the patient is admitted to inpatient hospital care for less than 8 hours on the same date, then Initial Hospital Care, from CPT code range 99221–99223, shall be reported by the physician. The Hospital Discharge Day Management service, CPT codes 99238 or 99239, shall not be reported for this scenario. When a patient is admitted to inpatient initial hospital care and then discharged on a different calendar date, the physician shall report an Initial Hospital Care from CPT code range 99221–99223 and a Hospital Discharge Day Management service, CPT code 99238 or 99239. When a patient has been admitted to inpatient hospital care for a minimum of 8 hours but less than 24 hours and discharged on the same calendar date, Observation or Inpatient Hospital Care Services (Including Admission and Discharge Services), from CPT code range 99234–99236, shall be reported.''

We also intended to retain the 8 to 24-hour policy for observation care, as it is reflected in relevant part in the Medicare Claims Processing Manual, Chapter 12, section 30.6.8.B:

''When a patient receives observation care for less than 8 hours on the same calendar date, the Initial Observation Care, from CPT code range 99218–99220, shall be reported by the physician. The Observation Care Discharge Service, CPT code 99217, shall not be reported for this scenario. When a patient is admitted for observation care and then is discharged on a different calendar date, the physician shall report Initial Observation Care, from CPT code range 99218–99220, and CPT observation care discharge CPT code 99217 . . . . When a patient receives observation care for a minimum of 8 hours, but less than 24 hours, and is discharged on the same calendar date, Observation or Inpatient Care Services (Including Admission and Discharge Services) from CPT code range 99234–99236 shall be reported. The observation discharge, CPT code 99217, cannot also be reported for this scenario.''

We note that the policy for observation care refers to CPT codes that will no longer be valid effective January 1, 2023. Per the discussion in section II.3.a., we are adopting the new CPT coding that consolidates Hospital Inpatient and Observation Care. Thus, we clarify that we intended to propose that while the policies reflected in the Medicare Claims Processing Manual (IOM 100–04) at Chapter 12, sections 30.6.8.B. and 30.6.9.1.C), would still apply, both hospital inpatient and observation care coding should be billed as follows: When a patient receives hospital inpatient or observation care for less than 8 hours, only the Initial Hospital Inpatient or Observation Care (CPT codes 99221–99223) shall be reported by the practitioner for the date of admission.[107] Hospital or Observation Discharge Day Management (CPT codes 99238–99239) shall not be reported for this scenario. When a patient is admitted for hospital inpatient or observation care and then is discharged on a different calendar date, the practitioner shall report Initial Hospital Inpatient or Observation Care (CPT codes 99221–99223) and Hospital

[107] We believe this language is a more accurate reflection of this policy as it appears in 65 FR 65409, which reads, ''If a patient is admitted as a hospital inpatient or an observation care patient for less than 8 hours, we will pay for only the admission service (CPT codes 99221 to 99223 or 99218 to 99220) on that day. The discharge service is not a separately billable service.''

Inpatient or Observation Discharge Day Management (CPT code 99238 or 99239). When a patient receives hospital inpatient or observation care for a minimum of 8 hours and is discharged on the same calendar date (thus the stay is less than 24 hours), Observation or Inpatient Care Services (Including Admission and Discharge Services) from CPT code range 99234–99236 shall be reported. CPT codes 99238–99239 cannot also be reported for this scenario.

Despite the inadvertent misstatement of the policy in the proposed rule, our central rationale for wanting to retain the rule remains intact. We believed it was necessary to retain our ''8 to 24-hour rule'' to avoid making overpayments, encouraging improper billing of two E/M visits on the same day, or creating incentives to unnecessarily extend beneficiaries' hospital stays past midnight. Initial Hospital Inpatient and Observation Care codes (CPT codes 99221 through 99223 and 99234 through 99239) are billed ''per day,'' and have been valued to account for all services a practitioner furnishes during the day-long billing period. In an environment such as a hospital, where admissions can occur 24 hours a day, relying solely on the calendar date of an admission or observation stay, to determine a billing day can be misleading, which is why we proposed to retain the existing ''8 to 24-hour rule.''

Comment: One commenter expressed support for our proposal to retain the ''8 to 24-hour rule.'' The commenter questioned, however, whether there was a possible overlap between the ''8 to 24-hour rule'' and the ''23-hour rule.''

Response: We note that this is a distinct policy from the ''23-hour rule'' (which is discussed in greater detail in the CY 2011 PFS final rule at 75 FR 73226). We acknowledge that we have multiple policies that apply, for different purposes, to services delivered to hospital inpatients and outpatients. In light of the consolidation of the Hospital Inpatient and Observation Care code sets, we will begin an internal review of whether, and if so, how these policies interact; we welcome further engagement with the public as we consider whether future rulemaking is needed to reconcile any of our policies.

Comment: Several commenters requested that we consider how the ''8 to 24-hour rule'' interacts with the ''2-midnight rule.'' Specifically, commenters noted that the ''clocks'' for counting the ''8 to 24-hour rule'' versus the ''2-midnight rule'' may start running at different times, which the commenters regard as burdensome.

Response: We note that the ''8 to 24-hour rule'' is distinct from the ''2-midnight rule'' (which is discussed in the CY 2016 Outpatient Prospective Payment Schedule final rule at 80 FR 70305). We acknowledge that we have multiple time-based policies, applicable under different payment systems, which relate to services delivered to hospital inpatients and outpatients. In light of the consolidation of the Hospital Inpatient and Observation Care code sets, we will review how these policies interact and look forward to further engagement with the public.

Comment: Several commenters expressed concern either with the ''8 to 24-hour rule'' itself, or with perceived changes to the policy. One commenter noted, correctly, our current policy which is reflected in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.8.B: ''When a patient receives observation care for a minimum of 8 hours but less than 24 hours, and then is discharged on the same calendar date, Observation or Inpatient Hospital Care Services (Including Admission and Discharge Services), from CPT code range 99234–99236, shall be reported.'' However, the commenter noted that in the proposed rule at 87 FR 45990, we stated this policy differently—namely, that we did not specify that CPT codes 99234–99236 may be billed if a patient is in the hospital for ''more than 8 hours but less than 24 hours, and discharged *on the same date* [emphasis added].'' Commenters were concerned that we were articulating a new requirement that patients must have been in the hospital for a complete 24 hours before a Hospital Inpatient or Observation Care Discharge Day Management code (CPT codes 99238–99239) could be billed.

Several commenters observed that our proposed policy, as written in 87 FR 45990, required that an entire 24-hour period be completed before being able to bill the same-day admission/discharge CPT codes 99234–99236 (regardless of whether the 24-hour period spanned one calendar day or two.) Commenters stated that tracking a complete 24-hour interval would be difficult for their current recordkeeping systems.

Response: As explained above, it was not our intention to articulate a new policy, but rather to retain the current policy, and clarify that it would remain in effect even after the consolidation of the Hospital Inpatient and Observation Care codes. We also intended to specify that observation care should be billed according to the new consolidated CPT coding for hospital inpatient and observation care. In the policy, as presented in the proposed rule, the references to discharge either on ''the same calendar date'' or ''a different calendar date'' were removed in error. We apologize for this confusion.

We hope this clarification addresses the commenters' concerns. However, given the apparent confusion about the application of the ''8 to 24-hour rule'' in general, we welcome additional public engagement on this issue as we continue to review the 8 to 24-hour rule and other billing or resource valuation policies that may affect hospital inpatient and observation services in light of our adoption of the CPT-revised single set of codes for inpatient and observation care.

Comment: One commenter raised a concern that the ''8 to 24-hour rule,'' as proposed, differed from CPT billing guidance, noting that CPT code selection is based on calendar date and the CMS policy (as represented in the proposed rule) is based on the time of service. The commenter stated that they understood the rationale for requiring at least 8 hours of service to report CPT codes 99234–99236, but did not agree with the apparent proposal to require that more than 24 hours must elapse before any code *other* than CPT codes 99234–99236 may be billed. The commenter also suggested that the RUC surveys and valuations for CPT codes 99234–99236 did not contemplate that these codes would span a mandatory 24-hour interval.

Response: We believe that some of the commenter's concerns may be alleviated by the clarification of our ''8 to 24-hour rule'' as discussed in the prior response—namely that CPT codes 99234–99236 may be billed if a patient receives more than 8 hours of care and is discharged on the same calendar date; we are not requiring that a full 24 hours must have elapsed.

We note that the difference between our current ''8 to 24-hour rule'' (as clarified above) and the CPT reporting instructions effective beginning in 2023 appears to center on how to handle stays lasting less than 8 hours, and the definition of ''encounter'' (or lack of a definition) when CPT instructs that same-day admission and discharge codes may be reported when there is an admission encounter and a discharge encounter on the same day. (2023 CPT Codebook, p. 17). We remain concerned that, while unusual, very short hospital stays crossing a single midnight could be reported inappropriately using two codes, when the resources expended are better accounted for in one; or that a same-day admission and discharge code might be inappropriately reported instead of an initial visit code, where the latter would more appropriately describe the furnished service. We also

acknowledge that there may be circumstances in which patients may be in the hospital for short stays, but still require significant practitioner time. We believe practitioners may be able to bill the prolonged HCPCS code G0316 in these circumstances, which is discussed in section II.F.3.f. and Table 24.

Since the AMA's public comment indicated that they will refer issues regarding multiple same-day visit billing back to CPT for review, we recommend that they include these issues in their review. We will continue to review any future clarifications or reporting instruction changes that may be made by CPT.

Comment: One commenter requested that we delay enforcement of the 8 to 24-hour rule for one year in light of all of the changes to the Hospital Inpatient and Observation Care codes.

Response: The ''8 to 24-hour rule,'' itself, is not a new policy, but we acknowledge the need for ongoing review of this policy in light of the coding and valuation changes that take effect in 2023 for hospital inpatient and observation services.

After consideration of public comments received, we are finalizing our proposal to retain the 8 to 24-hour rule as clarified above. We are retaining our 8 to 24-hour policy and updating it only to reflect the consolidation of the Hospital Inpatient and Observation Care code families. As updated, our final policy is summarized in Table 22.

TABLE 22—SUMMARY OF FINAL POLICY FOR THE ''8 TO 24-HOUR'' RULE

Hospital length of stay	Discharged on	Code(s) to bill
<8 hours	Same calendar date as admission or start of observation.	Initial hospital services only.*
8 or more hours	Same calendar date as admission or start of observation.	Same-day admission/discharge.*
<8 hours	Different calendar date than admission or start of observation.	Initial hospital services only.*
8 or more hours	Different calendar date than admission or start of observation.	Initial hospital services* + discharge day management.

* Plus prolonged inpatient/observation services, if applicable.

c. Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit

According to the 2023 CPT Codebook (p. 15), an ''initial'' service may be reported when ''the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay. When advanced practice nurses and physician assistants are working with physicians they are in the exact same specialty and subspecialty as the physician.'' The revised CPT codes 99231 through 99233 describe subsequent hospital inpatient or observation care services similarly. According to the 2023 CPT Codebook (2023 CPT Codebook, p. 15), a ''subsequent'' service is reported when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay.

As we do not recognize subspecialties, we proposed slightly amended definitions of ''initial'' and ''subsequent'' service:

- An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.

These are the same definitions that we proposed for ''initial'' and ''subsequent'' in the context of nursing facility visits below. We also proposed that for both initial and subsequent visits, when advanced practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician (please refer to additional discussion in section II.F.2 above).

Comment: One commenter supported our proposed definition of initial and subsequent visits, noting that, given the large number of subspecialties, tracking ''initial'' or ''subsequent'' visits based on subspecialties is cumbersome.

Response: We thank the commenter for their support.

Comment: Several commenters requested that CMS adopt the CPT definition of ''initial'' and ''subsequent,'' which includes consideration of subspecialties.

Response: As noted in our discussion above in section II.F.2, we are continuing to consider whether we could better align our payment taxonomy with clinical practice, including whether to recognize subspecialties. At this time, however, we are retaining our current taxonomy (which does not include recognition of subspecialties) as described in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 26, section 10.8, *et seq.*

Comment: Several commenters requested clarification on how these definitions would apply when care was provided by NPPs. The commenters questioned whether care provided by NPPs would be considered as having been delivered by a different specialty. Several commenters also asked if we were revising our specialty taxonomy as it pertains to NPPs.

Response: We are not revising our specialty taxonomy for NPPs. As noted in our discussion above in section II.F.a.2, we are continuing to consider whether we could better align our payment taxonomy with clinical practice, including whether (and how) to recognize NPPs as being in the same specialty as the physician with whom they work. At this time, however, we are retaining our current taxonomy (which includes recognition of NPPs as being in their own specialties) as described in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 26, section 10.8, *et seq.*

After consideration of public comments, we are finalizing our definition of initial and subsequent visits as proposed.

d. Transitions Between Settings of Care and Multiple Same-Day Visits for Hospital Patients Furnished by a Single Practitioner

We proposed to retain our current policy that, for the purposes of reporting an initial hospital inpatient or observation care service, a transition from observation status to inpatient status does not constitute a new stay (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.8.D). For instance, if a practitioner places a beneficiary in observation status on one date of service (and bills an initial observation visit to be described under CPT code 99221 through 99223), and then determines later in the stay that the beneficiary should be admitted to the hospital as an inpatient, the practitioner would not bill a second initial visit for the hospital inpatient stay. Rather, the practitioner would bill the work done on the inpatient admission day as a subsequent visit (CPT codes 99231, 99232, or 99233). This policy aligns with language in the 2023 CPT Codebook instructions. (2023 CPT Codebook, p. 16).

We also proposed to retain our policy that, if a patient is seen in an office setting on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same practitioner, both visits are payable to that practitioner, even if less than 24 hours has elapsed between the visit and the hospital inpatient or observation care (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.1.B). We also proposed, however, to retain our current policy that, when a patient is admitted to outpatient observation or as a hospital inpatient via another site of service (such as, hospital ED, office, nursing facility), all services provided by the practitioner in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed *on the same date as the admission* (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.1.A). This policy differs somewhat from the instructions provided in the 2023 CPT Codebook (p. 15–16), which allows for payment of both visits on the same date using Modifier 25.

We believe it is important to retain both policies, as they promote appropriate payment in situations in which the beneficiary visits the practitioner in a non-hospital setting, before the practitioner determines that hospital admission is necessary. The codes for initial hospital inpatient or observation visits (CPT codes 99221 through 99223) are billed ''per day'' and include all work furnished by the practitioner on the day of admission. The initial hospital inpatient and observation care codes do not include work furnished by the practitioner prior to the date of admission. Thus, under our proposal, for example, if a practitioner sees a beneficiary in an office setting at 5 p.m. on April 1st, and the practitioner then admits the beneficiary to the hospital at 7 a.m. on April 2nd, these would be separately billable payments, because initial hospital inpatient or observation care codes (CPT code 99221 through 99223) billed for April 2nd would not retroactively cover the work furnished on April 1st. However, if the practitioner sees the beneficiary in the office setting at 7 a.m. on April 1st and then admits the beneficiary at 9 p.m. on April 1st, all time the practitioner spent furnishing services to that beneficiary would be reportable under the initial hospital inpatient or observation care code (CPT code 99221 through 99223).

We also proposed to retain our current billing policy in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.1.A that a practitioner may bill only for an initial hospital or observation care service if the practitioner sees a patient in the ED and decides to either place the patient in observation status or admit the patient as a hospital inpatient. For discussion of additional policy proposals regarding patients seen in both the ED and the hospital, refer to section II.F.5. on Emergency Department Services.

We proposed to preserve our current billing policies for patients in swing beds, which are as follows: If the inpatient care is being billed by the hospital as inpatient hospital care, the hospital care codes (CPT codes 99221 through 99223 and 99231 through 99239) apply (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.D). If the inpatient care is being billed by the hospital as nursing facility care, then the nursing facility codes (CPT codes 99304 through 99316) apply. Please refer to section II.F.6 below on Nursing Facility Care Services for additional discussion of billing hospital inpatient or observation care and nursing facility care.

Comment: Several commenters did not support our proposal to retain the current policy regarding the billing of multiple visits in different settings by the same practitioner for the same patient on the same date. Commenters observed that our policy does not align with CPT guidance on multiple same-day visits. Several commenters also noted that Medicare billing policy may allow for separate billing of multiple same-day E/M visits in certain situations.

Response: We note that the policies in this section are restatements of longstanding policies regarding billing by the same practitioner for multiple same-day E/M visits furnished to the same patient. We acknowledge that our policies in some cases differ from CPT reporting instructions. We also agree that, as noted in several places in our manual and noted in this rule, there are circumstances in which we will allow payment for multiple same-day E/M visits. The goal of our policies is to avoid duplicative payments, where the work involved in multiple interactions with the same patient on the same day may overlap. We plan to consider different approaches to this issue in future rulemaking cycles.

We will be monitoring billing patterns in the claims data, as we continue to consider these issues. In its public comment, the AMA indicated that it may refer the issue of multiple same-day visit billing back to CPT for additional review. We will also review any future changes that may be made to CPT reporting instructions.

Comment: One commenter noted that, in our discussion of our proposal at 87 FR 45991 regarding the transition from observation status to inpatient, we stated, ''For instance, if a practitioner places a beneficiary in observation status on one date of service (and bills an initial observation visit to be described under CPT code 99221 through 99223), and then determines later in the stay that the beneficiary should be admitted to the hospital as an inpatient, the practitioner would not bill a second initial visit for the hospital inpatient stay. . . .'' The commenter recommended that we clarify that in this instance, ''later in the stay'' should refer to ''later in the day.'' The commenter observed that a practitioner would not be able to submit two claims (one for the observation care and one for the hospital care) for care delivered on the same day.

Response: We reiterate that we proposed to align our policy with the guidance in the 2023 CPT Codebook at p.16, where it says, ''For the purpose of reporting an initial hospital inpatient or observation care service, a transition from observation level to inpatient does not constitute a new stay.'' We agree with the commenter that a practitioner cannot submit two separate visits for Hospital Inpatient or Observation Care for care delivered to the same patient on the same date. However, the practitioner

can report prolonged inpatient or observation services, as applicable, if time is used to select visit level.

Comment: One commenter requested clarification of the policy for physicians who see patients in the ED who are then placed in observation status.

Response: We thank the commenter for this clarification request. First, we note that there was a typographical error in our proposed rule at 87 FR 45991. We had intended to state that we are retaining the policy in Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.1.A (not, as we stated in the proposed rule, section 30.6.1.A). We clarify that we proposed to retain the policy reflected in section 30.6.9.1.A, which reads, ''A/B MACs (B) pay for an initial hospital care service if a physician sees a patient in the emergency room and decides to admit the person to the hospital. They do not pay for both E/M services. Also, they do not pay for an emergency department visit by the same physician on the same date of service.'' (We note that where the manual refers to ''physicians,'' the policy applies to both physicians and qualified NPPs, as appropriate.) In order to align our billing policies with the consolidated CPT coding (discussed in section II.3.a.), this policy would apply to hospital inpatient and observation care billed under CPT codes 99221–99223 and 99231–99236.

Comment: One commenter requested that we review our billing policy for people transitioning between observation status and NF settings.

Response: We thank the commenter for their feedback. We will continue to review policies relating to the consolidation of coding for Hospital Inpatient and Observation Care, and identify policies that may need further adjustment or clarification in future rulemaking.

After consideration of public comments, we are finalizing the following policies as proposed in this section:

- For the purposes of reporting an initial hospital inpatient or observation care service, a transition from observation status to inpatient status does not constitute a new stay.
- If a patient is seen in an office setting on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same practitioner, both visits are payable to that practitioner, even if less than 24 hours has elapsed between the office visit and the hospital inpatient or observation care.
- When a patient is admitted to outpatient observation or as a hospital inpatient via another site of service (such as, hospital ED, office setting, nursing facility), all services provided by the practitioner in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed *on the same date as the admission.* Prolonged time can be counted toward reporting of prolonged inpatient/observation services (see Table 24).
- A practitioner may bill only for an initial hospital or observation care service if the practitioner sees a patient in the ED and decides to either place the patient in observation status or admit the patient as a hospital inpatient.
- If the inpatient care is being billed by the hospital as inpatient hospital care, the hospital care codes (CPT codes 99221 through 99223 and 99231 through 99239) apply. If the inpatient care is being billed by the hospital as nursing facility care, then the nursing facility codes (CPT codes 99304 through 99316) apply.

e. Impact of Changes to Hospital Inpatient or Observation Codes on Billing and Claims Processing Policies

We proposed that, starting in CY 2023, hospital inpatient and observation care by practitioners will be billed using the same CPT codes—CPT codes 99221 through 99223, 99231 through 99233, and 99238 and 99239. (We noted that currently, both hospital inpatient and observation care are already billed under CPT codes 99234 through 99236 for same-day discharge). Therefore, though the current observation care codes (CPT codes 99218 through 99220 and 99224 through 99226) are being deleted, practitioners will still be able to furnish and bill for observation services. We solicited feedback from the public on potential challenges to billing or claims processing policies for hospital inpatient or observation care as reflected in the Medicare Claims Processing Manual (IOM 100–04, Chapter 12), including possible impact on: billing for patients during a global period (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, sections 30.6.8.E and 30.6.9.2.A); documentation requirements (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, sections 30.6.8.C and 30.6.9.1.D); modifiers associated with hospital inpatient or observation care claims (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.1.F); and any other issues not otherwise discussed in this proposed rule that may need to be addressed through additional guidance.

Comment: We received a number of responses to our request for information about policies potentially impacted by the consolidation of Hospital Inpatient and Observation Care codes. These comments included requests for clarification on or review of:

- Changes (if any) to place of service (POS) for observation care claims;
- Changes (if any) to billing in circumstances where practitioners previously would have billed O/O E/M codes; and
- Changes (if any) to the use of the AI modifier to identify the attending practitioner on claims.

We also received a recommendation to create a new POS code for patients in observation status to aid in reporting and tracking of E/M services for patients admitted under observation status versus patients seen in the emergency department.

Response: We thank commenters for their feedback. We will continue to engage with the public and review our policies in light of the consolidation of the Hospital Inpatient and Observation Care codes. At this time, we are not making changes to POS policy (including the POS that should be placed on a claim for a patient receiving observation care). We are also not changing policies affecting billing, at this time, when multiple practitioners furnish E/M services to the same patient on the same day (such as the policy in Chapter 12 of the Medicare Claims Processing Manual (IOM 100–04), section 30.6.8.A, which specifies that while the practitioner who orders the observation care for a patient may bill for observation care, other practitioners providing additional evaluations for the patient bill their services as O/O E/M codes.) We are also not currently making any changes to current policy on the use of the AI modifier.

We will consider the questions, concerns, and suggestions provided by commenters in our ongoing review of hospital inpatient and observation care policy. Absent further clarifications or additional rulemaking, billing practitioners and providers should continue to submit claims as they would have prior to the consolidation, though using the revised CPT codes 99221–99223, 99231–99233, 99238–99239, and G0316 (as applicable) to reflect observation care services (and unless otherwise specified in this final rule).

Comment: One commenter requested clarification of guidance in the Medicare Claims Processing Manual, IOM 100–04, Chapter 4, regarding how time is counted and reported for HCPCS code G3078 (Hospital observation service, per hour).

Response: We believe that the commenter's request pertains to payment made for observation under the

OPPS, which is outside the scope of this rulemaking as we only address observation care billed by practitioners under the PFS. We direct commenters with questions regarding hospital billing or payment to their MACs for further assistance.

After consideration of public comments, we are finalizing our proposal that, starting for services furnished in CY 2023, hospital inpatient and observation care furnished by practitioners will be billed using CPT codes 99221 through 99223, 99231 through 99233, 99234 through 99236, 99238 and 99239, and G0316 (as applicable). As noted above, we will also review our billing policies and consider updates as necessary.

f. Prolonged Services for Hospital Inpatient or Observation Care

As part of its E/M revisions, the CPT Editorial Panel made several changes to prolonged codes that currently can be billed with inpatient or observation codes. In its February 2021 meeting, the CPT Editorial Panel deleted Prolonged Service with Direct Patient Contact (Except with Office or Other Outpatient Services), including CPT code 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour; List separately in addition to code for inpatient or observation Evaluation and Management service*) and CPT code 99357 (*each additional 30 minutes*), effective January 1, 2023. The 2022 CPT Codebook instructions indicate that CPT codes 99356 and 99357 can be used in conjunction with hospital inpatient or observation care (CPT codes 99218 through 99236). We refer readers to instructions on pages 41–42 of the 2022 CPT Codebook, for example.

To replace deleted CPT codes 99356 and 99357, the CPT Editorial Panel created CPT code 99418 (*Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time.) (List separately in addition to the code of the inpatient and observation Evaluation and Management services*), which was referred to in the CY 2023 PFS proposed rule under its placeholder CPT code 993X0. Additional guidance from the 2023 CPT Codebook states, ''Code 99418 is used to report prolonged total time (that is, combined time with and without direct patient contact) provided by the physician or other qualified health care professional on the date of an inpatient E/M service (that is, CPT codes 99223, 99233, 99236, 99255, 99306, 99310). Prolonged total time is time that is 15 minutes beyond the time required to report the highest-level primary service.'' (2023 CPT Codebook, p. 29.)

We did not propose to adopt CPT code 99418, as we believed that the billing instructions for CPT code 99418 would lead to administrative complexity, potentially duplicative payments, and limit our ability to determine how much time was spent with the patient using claims data; these reasons are discussed in further detail below. We instead proposed to create a single G-code that describes prolonged inpatient or observation services, and that could be reported in conjunction with CPT codes 99223, 99233, and 99236. This G-code would be G0316 (referred to in the proposed rule as GXXX1):

- *G0316 Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report G0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99415, 99416, 99418). (Do not report G0316 for any time unit less than 15 minutes).*

In parallel to CPT's coding revisions for prolonged inpatient or observation services, we proposed that the G0316 prolonged code could only be applied to the highest-level hospital inpatient or observation care visit codes (CPT codes 99223, 99233, and 99236), and could only be used when selecting the E/M visit level based on time. In other words, we proposed that a prolonged code would only be applied once the greatest amount of time for initial, subsequent, or same-day discharge visits has been exceeded.

We proposed to use G0316 instead of CPT code 99418 because we disagreed with the CPT instructions regarding the point in time at which the prolonged code should apply. According to the 2023 CPT Codebook, CPT code 99418 which represents a 15-minute interval, would apply to: CPT code 99223 when a practitioner reaches 90 minutes; CPT code 99233 when 65 minutes is reached; and CPT code 99236 when 100 minutes is reached. Each of these times represents only 15 minutes more than the codes' descriptor times. We disagreed with this instruction, and we believed that a prolonged code should only be applicable after the total time for the primary service is exceeded (the total time used or assumed in valuation of the primary service, plus the full 15-minutes described by the prolonged code).

We noted that CPT code 99236, per the RUC-recommended times, includes not only 85 minutes of intraservice time (performed on the date of encounter) but an additional 12 minutes of post-service time. The RUC based this recommendation on a survey timeframe which was within 3 days of the date of encounter. We were concerned that the CPT instructions for CPT code 99418, as it applies to CPT code 99236, would result in duplicative payment, since the 12-minute post-service time was factored into the proposed valuation of CPT code 99236. It would be inappropriate to pay for a prolonged code based on post-service time that is already accounted for in the base code. We believed that the instruction for when to apply CPT code 99418 to the primary service CPT code 99236 would not accurately take into account this post-service time.

We proposed that the prolonged service period described by G0316 could begin 15 minutes after the total times (as established in the Physician Time File) for CPT codes 99223, 99233, and 99236 have been met. Additionally, we proposed that the proposed G0316 prolonged code would be for a 15-minute increment, and the entire 15-minute increment must be completed in order to bill G0316. Note that for administrative simplicity, we proposed to round the time when the prolonged service period begins to the nearest 5 minutes. For the times below, CPT code 99223, which has a RUC-proposed total time of 74 minutes, would be treated as though it has 75 total minutes. CPT code 99233, which has a RUC-proposed total time of 52 minutes, would be treated as though it has 50 total minutes; and CPT code 99236, which has a RUC-proposed total time of 97 minutes will be treated as though it has 95 total minutes. The rounding here is solely for the purpose of calculating a proposed prolonged period, and would not affect the total times for these CPT codes in the time file. We note that the time file is included in the public files provided as part of each year's finalized PFS, which are posted at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*.

Thus, a practitioner could bill G0316 for base code CPT code 99223 when 105

minutes is reached for an initial visit on the date of encounter. For the purposes of applying the proposed prolonged code, the CPT code 99223 total time is rounded to 75 minutes on the date of encounter. The prolonged service period would begin at 90 minutes, 15 minutes beyond 75 minutes. A practitioner would bill HCPCS code G0316 once the 15-minute increment for G0316 is completed, at minute 105.

A practitioner could bill G0316 for the base code CPT code 99233 when 80 minutes is reached for a subsequent visit on the date of encounter. For the purposes of applying the prolonged code, the CPT code 99233 total time is rounded to 50 minutes on the date of encounter. The prolonged service period would begin at 65 minutes, 15 minutes beyond 50 minutes. A practitioner would bill HCPCS code G0316 once the 15-mimute increment for G0316 is completed, at minute 80.

A practitioner could bill HCPCS code G0316 for base code CPT code 99236 at 125 minutes for same-day discharge. For the purposes of applying the prolonged code, the CPT code 99236 total time is rounded to 95 minutes completed within 3 calendar days of the encounter. The prolonged service period would begin at 110 minutes, 15 minutes beyond 95 minutes. A practitioner could bill HCPCS code G0316 once the 15-minute increment for G0316 is completed, at minute 125.

Refer to summary Table 18 in our proposed rule for a chart showing the proposed billing timeframe for G0316.

We also proposed that the proposed G0316 would apply to both face-to-face and non-face-to-face time spent on the patient's care within the survey timeframe. For CPT codes 99223 and 99233, this would be time spent on the date of encounter. For CPT code 99236, this would be time spent on the same date or within 3 subsequent calendar days. Since we proposed that prolonged services on any date within the service period (with or without direct patient contact, on the same or different date) would be reportable under HCPCS code G0318, we also proposed that CPT codes 99358–9 could not be billed for base codes CPT codes 99221 through 99223 and 99231 through 99236.

This approach was consistent with our final policy for O/O E/M visits, which requires the use of the prolonged code, G2212 (*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact*) for prolonged O/O E/M services. We continued to be concerned about program integrity, duplicative payments for time counted in both E/M base codes and prolonged E/M services codes, the administrative complexity of having multiple prolonged service codes, and our ability to tell how much time was spent with the patient using claims data (see our previous discussion of these issues in our CY 2020 and CY 2021 PFS final rules at 84 FR 62849 through 62850, and 85 FR 84572 through 84575, respectively). If we proposed to adopt the CPT codes for prolonged inpatient and observation E/M visits, we would not be able to identify the time spent with patients in the claims data alone, because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors.

We received many comments regarding our proposal for Medicare-specific coding for prolonged Other E/M services. We address comments that apply across the Other E/M visit families in this final rule in section II.F.11 below (Prolonged Services). We received a few comments that apply in isolation to the Inpatient/Observation visit family, and we address those as follows.

Comment: One commenter questioned how the time was calculated for the application of G0316. The commenter noted that the revised CPT descriptors for CPT codes require at least 75 minutes for CPT code 99223, at least 50 minutes for 99233, and at least 85 minutes for 99236. The commenter questioned why G0316 would not apply to the base codes after an additional 15 minutes beyond the descriptor time had been reached. In particular, the commenter noted that they were not able to identify the ''post-service'' time that we applied to the total time for CPT code 99236, to calculate when G0316 would apply.

Response: We appreciate this commenter's inquiries. We discuss in section II.F.11 below, and our regulatory impact analysis for alternatives considered, why we are not choosing to allow reporting of prolonged services once the minutes of service reach 15 or more minutes beyond the time in the CPT code descriptor. Specific to G0316, in our proposed rule (87 FR 45992), we explained that 12 minutes of post-service time was included in the RUC-recommended total time for CPT code 99236 (which we are adopting in this final rule). Since the 12 minutes is already accounted for in the valuation for CPT code 99236, we do not believe it should be counted again toward reporting G0316. We refer readers to section II.F.11 below for additional discussion of this issue.

Comment: Several commenters requested clarification that if a practitioner performs non-face-to-face work on a day prior to a patient's hospital admission or placement on observation status, this time cannot be reported by the practitioner using G0316.

Response:. The service times for initial inpatient and observation care do not include work performed on prior days by the same practitioner, therefore we are not allowing time on those days to count toward prolonged services for those services. We refer readers to section II.F.11 below, where we discuss our rationale for not allowing practitioners to count time spent on days that were not included in the surveyed timeframes for Other E/M visits, since such time is not presumed to be part of the service for purposes of valuation. When the AMA surveyed practitioners to identify how much work is performed when furnishing initial inpatient/observation care (measured by how much time is commonly spent), the survey respondents indicated that they do not spend time on days prior to the visit for any of the inpatient or observation care codes. If the same practitioner spends time prior to the visit as part of another E/M visit in a different setting or as part of care management services, the prior time can be counted toward reporting of the prior visit or care management service. (We refer readers to our PFS Care Management website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management* for more information about billing for those services.

Comment: One commenter did not support the use of G0316 only in instances when the visit level was selected based on time, and believed that the prolonged code should apply when visits are selected based on MDM. The commenter suggested that many practitioners do not currently select the level of visit based on time. The commenter also contended that, because the G0316 code was based on time, it would contribute to practitioner burnout by rewarding long hours and would penalize practitioners for treating patients efficiently.

Response: We note that, as discussed above in section II.F.3.a, effective January 1, 2023, practitioners will have

the option of selecting the hospital inpatient or observation care codes by time or by MDM. We expect that more practitioners may begin selecting visit based on time as a result of this change. We refer readers to section II.F.11 below, where we discuss why we believe prolonged services should not be reportable for services that are not timed, and the intersection of our Medicare-specific prolonged service codes with practitioner incentives regarding time spent with patients.

After consideration of public comments, we are finalizing our proposal to create a new code G0316 for prolonged Hospital Inpatient and Observation Care services (applicable to primary service CPT codes 99223, 99233, and 99236), as proposed.

g. Valuation of Hospital Inpatient or Observation Care Services

The revised hospital inpatient or observation care codes (CPT codes 99221 through 99223 and 99231 through 99236) were surveyed for the October 2021 RUC meeting. The survey times captured the total time on the date of encounter by calendar date. In October 2021, the RUC referred these services to be resurveyed, because the survey did not include a request for distinct time before and after floor/unit time, and therefore, could not be compared to previous RUC surveys of these services. The RUC reviewed the resurveyed inpatient and observation services for the January 2022 RUC meeting.

We proposed to accept the RUC recommendations for work RVUs and times for CPT codes 99221 (work RVU 1.63, intraservice time 40 minutes, total time 40 minutes); 99222 (work RVU 2.60, intraservice time 55 minutes, total time 55 minutes); 99223 (work RVU of 3.50, intraservice time 74 minutes, total time 74 minutes); 99231 (work RVU 1.00, intraservice time 25 minutes, total time 25 minutes), 99232 (work RVU 1.59, intraservice time 36 minutes, total time 36 minutes); 99233 (work RVU 2.40, intraservice time 52 minutes, total time 52 minutes); 99234 (work RVU 2.00, intraservice time 45 minutes, total time 50 minutes); 99235 (work RVU 3.24, intraservice time 68 minutes, total time 76 minutes); and 99236 (work RVU 4.30, intraservice time 85 minutes, total time 97 minutes).

There are no PE inputs for these codes.

Comment: Many commenters supported our proposal to accept the RUC-recommended values for these codes.

Response: We thank commenters for their support.

Comment: Several commenters, although not challenging the RUC recommendations, voiced general concerns that O/O E/M valuations may continue to be low, or that any increases in facility-based E/M services will shift RVUs away from primary care.

Response: We thank the commenters for sharing their concerns. We will take these concerns into consideration as we continue to examine valuations for all E/M codes. Please see prior discussions of our review and revaluation of O/O E/M codes in the CY 2020 final rule (84 FR 62844) and the CY 2021 final rule (85 FR 84548).

Comment: Several commenters opposed the proposed values, particularly for initial Hospital Inpatient and Observation Care visit codes (CPT codes 99221–99223), for which we proposed reductions. Some of these commenters suggested that, to maintain relativity and rank order, it was important that the initial Hospital Inpatient or Observation Care codes be assigned higher work RVUs than O/O E/M codes. Other commenters suggested that the proposed valuations do not accurately reflect the complexity of hospital inpatient or observation care. One commenter, echoing concerns about relativity of initial Hospital Inpatient and Observation Care and new patient O/O E/M visits, suggested that we review the E/M visit valuations using an expert panel.

Response: We appreciate commenters' feedback. We disagree with the commenters that the proposed RVUs for CPT codes 99221–99223 are too low, especially given the reductions in total time for these codes. We also continue to disagree with the assertion that facility-based codes are always inherently (or proportionately) more intense than E/M services provided in other settings. We reaffirm our discussion of this issue in section II.F.1.

After consideration of public comments, we are finalizing the RVUs for CPT codes 99221–9223, 99231–99236 as proposed.

4. Hospital or Observation Discharge Day Management (CPT Codes 99217, 99238 and 99239)

a. Coding Changes to Hospital Inpatient or Observation Discharge Day Management Services

Effective January 1, 2023, the CPT Editorial Panel deleted the observation discharge code, CPT code 99217 *(Observation care discharge day management)* and revised the two hospital discharge day management codes, CPT codes 99238 *(Hospital inpatient or observation discharge day management; 30 minutes or less)* and CPT code 99239 *(more than 30 minutes*) so that CPT codes 99238 and 99239 may be billable for discharge of hospital inpatient or observation patients.

We proposed to adopt the revised CPT codes 99238 and 99239. We also proposed to retain our current hospital inpatient policy outlined in the Medicare Claims Processing Manual, Chapter 12, sections 30.6.9.2.B and 30.6.9.2.E, and expand it to include observation care. Specifically, we proposed that CPT codes 99238 and 99239 are to be billed by the practitioner who is personally responsible for discharge service (or, in the case of the death of the patient, the practitioner who personally performs the death pronouncement); services furnished by other practitioners, including: instructions to the patient, communication with the family/caregiver, and coordination of post discharge services would be reported as subsequent hospital inpatient or observation care with CPT codes 99231, 99232, and 99233. (Refer to the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, Manual, IOM 100–04, Chapter 12, sections 30.6.9.2.B and 30.6.9.2.E; we note that we incorrectly cited to 30.6.9.2.A in the proposed rule).

We proposed to retain our related policy that the same practitioner may not bill a hospital discharge CPT code 99238 or 99239 on the same day as a subsequent visit CPT codes 99231 through 99233. We refer readers to the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.2.C.

Comment: Several commenters requested clarification on the proposed policy at 87 FR 45993 (which codifies that the discharge day management code can only be billed by the practitioner ''personally responsible for'' the discharge service. Commenters suggested this policy is difficult to decipher in light of team approaches to care delivery.

Response: We appreciate commenters' feedback. First, we note that we intended to preserve the policy regarding billing of CPT codes 99238 and 99239, as reflected in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.2.B and 30.6.9.2.E. We intended to align this policy with both the consolidation of the Hospital Inpatient and Observation Care code sets and with the 2023 CPT Codebook guidelines. The 2023 Codebook (p.17) instruction for CPT codes 99238 and 99239 is that, ''Codes 99238, 99239 are to be used by the physician or other qualified health care

professional who is responsible for discharge services.'' We note that our longstanding policy in section 30.6.9.2.B is that only one hospital discharge day management service is payable per patient per hospital stay, and this code is billed by the ''attending physician.''

After consideration of public comments, we are finalizing the adoption of the revised descriptors for CPT codes 99238 and 99239 and other additional policies in this section as proposed or clarified.

- Only one claim for CPT code 99238 or 99239 may be submitted per patient, per hospital stay. The claim is submitted by the attending practitioner who is responsible for the discharge service. In the case of the death of the patient, CPT codes 99238 and 99239 are billed by the practitioner who personally performs the death pronouncement.
- The same practitioner may not bill both a hospital discharge CPT code 99238 or 99239 and a subsequent visit CPT codes 99231 through 99233 for the same patient on the same day. (Note also additional policies affecting the billing of CPT codes 99238 and 99239 discussed in II.F.3.b. above.)

b. Prolonged Services and Hospital Inpatient or Observation Discharge Day Management

Effective January 1, 2023, the CPT Editorial Panel deleted CPT code 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour*) and CPT code *99357 (each additional 30 minutes)* and replaced them with CPT code 99418 *(Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time).* CPT codes 99356 and 99357 were not previously billable with discharge day management CPT codes 99238 or 99239. (Refer to, for example, instructions on pages 41–42 of the 2022 CPT Codebook.) Additionally, according to 2023 CPT Codebook instructions (p.29), CPT code 99418 (referred to as CPT code 993X0 in the proposed rule) is not billable with CPT codes 99238 and 99239.

We proposed that a practitioner would not be able to bill prolonged services for hospital discharge (CPT codes 99238 or 99239). This means that CPT codes 99418, 99358–9 (prolonged E/M service on a date other than the face-to-face E/M, and the proposed G0316 code (discussed in section II.F.3. of this final rule) would not be payable where the discharge day management code is CPT codes 99238 or 99239. We believe the code descriptors for CPT codes 99238 and 99239 do not allow for additional payment of prolonged services. The descriptor for CPT code 99238 provides for hospital discharge day management, ''30 minutes or less.'' If a practitioner spends more than 30 minutes on a hospital discharge service for a patient, the practitioner would be able to bill CPT code 99239, which is defined in the code descriptor as ''30 minutes or more.'' Thus, a prolonged code (including CPT codes 99418, 99358, 99359, and our proposed G0316) would not be appropriate for CPT code 99238, because CPT code 99239 accounts for services that exceed 30 minutes.

The descriptor for CPT code 99239 states that the code is for ''more than 30 minutes'' of hospital discharge day management services. When the RUC surveyed this code, the surveyed timeframe was within 3 calendar days of the encounter. In other words, the descriptor time is more than 30 minutes, completed within 3 calendar days of the encounter. Neither the descriptor nor the CPT billing instructions provide an upper limit on how many minutes can be reported within the 3-day timeframe for CPT code 99239. All face-to-face and non-face-to-face activities performed by the practitioner during the date of encounter and within 3 calendar days from the date of encounter may be counted toward CPT code 99239, as applicable. Prolonged codes CPT codes 99418, 99358, 99359, and our proposed G0316 code are intended to pay for time not included in the primary E/M codes during the surveyed timeframe; as it appears that CPT code 99239 already includes all services furnished during the surveyed timeframe, we do not believe it is appropriate to allow any prolonged codes to be billed with CPT code 99239 as a base code.

Comment: One commenter noted that in the section of the proposed rule where this proposal was discussed (87 FR 45993), we misstated the descriptor for CPT code 99239 as ''30 minutes or more'' when it should be ''more than 30 minutes.''

Response: We agree with the commenter and thank them for their attention. We acknowledge our unintentional error.

Comment: One commenter requested clarification on the applicable timeframe for when time is counted for CPT code 99239—namely whether the 3-day timeframe described in the proposed rule for the completion of time refers only to days after discharge, or can include time prior to discharge.

Response: We clarify that the timeframe is within 3 calendar days after discharge. We note that time spent providing face-to-face or non-face-to-face care on a date prior to discharge would be counted toward an appropriate initial or subsequent Hospital Inpatient or Observation Care code (CPT codes 99221–99223 or 99231–99233), which are discussed in section II.F.3.

After consideration of public comments, we are finalizing this policy as proposed.

c. Valuation of Hospital Inpatient or Observation Discharge Day Management

The revised discharge day management codes (CPT codes 99238 through 99239) were surveyed for the January 2022 RUC meeting. We proposed to accept the RUC recommendations for CPT codes 99238 (work RVU 1.50, intraservice time 28 minutes, total time 38 minutes); and 99239 (work RVU 2.15, intraservice time 45 minutes, 64 minutes total time).

We proposed the RUC-recommended direct PE inputs for CPT codes 99238 and 99239 without refinement. We received one comment on this proposal.

Comment: One commenter expressed support for our proposal to accept the RUC recommendations for this code set.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing the RVUs for CPT codes 99238–99239 as proposed.

5. Emergency Department Visits (CPT Codes 99281–99285)

a. Coding

We have revalued the ED visit codes under the PFS four times: in 1997, 2007, 2020, and most recently in 2021 as part of the update for O/O E/M visits. In the past, consistent with AMA RUC recommendations, we revalued these services such that the values of levels 1 through 3 of the ED visits were equal to levels 1 through 3 new patient O/O E/M visits, and the levels 4 and 5 ED visits were valued higher than the levels 4 and 5 new patient O/O E/M visits to reflect higher typical intensity. In addition, in the CY 2018 PFS final rule (82 FR 53018), we finalized a proposal to nominate all five ED visit codes as potentially misvalued, based on information suggesting that the work RVUs for ED visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, some impacted parties

expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished. Accordingly, the RUC resurveyed and reviewed these five codes for the April 2018 RUC meeting, and provided a recommendation to CMS for consideration in CY 2020 rulemaking. In the CY 2020 PFS final rule (84 FR 62796), we finalized the RUC-recommended increases to the work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285. The RUC did not recommend, and we did not finalize, any change in direct PE inputs for the codes in this family. We noted that the RUC submitted these recommended values to CMS prior to the submission of the RUC-recommended revaluation of the O/O E/M visit code family.

In response to our finalizing of the RUC-recommended values for the ED visits, and to our comment solicitation in the CY 2020 PFS proposed rule regarding whether we should revalue certain services commensurate with increases to the O/O E/M visits (84 FR 62859 through 62860), a commenter submitted a public comment stating that relativity between the ED visits and O/O E/M visits should be maintained, and submitted a specific recommendation for CPT codes 99283–99285 that was higher than the RUC-recommended values. The commenter stated we should preserve the relationship between the ED and O/O E/M visit code sets that was established in prior years and that they believe would have likely been maintained had the O/O E/M visits been reviewed prior to the ED visits. In order to avoid the rank order anomaly whereby an ED visit would be valued lower than the analogous O/O E/M visit, we proposed and eventually finalized the values recommended by this commenter in the CY 2021 PFS final rule (85 FR 84562). This final policy increased the work RVU from 1.42 to 1.60 for CPT code 99283, from 2.60 to 2.74 for CPT code 99284, and from 3.80 to 4.00 for CPT code 99285.

Following the implementation of the revisions to the O/O E/M visits for the CPT 2021 code set, the CPT/RUC Workgroup on E/M standardized the rest of the E/M sections in the CPT code set. In February 2021, the CPT Editorial Panel revised the five ED visit codes to align with the principles included in the E/M office visit services by documenting and selecting level of service based on medical decision making, effective January 1, 2023. The descriptor for CPT code 99281 was revised such that the code may not require the presence of a physician or other qualified health care professional. The CPT Editorial Panel also revised the MDM level in the descriptor for CPT code 99282 from ''low'' to ''straightforward'' complexity, and from ''moderate'' to ''low'' complexity for CPT code 99283. These five codes were resurveyed and reviewed at the April 2021 RUC meeting with recommendations submitted to CMS for the CY 2023 PFS rulemaking cycle.

We received several comments related to our proposal to adopt the CPT revisions to the MDM guidelines for the ED visits. Below is a summary of the comments received and our responses.

Comment: Several commenters raised concerns related to the proposed changes to the MDM guidelines. Their concerns were that considerable training and education will be required to ensure clinicians are prepared to appropriately code their encounters, and that CMS should consider delaying implementation of the new MDM guidelines in order to ensure proper education and training can occur. Other commenters noted that the MDM guidelines do not reflect the level of MDM visits appropriately for the ED visits using MDM, and they will be applying to CPT for changes to the MDM guidelines for 2024. Some commenters requested a delay and recommended to retain the MDM guidelines in their current form until the AMA reviews the need for additional changes. Other commenters were supportive of CMS's collaboration with AMA CPT and the revisions made.

One commenter raised an issue with the current MDM guidelines for ED visits, involving a local MAC's interpretation and application of the term ''workup.''

Response: We appreciate the commenters' feedback. It is our understanding that the AMA E/M workgroup revised the MDM guidelines for CY 2023 to reflect changes specific to ED visits already, and that ED member physicians already provided input and made changes to these guidelines. We are unsure of how the issue involving the term ''workup'' would apply under the new MDM guidelines, and we recommend that interested parties ask CPT to clarify and consider any relevant revisions that might be needed for 2024. We understand that an ED specialty society will propose to CPT additional changes to the MDM guidelines that would impact ED visit level selection beginning in 2024, if passed by CPT. We will consider additional changes if they are made by CPT, but we believe we should adopt the changes that have been made to date for 2023, since they already reflect an initial round of input from ED physicians in the AMA Workgroup, and a consensus that was reached at CPT. We will watch for additional changes recommended by CPT, and may consider any further changes in future rulemaking.

Comment: One commenter agreed with our proposal to adopt the CPT framework for ED visits, whereby ED visit level would be based on MDM rather than time.

Response: We thank the commenter for their support.

Comment: One commenter requested clarification on CPT code 99281, and whether the proposed guideline is intended for professional services billing by the practitioner in charge of oversight of care, or is the new code for hospital billing only.

Response: The level 1 ED visit (CPT code 99281) currently describes services by a physician or qualified health care professional (QHP), requiring a problem-focused exam and straightforward MDM, among other physician/QHP work. For 2023, this code is revised to describe an ED visit for the E/M of a patient that may not require the presence of a physician or other QHP. The purpose of this CPT code revision, as we understand it, was to create a more parallel structure between ED and O/O visits, since as of CY 2021, level 1 O/O visits may not require the presence of a physician/QHP. An example in the ED setting might be a patient presenting for suture removal for a laceration repair that was performed by another provider in a different location, where the wound is healing well. We are maintaining the active payment status for CPT code 99281, and we will be monitoring claims data to assess billing patterns for this and other E/M visits under the new framework.

b. Sites of Service and Multiple Same-Day E/M Visits for Emergency Department Patients

As we discussed in the previous section (Hospital Inpatient or Observation Care (CPT codes 99218–99236)) the CPT Editorial Panel has revised CPT codes 99221 through 99223 to include both inpatient hospital and observation care services. (Note our proposal in that section regarding billing policy for transitions between ED and hospital inpatient or observation care.) We also proposed to modify our policy regarding when to bill ED codes

CPT codes or hospital inpatient care (CPT codes 99221 through 99223), as further described in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.11.E., to clarify that these policies apply to observation care billed under CPT codes 99221 through 99223 as well. We proposed that, if a physician advises their own patient to go to an ED of a hospital for inpatient care or observation and the physician subsequently is asked by the ED physician to come to the hospital to evaluate the patient and to advise the ED physician as to whether the patient should be admitted to the hospital, placed in observation status, or sent home, the physicians should bill as follows:

- If the patient is admitted to the hospital or placed in observation status by the patient's personal physician, then the patient's personal physician should bill only the appropriate level of the initial hospital inpatient or observation care (CPT codes 99221—99223), because all E/M services provided by that physician in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed on the same date as the admission. The ED physician who saw the patient in the ED should bill the appropriate level of the ED codes.
- If the ED physician, based on the advice of the patient's personal physician who came to the ED to see the patient, sends the patient home, then the ED physician shall bill the appropriate level of ED service. The patient's personal physician shall also bill the level of ED code that describes the service they provided in the ED. If the patient's personal physician does not come to the hospital to see the patient, but only advises the ED physician by telephone, then the patient's personal physician may not bill the ED codes.

Similarly, we proposed that if the ED physician requests that another physician evaluate a given patient, the other physician should bill an ED visit code. We also proposed that if the patient is admitted by the second physician performing the evaluation, that physician shall bill an initial hospital inpatient or observation care code (CPT codes 99221 through 99223, as appropriate), and not an ED visit code. This policy appears in the Medicare Claims Processing Manual, (Pub. L. 100–04, Chapter 12, section 30.6.11.F), and we are clarifying that this policy applies to both hospital inpatient and observation care billed under CPT codes 99221 through 99223.

Finally, we noted that the 2023 CPT Codebook provides instructions that critical care and ED services may be billed on the same day under certain circumstances. We referred readers to the CY 2022 PFS final rule (86 FR 65163), where we finalized our policy that critical care and ED visits may be billed on the same day if performed by the same physician, or by physicians in the same group and specialty if there is documentation that the E/M service was provided prior to the critical care service at a time when the patient did not require critical care, that the service is medically necessary, and that the service is separate and distinct, with no duplicative elements from the critical care service provided later in the day, and that practitioners may bill for both services. Practitioners must use modifier -25 on the claim when reporting these critical care services. This policy is also in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.12.6.

Please refer to the next section, ''Nursing Facility Services'' (section II.F.6) for discussion of policies regarding patients seen in the ED and the nursing facility on the same day.

We received comments specific to the ED to nursing facility transition. Please refer to the nursing facility section below (section II.F.6).

After consideration of public comments, we are finalizing as proposed and will continue to consider for possible future rulemaking for these visits.

c. Valuation

We proposed the RUC-recommended work RVU for four of the five codes in the ED Visits family. We proposed a work RVU of 0.25 for CPT code 99281 (*Emergency department visit for the evaluation and management of a patient, that may not require the presence of a physician or other qualified health care professional*), a work RVU of 0.93 for CPT code 99282 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*), a work RVU of 1.60 for CPT code 99283 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), and a work RVU of 4.00 for CPT code 99285 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making*).

We disagreed with the RUC-recommended work RVU of 2.60 for CPT code 99284 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*) and we proposed to maintain the current work RVU of 2.74. The survey conducted for CPT code 99284 maintained unchanged a work time of 40 minutes, and the level of medical decision making in the code's descriptor also remains unchanged at ''moderate'' complexity. Therefore, we continue to believe that the levels 4 and 5 ED visits are more accurately valued higher than the levels 4 and 5 new patient O/O E/M visits to reflect their higher typical intensity. This has been the historic relationship between these codes, and we previously finalized a proposal in the CY 2021 PFS final rule, increasing the work RVU from 2.60 to 2.74 for CPT code 99284. Given that there has been no change in the surveyed work time or level of MDM for this service, we continue to believe that the work RVU of 2.74 that we finalized in the CY 2021 rule cycle remains the most accurate valuation for CPT code 99284 (85 FR 84562).

The RUC did not recommend and we did not propose any direct PE inputs for these five ED visit codes.

Comment: We did not receive any comments in opposition to the proposed values for this family, except for the level 4 ED visit. Most commenters expressed their support for the proposed work RVU of 2.74 for CPT code 99284. Commenters stated they appreciated that CMS continues to recognize that the work RVU for a level 4 ED visit should be higher than for the corresponding level 4 O/O E/M visit, and that they supported our proposal to retain the historic relativity between the new patient O/O outpatient E/M codes and the ED E/M codes.

Response: We appreciate the support for our proposed work RVUs from the commenters.

Comment: A few commenters disagreed with the proposed work RVU of 2.74 for CPT code 99284 and instead supported the RUC-recommended work RVU of 2.60. The commenters stated that the RUC agreed that the work RVU for the ED codes should be equivalent to the office/outpatient visit codes, based on level of MDM and urged CMS to finalize the RUC recommendation. Commenters stated that, although CPT codes 99204 and 99284 would share the same work RVU of 2.60 under the RUC's recommendations, this was appropriate, because they asserted that CPT code 99284 would have notably higher

intensity due to its shorter work time of 40 minutes (as compared with 60 minutes for CPT code 99204). Commenters also stated that the proposed work RVU of 2.74 would create a rank order anomaly within the family of ED codes, since the intensity of CPT code 99284 would be higher than the intensity of CPT code 99285. The commenters urged CMS to finalize the RUC recommendations for all five ED codes, including the work RVU of 2.60 for CPT code 99284.

Response: We appreciate commenters' feedback. We disagree with the commenters and continue to believe that CPT code 99284 is more accurately valued at a higher rate than CPT code 99204 at the proposed work RVU of 2.74. As we noted in the proposed rule, the survey conducted for CPT code 99284 maintained—unchanged—a work time of 40 minutes, and the level of medical decision making in the code's descriptor also remains unchanged at ''moderate'' complexity. We do not agree that the work RVU of CPT code 99284 should be reduced to match the work RVU of CPT code 99204, given that the code remains essentially unchanged. This is especially true, given that this has been the historic relationship between these codes, and that we previously finalized a proposal in the CY 2021 PFS final rule to increase the work RVU from 2.60 to 2.74 for CPT code 99284 specifically so that these codes would not share the same work RVU.

We also disagree with the commenters that our proposed work RVU of 2.74 creates a rank order anomaly within the ED family. The small difference in intensity between CPT codes 99284 and 99285 (about 3 percent higher for CPT code 99284) is counterbalanced by the much longer work time of CPT code 99285. We do not believe that the work RVU of CPT code 99284 should be deliberately lowered to manipulate the intensity into a lower value than CPT code 99285. We also note that it is very common for intensity to be slightly lower for codes with longer work times, even within families where the code descriptors reflect more difficult MDM. For example, in the office/outpatient visit code family, CPT code 99204 has a slightly higher intensity than CPT code 99205. This does not constitute a rank order anomaly within the family (or serve to justify lowering the work RVU for code 99204); rather, it is an artifact of the longer work time associated with CPT code 99205 as compared with CPT code 99204. We continue to disagree that intensity would constitute a rationale for finalizing the RUC's recommended work RVU of 2.60 for CPT code 99284.

After consideration of public comments, are finalizing the work RVUs and direct PE inputs for all five codes in the Emergency Department Visits as proposed.

d. Prolonged Services

We proposed that the prolonged services described by HCPCS codes G0316, G0317, and G0318 would not be reportable in conjunction with ED visit codes, because the ED visit codes are not reported based on the amount of time spent with the patient.

We did not receive any comments specific to this proposal, therefore we are finalizing as proposed. We refer readers to section II.F.11 below for a discussion of comments received on prolonged Other E/M services generally. Our final policy for ED visits is reflected in summary Table 24 in section II.F.12.e. of this final rule.

6. Nursing Facility Visits (CPT Codes 99304–99318)

a. Coding Overview

The codes in the Nursing Facility (NF) services family are used to report E/M services primarily to patients in nursing facilities and skilled nursing facilities. Following the implementation of the revisions to the O/O E/M visits (CPT codes 99201 through 99215) for the CPT 2021 code set, the CPT/RUC Workgroup on E/M met to standardize the rest of the E/M sections in the CPT code set. We have received valuation recommendations from the AMA RUC for the Nursing Facility Visit codes (CPT codes 99304 through 99318) following completion of its survey and revaluation process for these codes. In its April 2021 meeting, the RUC provided us the results of its review, and recommendations for work RVUs, practice expense inputs, and physician time (number of minutes) for the revised Nursing Facility Visits E/M code set. Therefore, we proposed changes in coding and values for the revised Nursing Facility Visits E/M code set. This code set is effective beginning in CY 2023, and the proposed values, if finalized, would go into effect with those codes as of January 1, 2023. In its February 2021 meeting, the CPT Editorial Panel deleted CPT code 99318, the annual nursing facility assessment code and revised the remaining nursing facility code to better align with the principles included in the E/M office visit services by documenting and selecting level of service based on total time or MDM. The remaining codes, initial and subsequent daily visits and nursing facility discharge day management codes were revised. Similar to what was done for the office visit codes, for CY 2023, we proposed when total time on the date of encounter is used to select the appropriate level of a nursing facility visit service code, both the face-to-face and non-face-to-face time personally spent by the physician (or other qualified health care professional that is reporting the office visit) assessing and managing the patient are summed to select the appropriate code to bill. Additionally, the codes have new descriptor times, assigned for when time is used to select visit level (We noted that we did not adopt the CPT Codebook instructions regarding the application of prolonged codes to CPT codes 99306 and 99310; see additional discussion under the subsection ''Prolonged Codes for NF Care'' in this section.). CPT provides that initial nursing facility care (CPT codes 99304 through 99306) may be used once per admission, per practitioner, regardless of the length of stay in the NF; and that an initial service can be reported if the patient has not received any face-to-face professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay, or if the patient is a new patient as defined by CPT (2023 CPT Codebook, p.24). However, we proposed an alternative definition of initial NF visit, consistent with our current policy (see below).

These nursing facility visits are noted by the RUC to be typically performed in the skilled nursing facility which requires a higher level of care than the nursing facility. The survey time captured includes pre-service time 1 day before the date of encounter, intra-service time is all the time on the date of encounter, and post-service time is 3 days after the date of encounter. The RUC's recommendations for this code family are consistent with the 25th percentile of the survey results and is based on a comparison of the survey codes with the selected the O/O CPT codes as a crosswalk to the key reference services.

While we have thoroughly reviewed the times and descriptors for all the codes in this family, and we proposed to accept the RUC recommendations as explained below, we noted our concerns regarding instances of inconsistencies and errors, where the time described in certain CPT code descriptors does not correctly relate to the time that would be used to select visit level for the

Nursing Facility visit (for example, CPT code 99306 and 99310 have the same times noted in the descriptors, where one is an initial visit and one is a subsequent visit). In general, the specialty societies and the RUC have advocated for increasing the work RVUs for the Nursing Facility visits, as compared to their previous values, regardless of some of the survey times, on the basis that values for these Nursing Facility visit codes should be valued the same as the values for the comparable O/O E/M visits. We considered the survey results, especially reductions in pre-, intra-, and post-service time, and noted that the comparison to O/O E/M visits is not accurate. These code families are incomparable for a few reasons, including, but not limited to: (1) the two families have a different number/stratification of levels for the visits, thus a one-to-one crosswalk is not possible; (2) times in the code descriptors detailing the typical time spent at the patient's bedside or hospital unit vary significantly; and (3) the patient populations differ substantially, when considering typical patients who require nursing facility services versus those in the general beneficiary community. Additional reasons are laid out in our overview section above. We do not believe that a comparison of these two code families can technically be made on a code-by-code basis. However, given the recent changes to the O/O E/M visit values that we finalized in the CY 2020 PFS final rule (84 FR 62846) and our interest in maintaining continuity in the overall code set, we proposed to accept the RUC recommendations for the work time values and work RVUs for these Nursing Facility visit codes and solicited public comment on our concerns for some of the codes as noted below in this section.

We proposed to adopt a number of billing policies reflected in our current Medicare Claims Processing Manual, Chapter 12, section 30.6.13:

- We proposed that the initial comprehensive assessment required under 42 CFR 483.30(c)(4) shall be billed as an initial NF care visit (CPT code 99304 through 99306). We proposed that a practitioner may bill the most appropriate initial nursing facility care code (CPT codes 99304 through 99306) or subsequent nursing facility care code (CPT codes 99307 through 99310), if the practitioner furnishes services that meet the code descriptor requirements, even if the service is furnished prior to the initial comprehensive assessment required under § 483.30.

A practitioner who bills an initial NF visit (CPT codes 99304 through 99306) for the initial comprehensive assessment required under § 483.30(c)(4) may bill subsequent NF visits (CPT codes 99307 through 99310), if the practitioner furnishes medically necessary face-to-face and non-face-to-face care that meets the requirements in the NF services code descriptors (CPT codes 99307 through 99310) to the beneficiary prior to the completion of the initial comprehensive assessment required under § 483.30. We proposed to allow for an initial or subsequent NF visit to be furnished and billed by the appropriate practitioner (physician, physician assistant, nurse practitioner, or clinical nurse specialist as specified in § 483.30 for the type of visit furnished) regardless of whether the initial comprehensive assessment was performed.

- We proposed to retain our policy to not pay a physician for an ED visit or an office visit and a comprehensive nursing facility assessment on the same calendar day, because it would be duplicative care. If the practitioner saw the patient in the nursing facility once on a given date, they have performed a lot of the work that is included in the other visit E/M visits, for example an ED visit. The services furnished on the same date and provided in sites other than the nursing facility are already bundled into the initial nursing facility care code when performed on the same date as the nursing facility admission by the same physician.

We noted that the Medicare Claims Processing Manual also states that ED visits provided on the same day as a comprehensive nursing facility assessment are not paid, regardless of whether the ED and nursing facility visits are by the same or different practitioners (Chapter 12, section 30.6.11.D). We proposed to retain this policy as well. We noted that the 2023 CPT Codebook does not limit the number of visits that can be billed. We proposed that more than one ED and nursing facility visit could not be billed if both visits are furnished by the same practitioner on the same date of service.

- We proposed to adopt the 2023 CPT Codebook guidance that, for reporting initial nursing facility care, transitions between skilled nursing facility level of care and nursing facility level of care do not constitute a new stay. (2023 CPT Codebook, p. 24.)
- We proposed that an initial service is one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay. We proposed that a subsequent service is one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay. This is the same definition that we proposed for ''initial'' and ''subsequent'' in the context of inpatient and observation services above. According to CPT instructions, an ''initial'' service may be reported when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay. As we do not recognize subspecialties, we proposed to apply these slightly amended definitions of ''initial'' and ''subsequent'' service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested clarification regarding whether we intended to retain our current policy, as reflected in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, section 30.6.9.2.D, which allows for payment of the hospital discharge day management code (CPT codes 99238 or 99239) in addition to a separate nursing facility admission code when they are billed by the same practitioner with the same date of service.

Response: Consistent with our proposed retention of our other policies regarding billing by the same practitioner providing multiple E/M services to the same patient on the same day, it was our intention to retain this policy as well. We thank the commenter for bringing this additional related policy to our attention.

Comment: One commenter asked that we permit billing of an ED E/M visit on the same day as a NF admission/comprehensive assessment, whether by the same or another practitioner.

Response: The main goal of our proposed policies in this area was to maintain our current policy while we continue to consider, for potential future rulemaking, what our policies should be broadly regarding multiple, same-day E/M visits. In section 30.6.7.C, Chapter 12 of the Medicare Claims Processing Manual (Pub. 100–04), we state, ''MACs may not pay a physician

for an emergency department visit or an office visit and a comprehensive nursing facility assessment on the same day. Bundle E/M visits on the same date provided in sites other than the nursing facility into the initial nursing facility care code when performed on the same date as the nursing facility admission by the same physician.'' Therefore, we believe payment for a NF initial visit can be made to a practitioner other than the practitioner who furnished the ED visit on the same day, and we will retain this policy in 2023. If the NF initial visit and ED visit are furnished by the same practitioner on the same day, and time is used to select NF visit level, the time spent by the practitioner for the ED visit can be counted toward prolonged NF services (G0317) (see Table 24). We will continue to consider this issue for potential future rulemaking, if needed.

After consideration of public comments, we are finalizing the following, as proposed.

- The initial comprehensive assessment required under 42 CFR 483.30(c)(4) will be billed as an initial NF visit (CPT code 99304–99306). A practitioner may bill the most appropriate initial nursing facility care code (CPT codes 99304–99306) or subsequent nursing facility care code (CPT codes 99307–99310), if the practitioner furnishes services that meet the code descriptor requirements, even if the service is furnished prior to the required initial comprehensive assessment.
- A given practitioner cannot bill an initial NF visit and another E/M visit (such as an O/O visit or ED visit) on the same date of service, for the same patient. However, the time the practitioner spends furnishing a visit in another setting can be counted toward reporting prolonged NF services, if requirements for reporting prolonged NF services are met.
- We are adopting the CPT instruction for reporting initial nursing facility care, which provides that transitions between SNF level of care and nursing facility level of care do not constitute a new stay.
- An initial service is one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay. A subsequent service is one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay.

b. Valuation

For CPT codes 99304 through 99310, we proposed to adopt the RUC-recommended work RVUs for all of the nursing facility E/M visit codes given the new times surveyed by the RUC and specialty societies. Specifically, we proposed a work RVU of 1.50 for CPT code 99304 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*), a work RVU of 2.50 for CPT code 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), a work RVU of 3.50 for CPT code 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*), a work RVU of 0.70 for CPT code 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*), a work RVU of 1.30 for CPT code 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*), a work RVU of 1.92 for CPT code 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*), and a work RVU of 2.80 for CPT code 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*). We proposed the RUC-recommended direct PE inputs for all the codes in the family, CPT codes 99305 through 99310.

While we proposed to accept the RUC recommendations for CPT code 99306, we considered maintaining the current work RVU of 3.06, since there was no change in the overall time. To support their recommendation, the RUC cited the survey key reference service, CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter*), which has a much higher time noted in the descriptor and does not seem to be a valid comparison or support the increase in value to the RUC survey 25th percentile. There was no change in time for this service, and the code the RUC used for comparison has a higher total time. We also requested comment on the accuracy of the time noted in the descriptor for CPT code 99306. We noted that it is not clear to us why CPT code 99306, which is an initial service, would have the same descriptor time and medical decision making as CPT code 99310 which describes a subsequent visit. We sought clarification, especially with regard to the similarities between the code descriptors for these two services (CPT codes 99306 and 99310).

For CPT code 99308, we proposed to accept the RUC recommendations; however, we considered maintaining the current work RVU of 1.16 given there was a decrease in the total time for the service and no change in the descriptor time. We solicited comment regarding the RUC recommendations that the total time be rounded down to 15 minutes instead of rounding up to twenty minutes, when using total time on the date of the encounter for code selection (minutes must be met or exceeded), and sought clarification on this difference. In light of the changes made to the O/O E/M visits, however, we proposed the RUC-recommended work RVU of 1.30 for CPT code 99308, but stated that we would appreciate comments regarding rounding.

For CPT code 99309, we proposed a work RVU of 1.92. When compared to CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient,*

which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter), we are acknowledging the increase in time required to bill CPT code 99309. We noted that the descriptor time for CPT code 99309 went up since these codes were last revalued. We are focusing on the time in the descriptor, and if there is a change in the level of MDM. In light of recent changes made to the O/O E/M visits, however, we proposed the RUC-recommended work RVU of 1.92 for CPT code 99309.

Although we proposed to adopt all the RUC-recommended work RVUs and times for this code family as explained above, we solicited comment regarding the discrepancies in times, which have implications both for valuation of individual codes (and for PFS ratesetting in general), since the intraservice times and total times are used as references for valuing many other services under the PFS. After reviewing the RUC recommendations, in conjunction with the revised code descriptors and documentation guidelines for CPT codes 99304 through 99310, we proposed to accept the RUC-recommended work and time values for the revised nursing facility visit codes with the PE refinements noted by the RUC for CY 2023.

We received public comments on these valuation proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported and commended CMS for proposing the RUC-recommended work RVUs for all the nursing facility codes, and stated that it is important to adopt them in the final rule.

Response: We thank the commenters for their support.

Comment: In their public comment, the AMA addressed the questions asked by CMS related to the times in the code descriptors for CPT codes 99306 and 99310. The AMA explained that the wording of these code descriptors was intentional, such that descriptor times and MDM are the same, and that these codes only differ in their inclusion of the terms ''*initial*'' versus ''subsequent,'' enabling practitioners to use these terms to decide which code to bill. Although the intra-service time for CPT code 99306 was 50 minutes, CPT assigned a descriptor time of 45 minutes (which is the same descriptor time for 99310) to provide a consistent pattern of time increments, simplifying reporting. This results in descriptor times for CPT codes 99304, 99305, and 99306 that are 10 minutes apart (25, 35, and 45 minutes, respectively), providing an easy incremental pattern for those who are reporting these services based on time.

Response: We appreciate the AMA's clarification. We note that this incremental pattern was not applied by CPT to CPT codes 99307 and 99308, and CPT does not appear to consistently apply this approach within or across E/M visit families, historically or for 2023. For example, the new descriptor times for home/residence visits are not separated by identical increments, nor are the parallel 2022 domiciliary codes or the 2023 inpatient/observation visit descriptor times. To help distinguish initial and subsequent NF visits having high MDM, and better match the descriptor time to the intraservice time, CPT could have adopted a descriptor time of 50 minutes for CPT code 99306. To avoid creating Medicare-specific codes for NF visits, for CY 2023 we are adopting the CPT code descriptors as revised for CPT codes 99306 and 99310. However, we recommend that CPT revise the descriptor for CPT code 99306, and clarify the methodology being used to establish CPT code descriptor times within and across E/M visit families. Applying a consistent methodology seems important for establishing relativity within and across families.

Comment: In their public comment, the AMA explained that the descriptor time for CPT code 99308 was rounded down, from 18 minutes intraservice time to 15 minutes in the descriptor, to maintain a 15-minute incremental reporting pattern for time among the subsequent NF visit codes. As discussed above, we note that CPT does not consistently apply this approach within or across E/M visit families when establishing descriptor times, historically or for 2023. Applying a consistent methodology seems important for establishing relativity within and across families. We recommend that CPT revise the descriptor for CPT code 99308 to 20 minutes and clarify the methodology being used to establish CPT code descriptor times within and across E/M visit families. To avoid creating Medicare-specific codes for NF visits, for 2023, we are adopting the CPT code descriptor as revised for CPT code 99308.

Regarding valuation for CPT code 99308, the RUC appears to have recommended the increased work RVU based upon a slightly increased intraservice time, despite a slight decrease in total time. We note that the specialty societies had requested an even higher work RVU (the median), which the RUC did not accept. Since the total time decrease was small, we are finalizing our proposal to accept the RUC-recommended work RVU (the survey 25th percentile), which will increase the work RVU for CPT code 99308 from 1.16 to 1.30.

Comment: MedPAC agreed with the concerns we expressed regarding the times in the descriptors and the associated RUC-recommended valuations for this family, and was not in support of the proposal to accept the RUC recommendations for this code family. MedPAC suggested that the RUC address these concerns by revising the RVUs or that CMS develop its own RVUs for these services since nursing facility E/M visit codes are used as reference codes for valuing many other services in the fee schedule. MedPAC opined that assigning inaccurate work RVUs to these E/M codes could, therefore, lead to inaccurate payments—not just for these services, but also for a variety of other services that are valued in relation to these visits. MedPAC suggested that CMS ask the RUC to revisit its valuation of the nursing facility E/M visit codes; alternatively, CMS could propose its own work RVUs in next year's proposed rule. In the interim, MedPAC further suggested that CMS should retain the current RVUs for nursing facility E/M visit codes.

Response: We had considered proposing to maintain the work RVUs for several of the codes, as stated above for the nursing facility code set, or alternatively, creating new coding or assigning different work values to address the concerns we identified for this code set. However, after reviewing our options and considering the potential impact on interested parties, including the process through which the codes would be revalued, we concluded it would be least disruptive to adopt the revised code set and values as proposed. As discussed above, we are recommending that the CPT Editorial Panel reconsider the descriptor times for several of the codes in this family, and apply a more consistent approach to descriptor times within and across families. We intend to monitor this code set and will propose any necessary changes through future rulemaking.

After consideration of public comments, we are finalizing as proposed, to accept the RUC recommendations for this code family and adopt the CPT codes as revised. However, we recommend that the CPT Editorial Panel reconsider the descriptor times for several codes in this family, and provide more transparency and

consistency when establishing descriptor times for E/M visits.

c. Prolonged Services

We proposed that prolonged nursing facility services by a physician or NPP would be reportable using prolonged service HCPCS code G0317, which would be used to account for additional time spent when the total time for the NF service (specified in the time file) is exceeded by 15 or more minutes. The long descriptor would be *G0317* (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99418). (Do not report G0317 for any time unit less than 15 minutes)).* We proposed that the practitioner would include any prolonged service time spent within the surveyed timeframe, which includes the day before the visit, the day of the visit, and up to and including 3 days after the visit (please see summary Table 18 in our proposed rule). We proposed that prolonged physician or NPP NF services would be reportable when the total time (in the physician time file) is exceeded by 15 or more minutes which would be once 95 minutes are spent for initial NF visits, and once 85 minutes are spent for subsequent NF visits, and for each additional 15 minutes furnished thereafter. Consistent with CPT coding guidance as indicated below, there would not be any frequency limitation; therefore, we proposed that physicians and NPPs would be able to bill G0317 for each additional 15-minute increment of time beyond the total time for CPT codes 99306 and 99310.

Since G0317 includes time without direct patient contact, there would no longer be a need to use CPT codes 99358 and 99359 (prolonged E/M service on a date other than the face-to-face E/M) in conjunction with NF visits. Therefore, we proposed to change the payment status for CPT codes 99358 and 99359 to ''I'' (*Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services*). This is consistent with our final policy for O/O E/M visits, where prolonged time can no longer be reported using CPT codes 99358 and 99359. We continue to be concerned about program integrity, counting time that was not included in the surveyed timeframe, and the administrative complexity of having multiple prolonged service codes associated with a given primary service (see our previous discussion of these issues in our CY 2020 PFS final rule at 84 FR 62849 through 62850). As we stated in that rule, many other codes are available to report prolonged E/M work associated with an E/M visits that occurs outside of the timeframe included in the visit, such as CCM, TCM, PCM, behavioral health integration (BHI), and other care management service codes. We designed these codes to be used to report time spent outside the direct patient contact (but still in management/consideration of that given patient's case) on dates other than the E/M visit. While these care management codes are not identical to the prolonged visit codes, they can be used to report a number of similar activities. Additional information about those codes can be found on our PFS Care Management website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management*. We also direct the reader to section II.E. of this final rule, where we proposed additional care management service codes for pain management and BHI.

When prolonged nursing facility services are furnished by a physician or NPP, they would be reportable under HCPCS code G0317. We believe that allowing practitioners to report CPT code 99418 after the minimum time requirement for the highest level subsequent visit is met and then exceeded by at least 15 minutes would result in double-counting time. As a specific example, CPT code 99310 requires that 45 minutes must be met or exceeded up to 60 minutes. If the reporting practitioner spent 55 minutes of time, those 55 minutes would be billed and are included in the services described by CPT code 99310. After 60 minutes has been met, any additional time should be counted toward the 15 minutes required to report the add on CPT code for the prolonged service. Similar to the policy we finalized in the CY 2020 PFS final rule for the O/O E/M visits (84 FR 62849), which states that when the time of the reporting physician or NPP is used to select O/O E/M visit level, HCPCS code G2212 could be reported when the maximum time for the level 5 O/O E/M visit is exceeded by at least 15 minutes on the date of service.

In addition, we noted that the CPT code descriptor for CPT code 99418 does not include nursing facility. Further, the timeframes do not align for CPT codes 99418, 99358, and 99359. The survey time for CPT code 99418 is for time on the date of service, and when the nursing facility visit codes were resurveyed by the RUC, the survey time included the day before, the day of, and up to and including 3 days post the date of service. We proposed Medicare-specific coding in order to avoid duplicative counting of time, administratively simplify prolonged service coding, and better enable us to determine how much total time was spent with the patient. If we proposed to merely accept the CPT prolonged service coding changes, we would not be able to identify the time spent with patients in the claims data alone. This is because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. Consistent with CPT's approach, we proposed that practitioners and NPPs would only be able to report the prolonged services code for NF (G0317) in conjunction with the highest level codes in the family (CPT code 99306 and 99310). This would also be consistent with our policy for O/O E/M visits (see (84 FR 62849).

We received many comments regarding our proposal for Medicare-specific coding for prolonged Other E/M services. We address comments that apply across the Other E/M visit families in this final rule in section II.F.11 below (Prolonged Services).

7. Nursing Facility Discharge Management (CPT Codes 99315–99316)

a. Coding

CPT codes 99315 (*Nursing facility discharge day management; 30 minutes or less*) and 99316 (*Nursing facility discharge day management; more than 30 minutes*) were identified for RUC review in October 2021 and were then postponed so that they could be reviewed at the same time as the inpatient hospital and observation care codes, in January 2022. Due to changes in physician work, changes in technology, patient population, and length of stay, the RUC determined that the nursing facility discharge services could be reviewed separately from the inpatient hospital discharge day services.

The nursing facility discharge day management codes are used to report the total duration of time spent by a physician or other qualified health care

professional for the final nursing facility discharge of a patient. The codes include, as appropriate, final examination of the patient and discussion of the NF stay, even if the time spent on that date is not continuous. Instructions are given for continuing care to all relevant caregivers, as well as for preparation of discharge records, prescriptions, and referral forms. These services require a face-to-face encounter, which may be performed on a calendar date prior to the actual discharge date. The time of the face-to-face encounter performed on a date prior to the discharge date is counted toward CPT code 99315 and CPT code 99316 and not reported separately.

We proposed to retain our policy that CPT codes 99315 and 99316 (as appropriate) shall be reported for a face-to-face visit with the patient provided by the physician or the qualified NPP, which is required in order to report the SNF/NF discharge day management service. The NF discharge day management visit shall be reported for the date of the actual visit by the physician or qualified NPP, even if the patient is discharged from the facility on a different calendar date. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.13.I.) Additionally, we proposed that a physician or qualified NPP may report CPT codes 99315 or 99316 for a patient who has expired only if the physician or qualified NPP personally performed the death pronouncement.

b. Valuation

We proposed the RUC-recommended work RVU of 1.50 for CPT code 99315. We considered maintaining the current work RVU of 1.28 for CPT code 99315, based on the total time ratio between the current time of 40 minutes and the recommended time established by the survey of 40 minutes. Utilizing our total time ratio methodology this ratio equals 100 percent, and 100 percent of the current work RVU of 1.28, which indicates there is no change to the physician service and no change in the physician total time. We believe that, since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In this case, there was no change in total time. However, maintaining CPT code 99315 at the current value of a work RVU of 1.28 would cause a rank order anomaly with CPT code 99308. Also, given the remaining NF codes were revised to align with the principles included in the O/O E/M visit services by documenting and selecting level of service based on total time or MDM, we concluded that the increase of the work RVU to 1.50 for CPT code 99315 would be appropriate.

We proposed the RUC-recommended work RVU of 2.50 for CPT code 99316. We considered proposing a work RVU of 2.22 based on the total time ratio between the current time of 54 minutes and the recommended time established by the survey of 63 minutes. When we reviewed CPT code 99316, we found that the recommended work RVU was higher than nearly all of the other global XXX codes with similar time values, and we do not believe that this code would have an anomalously high intensity. As we stated earlier, in light of changes made to the O/O E/M visits and the changes to include documenting and selecting level of service based on total time or MDM, we proposed the RUC-recommended work RVU of 2.50 for CPT code 99316. We proposed the RUC-recommended direct PE inputs for CPT code 99315 and the RUC-recommended direct PE inputs for CPT code 99316.

Comment: We only received comments in support of the proposed valuation for CPT codes 99315 and 99316.

Response: We appreciate the support for our proposed work RVUs for CPT codes 99315 and 99316, and are finalizing as proposed.

c. Prolonged Services

CPT code 99315 and CPT code 99316, the two codes for nursing facility discharge management, are set up as a base code with an add-on code with no ceiling of time. Since time on any day can be included when billing CPT code 99315 or 99316, there is no need for a prolonged service code for either of these two codes. Allowing for a prolonged service code for either of these two codes could result in double counting a physician or NPP's time spent during a nursing facility discharge, which would not be appropriate. Additionally, CPT code 99418 does not include Nursing Facility in the descriptor. Therefore, we proposed that prolonged services would not be reportable in conjunction with CPT codes 99315 and 99316 (NF discharge day management).

The following is a summary of the comments we received on our proposal and our responses.

Comment: We only received comments in support of our proposal that prolonged services would not be reportable in conjunction with CPT codes 99315 and 99316.

Response: We appreciate the support from the commenters and are finalizing as proposed. We refer readers to section II.F.11 below for a discussion of comments received on prolonged Other E/M services generally.

8. Annual Nursing Facility Assessment (CPT Code 99318)

a. Coding

CPT code 99318 (*Evaluation and management of a patient involving an annual nursing facility assessment, which requires these 3 key components: A detailed interval history; A comprehensive examination; and Medical decision making that is of low to moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 30 minutes are spent at the bedside and on the patient's facility floor or unit*) was recommended for deletion by CPT for 2023. In February 2021, the CPT Editorial Panel deleted CPT code 99318 and revised seven nursing facility codes to align with the principles included in the O/O E/M visits by documenting and selecting level of service based on total time or MDM.

We proposed to accept CPT's deletion of CPT code 99318. Our longstanding manual guidance states that an annual nursing facility assessment visit code may substitute as meeting one of the required physician visits, as specified in 42 CFR 483.30 (c)(1), if the code requirements for CPT code 99318 are fully met (Medicare Claims Processing Manual (Pub. 100–04) Chapter 12, section 30.6.13 (B)). Due to the longstanding nature of the manual section, we believe some provisions may be outdated, and it is possible to satisfy this requirement through other codes. We solicited comment on whether there is a need to keep this code for Medicare purposes. As we consider accepting the CPT's deletion of CPT code 99318, we are concerned that the absence of a similar code could cause an unwarranted increase in valuation of other services under the PFS, and CMS would not have a means of tracking how often these visits are occurring. While CPT code 99308, CPT code 99309, and CPT code 99310 could be used to report the required annual visit, if we were to accept deletion of CPT code 99318, we believe most of the utilization for that former code would instead be reported under CPT code 99309, with a RUC-recommended work RVU of 1.92 which is described in the valuation section below.

b. Valuation

After considering the utilization and the need for the service described by CPT code 99318, we proposed to accept the CPT's deletion of CPT code 99318. Given the proposed deletion of CPT code 99318, the RUC recommends that 10 percent of the CPT code 99318 utilization would go to CPT code 99308, with a work RVU of 1.16; 85 percent of the utilization would go to CPT code 99309, with a work RVU of 1.55; and 5 percent of the utilization would go to CPT code 99310, with a work RVU of 2.35.

The following is a summary of the comments we received on our proposal and our responses.

Comment: All commenters supported the CPT Editorial Panel decision to delete CPT code 99318, and stated that the service is reported sufficiently with other codes.

Response: We appreciate the feedback from the commenters regarding our proposal to accept the CPT Editorial Panel decision to delete CPT code 99318 and are finalizing as proposed to accept the CPT's deletion of CPT code 99318. We are also finalizing our proposal to accept the RUC-recommended utilization estimates for visits that would have been reported under this code.

9. Home or Residence Services (CPT Codes 99341, 99342, 99344, 99345, 99347–99350)

a. Coding

Beginning in 2023, the CPT Editorial Panel is merging the two E/M visit families currently titled ''Domiciliary, Rest Home (eg, Boarding Home), or Custodial Care Services'' and ''Home Services.'' The new family will be titled ''Home or Residence Services,'' and the codes in this family will be used to report ''evaluation and management services provided in a home or residence. . .[and] when the residence is an assisted living facility, group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), custodial care facility, or residential substance abuse treatment facility. For services in an intermediate care facility for individuals with intellectual disabilities and services provided in a psychiatric residential treatment center, see Nursing Facility Services.'' (2023 CPT Codebook, p.25–26). There are no changes to the included care settings from each respective family, rather the current care settings for each of the current families are being included within the new, merged family.

More specifically, in its February 2021 meeting, effective beginning in 2023, the CPT Editorial Panel deleted the nine CPT codes in the Domiciliary, Rest Home (for example, Boarding Home), or Custodial Care Services code family (CPT codes 99324–99328, and 99334–99337), and one CPT code in the Home Services family (CPT code 99343), to merge these services with the eight remaining home visit services. The eight remaining home services CPT codes (99341, 99342, 99344, 99345, and 99347–99350) were revised to describe Home or Residence Services to align with the principles of the O/O E/M visit codes by allowing physicians and NPPs to document and select the level of service based on total practitioner time or MDM level. These changes include combining the domiciliary, rest home and custodial care CPT codes with the home visit CPT codes, resulting in a single family of CPT codes that describe these types of services. In addition, CPT revised the descriptors to allow reporting that is based on time or MDM level—in alignment with the O/O E/M visit CPT codes. We proposed to accept these coding revisions.

The following is a summary of the comments we received and our responses.

Comment: The commenters supported our proposal to accept the CPT coding changes for Home or Residence Services codes.

Response: We appreciate the feedback from the commenters regarding our proposal, and are finalizing as proposed to adopt the CPT merger of the home and domiciliary visits into one family, and adopt the CPT codes as revised for reporting these services.

b. Valuation

The RUC survey time includes pre-service time 3 days before the date of encounter, intraservice time on the date of encounter, and post-service time that includes 7 days after the date of encounter. These eight CPT codes were reviewed at the October 2021 RUC meeting with recommendations submitted to CMS for the CY 2023 rule cycle. The RUC recommended the survey 25th percentile value for all CPT codes in the Home or Residence Services code family, except for CPT code 99350, for which the RUC recommended the median value. We proposed the RUC-recommended work RVU for all eight CPT codes in the Home or Residence Services CPT code family. We proposed a work RVU of 1.00 for CPT code 99341 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*), a work RVU of 1.65 for CPT code 99342 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), a work RVU of 2.87 for CPT code 99344 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*), a work RVU of 3.88 for CPT code 99345 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making*), a work RVU of 0.90 for CPT code 99347 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination straightforward medical decision making*), a work RVU of 1.50 for CPT code 99348 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), a work RVU of 2.44 for CPT code 99349 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*), and a work RVU of 3.60 for CPT code 99350 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making*).

We proposed the RUC-recommended direct PE inputs for CPT codes 99345 and 99347–99350 without refinement. For CPT codes 99341 and 99342, we are refining the direct PE inputs by removing supply item SK062 (patient education booklet). For CPT code 99344, we are refining the direct PE inputs by removing supply items SK062 (patient education booklet), SJ053 (swab-pad, alcohol), and SJ061 (tongue depressor). Per the PE Summary of Recommendations provided by the RUC, CPT codes 99341, 99342, 99344, and 99347 would typically have procedures performed on the same date of service. For those CPT codes, the RUC stated that they removed supplies that would be duplicative, such as gloves, alcohol wipes, booklet, and tongue depressor. However, we found that not all of these duplicative supplies had been removed from CPT codes

99341, 99342, and 99344 by the RUC. Therefore, we proposed to remove these duplicative supplies from CPT codes 99341, 99342, and 99344, and accept the remaining RUC-recommended direct PE inputs without refinement.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to accept the RUC-recommended RVUs for all of the Home or Residence Services codes.

Response: We appreciate the feedback from the commenters regarding our proposal.

Comment: A few commenters stated the RVUs for the Home or Residence Services code family were too low, and fail to adequately account for travel, addressing social determinants of health, and other comprehensive care. One commenter suggested that we maintain the current RVUs for codes 99341, 99344, 99345, 99347, and 99348, for which the RUC-recommended RVUs decreased, while supporting our proposal to accept the increased RVUs for codes 99342, 99349, and 99350 recommended by the RUC. Another commenter suggested that we increase the RVUs for the entire code family to reflect travel expenses, and expressed concern that unreimbursed travel will be detrimental to the care provided to very ill patients and threaten the financial viability of physician practices that provide home or residence visits.

Response: We continue to believe that the RUC-recommended RVUs are the appropriate values for CPT codes 99341, 99342, 99344, 99345, and 99347–99350. We appreciate the commenters' remarks, and we acknowledge the concerns regarding providing patient care and addressing social determinants of health and other issues during home or residence visits. Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service. The RUC survey for the Home or Residence Services code family did not include information on physician travel or mileage. Also, the CPT E/M guidelines for selecting the level of home or residence service, when performed based on time, specifically says not to count the time spent on travel (2023 CPT Codebook, p. 26). Therefore, we are finalizing the RUC-recommended work RVUs as proposed.

Comment: One commenter requested that we not refine the direct PE inputs for codes 99341, 99342, and 99344 as proposed. For CPT codes 99341 and 99342, we proposed removing supply item SK062 (patient education booklet). For CPT code 99344, we proposed removing supply items SK062 (patient education booklet), SJ053 (swab-pad, alcohol), and SJ061 (tongue depressor).

Response: Per the PE Summary of Recommendations provided by the RUC, CPT codes 99341, 99342, 99344, and 99347 would typically have procedures performed on the same date of service, which would already include some of the same supply items. For these CPT codes, the RUC stated that they had removed the PE inputs for supplies that would be duplicative with the procedure on the same day, such as gloves, alcohol wipes, a booklet, and a tongue depressor. Although the RUC did remove the duplicative supplies for CPT code 99347 from the direct PE inputs they recommended, we found that the RUC had not removed all of these duplicative supplies from CPT codes 99341, 99342, and 99344. Therefore, we proposed to remove these duplicative supplies from the direct PE inputs for CPT codes 99341, 99342, and 99344. We continue to believe these supplies are duplicative with a same-day procedure, and are, therefore, finalizing the direct PE inputs for CPT codes 99341, 99342, 99344, and 99347 as proposed.

After consideration of the public comments, we are finalizing the work RVU values for the Home or Residence Services code family as proposed. We are also finalizing the direct PE inputs for these codes as proposed.

c. Prolonged Services for Home or Residence Services

We proposed that prolonged home or residence services by a physician or NPP would be reportable using HCPCS code G0318 (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report G0318 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report G0318 for any time unit less than 15 minutes)*). Code G0318 would be reportable when the total time for the home or residence visit (specified in the time file) is exceeded by 15 or more minutes. Prolonged services (whether on the same date or another date within the surveyed timeframe) would be reportable as an add-on code to CPT codes 99345 or 99350 once the practitioner spends 15+ minutes beyond the total time finalized for the primary service (as specified in the time file). We would allow the physician or NPP to include any prolonged service time spent within the surveyed timeframe for the Home or Residence Services code family, which includes pre-service time 3 days before the date of encounter, intraservice time on the date of encounter, and post-service time that includes 7 days after the date of encounter. This means that for CPT code 99345, assuming we finalized the RUC-recommended total time of 126 minutes, prolonged services would be reportable once 141 or more minutes are spent by a physician or NPP providing the home or residence visit. Likewise, for CPT code 99350, assuming we finalized the RUC-recommended total time of 97 minutes, prolonged services would be reportable once 112 or more minutes are spent by a physician or NPP providing the home or residence visit. See Table 18 in our proposed rule for a table summarizing this information.

Since we proposed that prolonged services on any date within the service period (with or without direct patient contact, on the same or different date) would be reportable under G0318, we also proposed that CPT code 99358 (*Prolonged evaluation and management service before and/or after direct patient care; first hour*), CPT code 99359 (*Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (List separately in addition to code for prolonged service)*), and CPT code 99417 (*Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the outpatient Evaluation and Management services)*) cannot be billed for CPT codes 99345 and 99350. We proposed to change the status indicator for CPT codes 99358 and 99359 to ''I,'' which indicates that these codes are not valid for Medicare purposes, and that Medicare uses another code for reporting of, and payment for, these services.

We continued to be concerned about program integrity, duplicative time, counting time that was not included in the surveyed timeframe, the administrative complexity of having multiple prolonged service codes, and our ability to determine how much time was spent with the patient using claims data. If we proposed to merely accept

the CPT coding for prolonged home or residence E/M visits, we would not be able to identify from the claims data the time spent with patients. This is because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. See our previous discussion of these issues in our CY 2020 PFS final rule at 84 FR 62849 through 62850. As we stated in that rule, many other codes are available to report prolonged E/M work associated with an E/M visit that occurs outside of the timeframe included in the visit, such as CCM, TCM, PCM, behavioral health integration (BHI), and other care management service codes. We designed these codes to be used to report time spent outside the direct patient contact on dates other than the E/M visit. While these care management codes are not identical to the prolonged visit codes, they can be used to report a number of similar activities. Additional information about the care management codes can be found on our PFS Care Management web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management*. We also directed readers to our proposals for additional care management service codes for pain management and BHI.

We received many comments regarding our proposal for Medicare-specific coding for prolonged Other E/M services. We address comments that apply across the Other E/M visit families in this final rule in section II.F.11 below (Prolonged Services). We received a few comments that apply specifically to prolonged service codes for home or residence visits, and we address those as follows.

Comment: A few commenters stated it is unclear whether the time for prolonged code G0318 must occur on the date of the home or residence visit, or could be over the span of 3 days prior and 7 days after the home or residence visit occurs.

Response: The prolonged time can occur on the date of the visit, or within the 3 days prior or 7 days after the visit date. These 11 days comprise the service period used by the AMA RUC to develop recommended values for home or residence visits. See Table 24 for a summary of this information. We note that for ease of reporting, we are rounding to the nearest 5 minutes for the time threshold to report G0318, which results in a lower time by 1 or 2 minutes, shown in Table 24.

Comment: One commenter suggested that we allow code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) to be reported with the home or residence visit codes.

Response: Section 113 of the Consolidated Appropriations Act, 2021 delayed Medicare payment for G2211 until at least January 1, 2024. For further discussion on code G2211, see 2. Overview of Policy Proposals, in this section above, in this final rule.

After consideration of the public comments, we are finalizing our proposal to create new code G0318 for a prolonged home or residence visit. We are also finalizing our proposal to change the status indicator for prolonged CPT codes 99358 and 99359 to ''I,'' which indicates that these codes are not valid for Medicare purposes, and that Medicare uses another code for reporting of, and payment for, these services.

10. Cognitive Assessment and Care Planning (CPT Code 99483)

a. Coding and Valuation

In February 2021, the CPT Editorial Panel revised CPT code 99483 to replace ''50 minutes'' from its descriptor with a revised time value determined by the RUC survey to align with the principles underlying the O/O E/M CPT codes. The 2023 descriptor time for CPT code 99483 will be 60 minutes typical time instead of 50 minutes typical time.

Due to the increase in the valuation for O/O E/M visits in the CY 2021 PFS final rule (85 FR 84556), we finalized a proposal to increase the value of CPT code 99483 from 3.44 to 3.80 work RVUs as a service that is analogous to the O/O E/M visits, because CPT code 99483 includes a high-level O/O E/M visit. We stated that 99483 includes an evaluation of a patient's cognitive functioning and requires collecting pertinent history and current cognitive status, all of which require MDM of moderate or high complexity. To not create a rank order anomaly with CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter*) we increased 99483 by using the ratio of the increase between the CY 2020 and CY 2021 values for 99205 to commensurate with the increase to CPT code 99205.

We did not propose the RUC-recommended work RVU of 3.50, because we continued to believe that this service is appropriately valued more highly than the analogous O/O E/M visit code, CPT code 99205. Given what we viewed as the appropriate rank order among these services, we did not believe a reduction in work RVU, especially with a ten-minute increase in physician time, is warranted. In the interest of supporting access to this service, we instead proposed a slight increase from the current 3.80 to 3.84 to account for the increase in physician time with use of a total time ratio: we divided the RUC-recommended total time of 86 by the current total time of 85 and then multiplied the product by the current work RVU of 3.80 to arrive at 3.84. We proposed the RUC-recommended PE inputs without refinement.

Comment: Several commenters supported our proposal to increase the work RVU to account for the increase in physician time.

Response: We appreciate the support for this proposal and are finalizing as proposed a work RVU of 3.84 for CPT code 99483. We are finalizing as proposed the RUC-recommended PE inputs without refinement.

b. Prolonged Services

We proposed that prolonged services would not be reportable in conjunction with CPT code 99483, because it has a typical time in its descriptor, which is not necessarily the actual time spent. Accordingly, we would not know when the prolonged services exceeded the service time.

Comment: A commenter did not agree with our proposal that prolonged services codes cannot be reported with cognitive assessment and care planning services, stating that since the inception of the code, prolonged services have been allowed, and that if 99483 cannot be reported as a prolonged service, the practitioner may have incentives to instead use time and report it as 99205.

Response: Since our final policy for other types of prolonged Other E/M services allows prolonged services reporting once total time, as reflected in the time file, is exceeded by the appropriate increment (not once the CPT code descriptor time is exceeded by

that increment), we do not believe the presence of a typical time in the descriptor for CPT code 99483 should prevent reporting of prolonged Cognitive Impairment Assessment services. We are persuaded that it would be appropriate for CPT code 99483 to be billable with prolonged services. We believe this would be consistent with our approach to other prolonged Other E/M services, which is that prolonged services can be reported if the physician or NPP spends 15 or more minutes beyond the total time (as specified in the time file and shown in Table 24).

After consideration of the public comments, we are not finalizing our proposal that prolonged services would not be reportable in conjunction with CPT code 99483. Instead, we are finalizing that CPT code 99483 can be billed with HCPCS code G2212 (prolonged office/outpatient E/M services) when 15 or more minutes beyond the total time is spent by the physician or NPP (summarized in Table 24). We are rounding the total time to the nearest 5 minutes for ease of reporting, which results in a prolonged services reporting threshold of 100 minutes (1 minute lower than the total time of 101 minutes). Time that is spent by the physician or NPP on any date within the surveyed timeframe for CPT code 99483 (within 3 days prior or 7 days after the date of the in-person visit) may be counted toward the reporting of prolonged services. Accordingly, we are revising the long descriptor for G2212 to include reference to CPT code 99483 as a code that can be listed separately with G2212.

11. Prolonged Services

As discussed in the sections above, we proposed Medicare-specific coding for prolonged Other E/M services. We proposed three G codes (G0316, G0317 and G0318) for reporting of prolonged Other E/M services (one for each Other E/M family for which prolonged services would apply, namely inpatient/observation visits, nursing facility visits, and home or residence visits). This would be consistent with our previously finalized approach to prolonged O/O E/M services. In this section of our final rule, we address public comments regarding this proposal that apply across the Other E/M visit code families. We refer readers to individual sections above for public comments specific to a given code family.

Comment: Many commenters were disappointed with our proposal to use Medicare-specific coding for prolonged Other E/M services. Their overarching concern was potential confusion and administrative burden resulting from different approaches between Medicare and CPT, and the potential for variation among payers. Some commenters noted that CPT's approach, dividing prolonged time into time spent on the date of the visit (described by one code set) and time spent on another date (described by another code set), is more intuitive for reporting than combining all time spent during the service time (as surveyed and valued) into a single code set as we proposed. Some commenters suggested that we should not align reported time with surveyed timeframes, which they assert are relatively inaccessible (other than the table provided by CMS in the proposed rule). However, some commenters supported our proposal. These commenters agreed with CMS that the proposed Medicare-specific coding will avoid duplicative payment, and corrects a lack of transparency in the CPT reporting times in comparison to survey times and work valuation.

The AMA stated that it is imperative that physicians have one set of clear codes and guidelines to report prolonged services. The AMA's strong preference is for CMS to rely on the CPT codes and guidelines, and if not, the AMA Workgroup on E/M will reconvene to discuss whether revisions are needed to the CPT codes and guidelines. The AMA urged CMS to work with the CPT/RUC E/M Workgroup to bring CMS and CPT prolonged services policies into alignment. The AMA also expressed interest in receiving CMS input earlier in its processes, which could improve alignment with a given CMS rulemaking cycle.

In their public comment, the AMA outlined ways in which they had sought to align the revised CPT coding with CMS' historical approach to prolonged services, and avoid creating a global period for E/M visits. The AMA noted that, during the E/M Workgroup process and CPT processes, there was much debate about whether to divide total time for reporting purposes into multiple codes, according to whether the time was spent on the date of the visit or another date. The E/M Workgroup believed that total time on the date of the encounter would be simpler to track and document for the primary service.

The AMA also noted that their recommended valuations for prolonged service codes are mathematically correct and simpler administratively.

Regarding prolonged services on a date other than the face-to-face E/M service (CPT codes 99358–9), the AMA recognized the concerns of CMS and agreed that potential overlap should be eliminated. The AMA also noted that the other care management services have not eliminated the need to recognize a substantial amount of work that occurs on single day. They stated that they expected the volume for CPT codes 99358–9 to drop substantially, as reporting would no longer be allowed for time on the date of the encounter. The AMA stated that incorrect reporting should be addressed, but improper reporting by the few should not lead to these codes being eliminated. The AMA further stated that the CPT Editorial Panel may consider revisions to the prolonged service codes, but requested that CMS be an active participant in the public and open CPT processes rather than only in CMS rulemaking.

Response: We appreciate the commenters' concerns, and agree that the ideal approach would be a uniform CPT code set for reporting prolonged services. Generally, we prefer coding that is clear and consistent for practitioners to use, and we create Medicare-specific coding only when there is a significant program integrity concern or programmatic need, such as tailoring a code to a specific Medicare statutory benefit category.

Historically, time could only be used to select visit level when counseling and care coordination comprised more than half of the visit (See Medicare Claims Processing Manual (Pub. 100–04) Chapter 12, section 30.6.15.1.H). Prolonged services could be billed in that situation, only when the time for the highest-level visit in a given code family was exceeded by the prolonged services time increment. Prolonged services could also be billed for any visit level if the typical time was exceeded by the prolonged services time increment. Until 2017, prolonged services were only separately paid for face-to-face prolonged service time, which generally occurred on the date of the visit.

CY 2023 will be the first year in PFS history that almost any E/M visit level can be selected using time, whether that time was spent on the same day or another day. Almost all E/M visit codes have new times, new survey data, new valuations, new parameters for how visit level is selected, and revised MDM levels. Some of the highest volume code families will be merged, and a number of code families will have a different number of levels within the family than previously. It is hard to contemplate a single aspect of E/M visit coding that will not change in some way, and these services account for a high share of PFS spending. Therefore, it is appropriate for us to take a fresh look at our policy. In recent years, the E/M visit overhaul has

involved substantial work in a compressed timeframe, and our policy views have continued to evolve with each rulemaking cycle. We greatly appreciate and value the opportunity to attend the AMA meetings, but as a federal agency obligated under the Administrative Procedure Act and section 1871 of the Act to use notice and comment rulemaking procedures to establish regulations, and given that we generally use the AMA's CPT coding and RUC recommendations as the starting point to describe and value services to meet our statutory mandates for the PFS, it would not be appropriate for us to participate in AMA processes in a way that could steer its decisions. Additionally, CMS engages in an extensive internal deliberative process to develop its proposed and final policies that are ultimately issued through notice and comment rulemaking.

We have noted our concerns with the AMA's approach to prolonged services in several rulemaking cycles. We laid out many concerns with CPT codes 99358–9 when we adopted them in 2017 as an interim approach, given that at that time there were not many care management codes to account for physician time (81 FR 80228 through 80230). We laid out many more concerns in 2021 when finalizing our policy for prolonged O/O visits (84 FR 62847 through 62851). Although we initially adopted the CPT code for prolonged O/O services, we expressed our belief that there should be a single code for prolonged O/O service reporting, and subsequently finalized a Medicare-specific code because of our concerns about duplicative time counting under the revised CPT code (85 FR 84572 through 84575).

Prolonged service codes function like add-on codes for ''extra-long'' E/M visits. We believe the role of prolonged service codes is to account for time spent beyond the total service time, which is established in the AMA RUC survey for the primary service (the code with which the prolonged service code is billed, such as Level 3 home/residence visit), and reflected in the primary service's valuation. In contrast, the AMA seems to view prolonged services as accounting for time spent beyond intra-service time, which is only part of the visit. However, the total times recommended and used by the RUC to recommend values for the primary services, which we review and consider in establishing values for the PFS, are not limited to intra-service time. They include pre- and post-service time as well, and as such, the primary service is already valued to include total time. It would be redundant to reflect this time under the primary service code, and then again using prolonged service code(s) in addition to the primary service code.

We understand that viewing the service as a whole requires the billing practitioner to look back once the visit is completed to identify the total time spent furnishing the service, rather than billing one code at the end of the calendar date of the face-to-face visit, and another code to reflect additional time spent on other days. However, we do not see another way to more accurately account for time. If practitioners want to bill immediately for time spent on the date of a visit, or during the face-to-face portion of the service, then perhaps the AMA's surveys (and associated valuation recommendations) should be limited to that timeframe, instead of including other time. We do not believe it would be appropriate to adopt a policy suggesting that a practitioner can bill an extra code that describes time and work that was already reflected in the survey, valuation, and PFS payment as part of the pre-/post-service time for the primary visit code.

We laid out a summary table (Table 18 in the proposed rule), displaying information that we thought would help practitioners who may not be immediately aware of the surveyed timeframes for E/M visits, and who may lack familiarity with the AMA process where visits are assumed to take place over a number of days (and with different timeframes for different types of visits) and valued accordingly. We anticipate providing a similar table in our manual, website, and other subregulatory guidance to facilitate practitioner access to this information. We do not believe the solution lies in open-ended codes like CPT codes 99358–9, which have no beginning, end, or specified setting, seemingly could be used when a visit is not timed, and cannot readily be associated or connected with a particular face-to-face visit. Since practitioners may find it easier to follow time thresholds for reporting that are rounded, we are rounding all of the total times to the nearest 5 minutes, as reflected in Table 24. (This results in rounding down the reporting time thresholds for prolonged Other E/M services by 1 or 2 minutes in several instances).

We appreciate the AMA's understanding of the many issues we laid out for CPT codes 99358–9, describing prolonged time spent on a date other than the visit, and planning for additional review. We will continue to follow any additional developments on these codes and prolonged service coding generally should the AMA make additional changes.

Comment: In its public comment, the AMA defended payment for the 15-minute prolonged service code for one minute of service time by pointing out the conundrum of any time threshold, where small time increments can result in disproportionate RVU increases when transitioning between levels of service (for example, from a level 4 to level 5 O/O visit) where time is being used to select visit level. The AMA used examples from the O/O visit code set, rather than the Other E/M visit code set to demonstrate this point.

Response: We appreciate the AMA's feedback. Based on the AMA E/M Workgroup discussions, we understood that the AMA views prolonged services as a type of additional visit level, based solely on additional time. Viewed through that lens, it might be understandable to allow reporting of the code representing the next highest level, as soon as the floor of that next level is reached. However, CPT did not define prolonged services as an additional visit level. Also, we believe that prolonged services should describe additional time beyond the total time (not just the intra-service time), since the primary service is already valued based on total time.

Comment: One commenter recommended requiring a 15-minute time increment beyond the CPT code descriptor time, which they noted is the same as CPT's approach.

Response: We appreciate the commenter's feedback. We considered this approach in our proposed rule (87 FR 46426). However, our understanding is that the time in the CPT code descriptors for the Other E/M primary services generally corresponds to the intra-service time for the primary service. As previously discussed, we believe prolonged services should be billed to account for time surpassing the total time rather than just the intra-service time, since pre- and post-service time is already included in the primary service valuation.

We continue to believe that adopting the CPT codes for prolonged services would result in duplicative time counting, and reported times that do not align with work times used for valuation. Having three sets of codes for reporting time associated with a single visit is overly complex, and hinders our ability to assess how much time was spent, or trends in time spent, with patients using claims data under the new framework. However, we agree with commenters that a uniform code set for use by all payers for prolonged services is preferable to further reduce

administrative burden. After consideration of the public comments, we are finalizing our proposals for prolonged Other E/M services as proposed, and we will continue to work with the AMA to consider further refinements and standardization of this code set through notice and comment rulemaking. In Table 24, we provide a summary listing of the required time thresholds to report prolonged Other E/M services beginning in CY 2023, and show the time periods during which practitioners may count time spent toward prolonged service reporting.

12. Prolonged Services Valuation

a. Prolonged Services With Direct Patient Contact (CPT Codes 99354–99357)

The CPT Editorial Panel is deleting CPT codes 99354–99357 (*prolonged services with direct patient contact (except with office or other outpatient services)*). These codes are currently used to report prolonged E/M visit time involving direct patient contact by physicians or NPPs beyond the usual service in settings other than O/O settings. We proposed to accept this deletion, since this work would be reported instead under the Medicare-specific codes that we proposed for prolonged physician/NPP time, discussed in each family's section above.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed.

b. Prolonged Services on a Different Date Than the E/M (CPT Codes 99358–99359)

We noted that the RUC resurveyed and provided recommendations to revalue these codes. However, we proposed to assign an inactive status to these codes for purposes of Medicare payment as discussed above. We received comments on this proposal, which we discuss above as applicable within each family.

After consideration of the public comments, we are finalizing as proposed to assign an inactive status to these codes for purposes of PFS payment as discussed above.

c. Prolonged Clinical Staff Services (CPT Codes 99415 and 99416)

CPT code 99415 was created to describe the first hour of prolonged clinical staff services provided in addition to an office E/M visit, while CPT code 99416 was created to describe each additional 30 minutes beyond that first hour of prolonged clinical staff service time that was provided in addition to the O/O E/M visit. For these codes, we proposed the RUC-recommended direct PE inputs without refinement.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed.

d. Valuation of Prolonged Other E/M Services (HCPCS Codes G0316, G0317 and G0318)

As discussed above in the Overview section, we do not agree that there is necessarily inherently greater complexity of patient need or intensity of work for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) compared to the office settings. Therefore, we believe it would be more accurate to make payment based on the same time increment of physician work in these various settings. We proposed that the three prolonged visit HCPCS G codes G0316–G0318 (discussed above under each applicable family) be valued identically across settings, based on the RUC-recommended value for CPT code 99417. Therefore, we proposed a work RVU of 0.61 for these codes with a crosswalk to CPT code 99417. We likewise proposed direct PE inputs for these three codes that are identical to the RUC-recommended PE inputs for CPT code 99417 (prolonged office/outpatient services). For the purposes of ratesetting, our utilization for these services included the assumption that one third of the services currently reported with 99356 would be reported with each of HCPCS codes G0316, G0317, and G0318, and one third of the services currently reported with 99357 would be reported with each of HCPCS codes G0316, G0317, and G0318. We would continue to use HCPCS code G2212 as previously finalized in lieu of CPT code 99417.

Comment: The AMA stated that our approach to prolonged services would result overall in a decreased valuation for prolonged services, compared to their historical valuation. They noted this runs contrary to our original goal of shortening the prolonged service period, in order to increase prolonged services reporting (see 83 FR 35773, 59580).

Response: We appreciate this concern. Given the many changing aspects of E/M visit coding and payment, it does not seem feasible to estimate how prolonged services reporting and payment may change in 2023 compared to historical levels, and how this might impact the amount of time spent with patients. One of our key considerations in redesigning the prolonged services code set is whether we will be able to see more clearly how much time is spent with patients through claims data. We note that practitioners will be allowed to count time spent on visit documentation (documenting clinical information), which will help them reach reporting thresholds based on time earlier than they could historically. Regarding valuation compared to historical levels, the Medicare-specific coding has comparable or higher work per unit of time (see Table 23). We will monitor the claims data for prolonged services, and potentially consider future rulemaking if we observe under-reporting of prolonged services.

TABLE 23: Prolonged Services Work-Per-Unit of Time Comparison

Prolonged HCPCS Code	Work RVU	Total Time	Work-per-time unit (work RVU/total time)
CPT code 99356	1.71	60	0.0285
CPT code 99357	1.71	30	0.0570
CPT code 99358*	1.80	50	0.0360
CPT code 99359*	0.75	30	0.0250
CPT code 99418	0.81	20	0.0400
G0316	0.61	15	0.0400

*RUC-recommended values for 2023.

Comment: A commenter did not support the establishment of HCPCS codes G0316, G0317, and G0318, saying that this approach and our proposed work RVU of 0.61 for these G codes, inappropriately modifies the relativity between the prolonged visit codes and other services under the PFS. A commenter urged us to implement prolonged nursing facility and home/residence visits using CPT codes 99418 and 99417, and to adopt the RUC-recommended work RVUs of 0.81 and 0.61 respectively.

Response: As discussed in this final rule in section II.F.11 above (Prolonged Services), we do not agree that there is necessarily inherently greater service complexity or intensity of work for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) compared to the office settings. We are finalizing as proposed HCPCS codes G0316, G0317, and G0318 with a work RVU of 0.61 and direct PE inputs for these three codes that are identical to the RUC-recommended PE inputs for CPT code 99417.

e. Summary of Required Time Thresholds To Report Other E/M Prolonged Services

Table 24 summarizes the final rules for reporting Other E/M prolonged services by physicians or NPPs (See each family section above for detailed information).

TABLE 24: Required Time Thresholds to Report Other E/M Prolonged Services

Primary E/M Service	Prolonged Code*	Time Threshold to Report Prolonged	Count physician/NPP time spent within this time period (surveyed timeframe)
Initial IP/Obs. Visit (99223)	G0316	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	G0316	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	G0316	125 minutes	Date of visit to 3 days after
IP/Obs. Discharge Day Management (99238-9)	n/a	n/a	n/a
Emergency Department Visits	n/a	n/a	n/a
Initial NF Visit (99306)	G0317	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	G0317	85 minutes	1 day before visit + date of visit +3 days after
NF Discharge Day Management	n/a	n/a	n/a
Home/Residence Visit New Pt (99345)	G0318	140 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	G0318	110 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning (99483)	G2212	100 minutes	3 days before visit + date of visit + 7 days after
Consults	n/a	n/a	n/a

* Time must be used to select visit level. Prolonged service time can be reported when furnished on any date within the primary visit's surveyed timeframe, and includes time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we do not assign a frequency limitation.

13. Consultations (CPT Codes 99241–99255)

The RUC revised the code descriptors, deleted two codes, and revalued the RVUs of the consultation codes during its October 2021 and January 2022 RUC meetings. We did not review the RUC recommendations for the eight revised consultation codes (CPT codes 99242, 99243, 99244, 99245, 99252, 99253, 99254, and 99255). In our proposed rule, we noted that CMS stopped paying for the consultation codes beginning in CY 2010. We refer readers to 74 FR 61767 through 61775, where we discuss our payment policy for these services.

14. Payment for Multiple Same-Day Visits

Our manuals include many longstanding policies regarding when more than one Other E/M visit can be billed by the same practitioner for the same patient on the same date of service, particularly when a patient is being transferred among multiple care settings. In contrast, CPT code reporting instructions generally do not limit the number of visits that can be billed. We proposed to continue our longstanding policies for same-day visits, and refer the reader to the sections above regarding our final policies in application to each individual Other E/M family.

15. Split (or Shared) Services

The split (or shared) ''substantive portion'' policy for services furnished in facility settings was reflected in subregulatory guidance until it was withdrawn in May of 2021, in response to a petition under the Good Guidance regulation. In the CY 2022 PFS final rule (86 FR 65150 through 65159), we finalized a policy for E/M visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP provide the service together (not necessarily concurrently), and the billing physician personally performs a substantive portion of the visit. At that time, commenters were generally supportive of our approach, with some divide with regard to our definition of substantive portion. Some commenters preferred the use of MDM or one of the three key visit components as opposed to time for purposes of defining what is the substantive portion of the service.

a. Background

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. In the non-facility (for example, office) setting, the rules for ''incident to'' billing apply under this circumstance. However, ''incident to'' services are not available for services furnished in a facility setting. Longstanding CMS policy has been that, for split (or shared) visits in the facility (for example, hospital) setting, the physician can bill for the services if they perform a substantive portion of the encounter. Section 1833(a)(1)(N) of the Act specifies that payment is made for services furnished and billed by a physician at the PFS rate, while under section 1833(a)(1)(O)(i) of the Act, NPPs are paid for the services they furnish and bill for at a reduced PFS rate (85 percent of the PFS).

We defined substantive portion in the CY 2022 PFS final rule (86 FR 65152 through 65156) and provided for billing of split (or shared) visits in certain settings (86 FR 65156 through 65157) and for certain patient types (new and established) (86 FR 65156). After consideration of the public comments on the CY 2022 PFS proposed rule, we finalized a phased in approach to this policy (86 FR 65153). For CY 2022, we finalized the definition of substantive portion as one of the following: history, or exam, or MDM, or more than half of total time. In the CY 2022 PFS final rule (86 FR 65152 and 65153), we finalized that for CY 2023, the definition of substantive portion is more than half of total time.

As part of our ongoing engagement with interested parties, we are hearing continued concern about the implementation of our phased in approach with regard to defining ''substantive portion'' only as more than half of the total time of the visit, and continue to receive requests that we also recognize MDM as the substantive portion. Many of these concerns relate to practice patterns where the physician does not spend half or more of the time with the patient, as well as possible adjustments needed to the practice's internal processes or information systems used to track visits based on time, rather than MDM. After consideration of public feedback, we proposed to delay implementation of our definition of the substantive portion as more than half of the total time until January 1, 2024. We continued to believe it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time, and proposed that this policy will be effective beginning January 1, 2024. While we continued to believe that the definition of substantive portion we finalized in the CY 2022 PFS final rule is appropriate, delaying implementation of this aspect of our policy would also allow for the changes in the coding and payment policies for Other E/M visits to take effect for CY 2023, and allow for a one-year transition for providers to get accustomed to the new changes and adopt their workflow in practice. Additionally, this delay would allow interested parties another opportunity to comment on this policy, and gives us time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy. To reflect the proposed delay, we proposed to amend our regulation text at 42 CFR 415.140 to revise the definition of substantive portion, and noted the current definition of substantive portion applies for visits other than critical care visits furnished in CY 2022 and CY 2023.

We proposed to amend § 415.140 by adding to paragraph (a) ''and 2023'' after the phrase ''For visits other than critical care visits furnished in calendar year 2022''. Therefore, the proposed paragraph would specify, for visits other than critical care visits furnished in calendar year 2022 and 2023, *substantive portion* means one of the three key components (history, exam or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit.

We received comments related to our proposal to delay implementation of the definition of substantive portion, as more than half of the time spent by the physician and non-physician practitioner (NPP), until CY 2024. Below is a summary of the comments received and their responses.

Comment: Commenters were generally in support of the delay. We received a number of comments consistent with the public comments that we received and addressed in our CY 2022 final rule (86 FR 65152 through 86 FR 65156). These commenters believe that tracking the time for purposes of determining the substantive portion for billing is too burdensome, and they recommend that we allow MDM to serve as the substantive portion, potentially supported by an attestation statement from the billing practitioner in the medical record affirming that the billing practitioner furnished the MDM. Some commenters were concerned that defining the substantive portion of a service by time alone would disrupt collaborative and team-based care, and interfere with the way care is delivered in the facility setting. Some commenters also offered that there is significant variability in how much time it takes to perform elements of the visit, depending on the level of training and expertise of the physician and NPP. They stated that using MDM to direct the management of the patient's care determines the course of treatment for the patient, but it typically does not require the most time. Some commenters recommended that we remove our split (or shared) visit policy.

Response: We thank the commenters for their views and suggestions, and note that we have previously addressed these issues. These comments were consistent with the comments we received when we finalized in the CY 2022 PFS final rule (86 FR 65152 through 86 FR 65156). We appreciate hearing from these interested parties and will continue to consider the issues raised in their comments for possible future rulemaking.

Comment: The AMA indicated in its public comment letter that it intended to refer the definition of split (or shared) services back to CPT for potential further review.

Response: We will review any revisions made by the CPT Editorial Board to standardized language, including any definition of ''substantive portion'' for split (or shared) services. We will take any revised CPT definitions or guidance into consideration for possible future rulemaking.

Comment: One commenter suggested an alternative policy that would create a ''carve out'' for rural practitioners, whereby practitioners furnishing split (or shared) services in rural areas or Health Professional Shortage Areas (HPSAs) would be able to use MDM as the substantive portion. Some commenters suggested discontinuing differential PFS payment for physicians and NPPs, or suggested splitting the difference to 7.5 percent.

Response: We appreciate the commenters' concerns and will continue to consider the potential impact of our policy on rural or health professional shortage areas for future rulemaking. The differential payment to physicians and NPPs is a statutory requirement. Therefore, we do not have discretion to discontinue or modify the differential PFS payment rates for services furnished and billed by physicians and NPPs.

Comment: Several commenters were unclear how performance of the history or exam could be considered a substantive portion under the new CPT framework for facility E/M visits, where

MDM or time will be used to select the level of service.

Response: We thank the commenters for seeking clarification. Given the proposed delayed implementation of our substantive portion policy until CY 2024, our current policy remains in place. As such, when an E/M visit requires a medically appropriate history and/or physical exam, in accordance with its code descriptor, these service element(s) can qualify as the substantive portion, when performed.

After considering the public comments we received, we are finalizing our proposed policy to delay implementation of our definition of the substantive portion as more than half of the total practitioner time until January 1, 2024. We are revising our regulations at 42 CFR 415.140 accordingly.

16. Technical Correction to the Conditions for Payment: Split (or Shared) Visits

In the CY 2022 PFS final rule (86 FR 64996), we finalized our definition of split (or shared) visits as proposed, and codified it in a new section of our regulations at § 415.140. We established regulation text for this definition of split (or shared) visits. We subsequently discovered an inadvertent typographical error in the instructions we used to codify the new regulation at § 415.140. Specifically, we added the regulation text for § 415.140 under subpart D, Physician Services in Teaching Settings, rather than subpart C, Part B Carrier Payments for Physician Services to Beneficiaries in Providers. Because this regulation was inadvertently included with policies relating to teaching physician services, and is more appropriately placed with other policies relating to payment for physicians' services to beneficiaries in providers, we proposed to revise our regulation to correct this error. As such, we proposed to amend part 415 subpart D by removing the regulation at § 415.140 and relocating that section to subpart C, such that subpart D will then begin at § 415.150.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed.

17. Technical Correction for Split (or Shared) Critical Care Services

In the CY 2022 PFS final rule, starting at 86 FR 65159, we finalized a number of billing policies for critical care CPT codes 99291 *(Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes)* and 99292 *(each additional 30 minutes).* At 86 FR 65162, we stated in error, ''Similar to our proposal for split (or shared) prolonged visits, the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, the billing practitioner could report one or more units of CPT code 99292.'' We intended to state that CPT code 99292 could be billed after 104, not 75, or more cumulative total minutes were spent providing critical care. As correctly stated elsewhere in the CY 2022 PFS final rule (regarding critical care furnished by single physicians at 86 FR 65160, and regarding concurrent care furnished by multiple practitioners in the same group and the same specialty to the same patient at 86 FR 65162), our policy is that CPT code 99291 is reportable for the first 30–74 minutes of critical care services furnished to a patient on a given date. CPT code 99292 is reportable for additional, complete 30-minute time increments furnished to the same patient (74 + 30 = 104 minutes). We clarify that our policy is the same for critical care whether the patient is receiving care from one physician, multiple practitioners in the same group and specialty who are providing concurrent care, or physicians and NPPs who are billing critical care as a split (or shared) visit.

Comment: Although this was a technical correction, we received many comments on this policy. Commenters requested that we review or modify this billing policy. Many commenters urged us to adopt CPT's policy for reporting CPT code 99292 when 75 minutes had elapsed. Commenters also contended that this correction reflected a change in our billing policy for these codes. Some commenters also suggested that this policy amounted to an undervaluation for CPT code 99291. These commenters suggested that, while the purported time for CPT code 99291 is 30–74 minutes, our policy essentially extends the time covered by CPT code 99291 from 30–103 minutes.

Response: We agree with commenters that our policy as expressed in the CY 2022 final rule is different from the billing guidance in the CPT codebook. While we often align with CPT, there will be occasions when our billing policies differ. Specific to critical care, we noted in the CY 2022 PFS final rule at 86 FR 65159, ''We proposed to adopt the CPT prefatory language for critical care services as currently described in the CPT Codebook, *except as otherwise specified* [emphasis added].'' We then went on to specify in the CY 2022 PFS final rule a billing policy for reporting CPT code 99292 that is different from the CPT guidance.

We disagree that the technical correction reflects a change in policy as it was presented in the CY 2022 PFS final rule. At 86 FR 65160, we stated, ''Under our proposal, the physician or NPP would report CPT code 99291 for the first 30–74 minutes of critical care services provided to a patient on a given date . . . Thereafter, the physician or NPP would report CPT code 99292 for additional 30-minute time increments provided to the same patient.''

At 86 FR 65162, we specified, ''[The] total time spent by the practitioners could be aggregated to meet the time requirement to bill CPT code 99291. Under this proposal, once the cumulative required critical care service time is met to report CPT code 99291, CPT code 99292 could not be reported by a practitioner in the same specialty and group unless and until an additional 30 minutes of critical care services are furnished to the same patient on the same day (74 minutes + 30 minutes = 104 total minutes).''

At this time, as we were not proposing a new policy for CY 2023, we are retaining the CPT code 99292, as it was finalized in the CY 2022 PFS, and we again note that it can be billed after 104 cumulative total minutes were spent providing critical care. However, we will take commenters' concerns regarding alignment with CPT instructions and the valuation of CPT code 99291 under consideration.

G. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in Frontier States (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section

1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which has been extended by many successive amendments to the statute. The 1.0 floor for the work GPCI under section 1848(e)(1)(E) of the Act was most recently extended by section 101 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260, enacted December 27, 2020) through CY 2023 (that is, for services furnished no later than December 31, 2023). Therefore, as proposed, the CY 2023 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, were reflected in the CY 2023 proposed GPCIs.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since more than 1 year has passed since the previous GPCI update was implemented in CY 2020 and 2021, we proposed to phase in ½ of the proposed GPCI adjustment in CY 2023 and the remaining ½ of the adjustment for CY 2024.

We have completed our review of the GPCIs and are finalizing new GPCIs beginning for CY 2023 in this final rule. We also calculated a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS locality's proposed work, PE and MP expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are a useful metric for purposes of comparing overall costs and payments across fee schedule areas. The actual effect of GPCIs on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those reflected in the GAF.

As noted above, section 101 of the Consolidated Appropriations Act of 2021 extended the 1.0 work GPCI floor for services furnished through December 31, 2023. Therefore, the final CY 2023 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, reflected in the CY 2023 final GPCIs. See Addenda D and E to this final rule for the CY 2023 final GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89, and increased the number of Statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. The current 112 payment localities include 34 Statewide areas (that is, only one locality for the entire State) and 75 localities in the other 16 States, with 10 States having two localities, two States having three localities, one State having four localities, and three States having five or more localities. The remainder of the 112 PFS payment localities are comprised as follows: the combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 112 fee schedule areas, also referred to as payment localities, are defined alternatively by State boundaries (Statewide areas for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-State areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate geographically adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a State. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). The changes to the proposed CY 2023 GPCIs for each locality reflected the updated resource cost data in each area to better adjust PFS payments for geographic cost differences compared to national average costs. We noted that the changes in the proposed GPCIs reflect the statutory floors and limitations on variation discussed above that may advantage some rural localities. We described the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2023 GPCI update is available in a final report, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage

differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), formerly known as Occupational Employee Statistics (OES), wage data as a replacement for the 2000 Census data. The BLS OEWS data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OEWS wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OEWS is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OEWS data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs; for the CY 2017 GPCI update, we used updated BLS OEWS data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs; and for the CY 2020 GPCI update, we used updated BLS data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OEWS data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the CY 2023 GPCI update, we used updated BLS OEWS data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the proposed work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2020), we used 2014 through 2017 BLS OEWS data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OEWS is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the CY 2023 GPCI update, we used updated BLS OEWS data (2017 through 2020) as a replacement for the 2014 through 2017 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI.

In calculating the CY 2023 GPCI update for the office rent index component of the PE GPCI, we used the 2015 through 2019 American Community Survey (ACS) 5-year estimates as a replacement for the 2013 through 2017 ACS data. The 2016 through 2020 5-year estimates were supposed to be released in December 2021, but the release date was delayed to March 17, 2022. Therefore, the recent 2015 through 2019 5-year estimates, which preceded any COVID–19 impacts, were used in the CY 2023 GPCI update, rather than the 2016 through 2020 ACS data, which were not publicly released in time for the development of the proposed rule. The Census Bureau noted that COVID–19 impacted data collection for the 2020 ACS, and the resulting challenges have the potential to affect the quality of the data. In particular, the Census Bureau noted that there were lower response rates, and nonresponse bias was found in the data collected for 2020.[108] We will analyze the ACS data collected in 2020 and subsequent years that occurred during the COVID–19 pandemic, and consider using those data for the next GPCI update after we better understand their integrity and validity for our purposes. Because the office rent index is based on 5-year estimates, we expect minimal impact from the non-response bias in the CY 2020 data on the next GPCI update, but we will examine the subsequent years' ACS data that could be similarly impacted by conditions during the COVID–19 pandemic. Because the 2020 ACS data were not released in time for us to use them in the development of the proposed rule, and the public would not have an opportunity to comment on the use of those data if we were to adjust the proposed GPCIs in the final rule to

[108] *https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.*

reflect the 2020 ACS data, we noted that we would not consider using the 2020 ACS data for the CY 2023 final GPCIs.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). To ensure that premium data are homogenous and comparable across geographic areas, data were collected for policies with uniform coverage limits of $1 million per occurrence and $3 million aggregate ($1 million/$3 million). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million/$3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2020 GPCI update, we used premium data presumed in effect as of December 10, 2017. The CY 2023 MP GPCI update reflects premium data presumed in effect no later than December 31, 2020. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017, and refer readers to the CY 2017 PFS final rule (81 FR 80270) for additional discussion of those.

d. GPCI Cost Share Weights

For the CY 2023 GPCIs, we proposed to continue to use the current 2006-based MEI cost share weights for determining the proposed PE GPCI values. Specifically, we use the cost share weights to weight the four components of the PE GPCI: employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses, as shown in Table 22. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017 and CY 2020 GPCI updates.

We noted that we proposed to rebase and revise the MEI cost share weights for CY 2023, and we referred readers to the detailed discussion in section II.M. of the proposed rule, but we proposed to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 GPCIs, thus delaying the implementation of the rebased and revised MEI cost share weights for this purpose. We refer readers to our discussion about using the proposed rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and for the purposes of updating the GPCIs for CY 2023 in sections II.B. and VI. of this final rule. In those sections, we discuss our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have on PFS payments. We have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI, which was most recently done for CY 2014 (78 FR 74382 through 74383). However, in light of the overall impacts of making this change and in the interest of maintaining stability in payments, we proposed to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 final PE GPCIs. We believe that allowing interested parties the opportunity to review and comment on the proposed rebased and revised MEI cost share weights as discussed in section II.M. of the proposed rule and their potential impacts before we actually use such rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and updating the GPCIs is important. This approach maintains consistency in the data used to update both the GPCI and PFS ratesetting inputs for CY 2023; the proposal to delay implementation of the rebased and revised MEI cost share weights is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to section VI. of this final rule for additional discussion on this issue and impacts as it relates to PFS ratesetting and the GPCI update for CY 2023. We also refer readers to the comment solicitation in section II.B. of this final rule, where we discuss our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. In addition, we direct readers to the CY 2011 PFS final rule (75 FR 73256) where we similarly delayed implementation of updated MEI cost share weights in response to commenters' concerns about our separate, ongoing analysis that would inform future GPCI changes and the reallocation of labor-related costs from the medical equipment and supplies and miscellaneous component to the employee compensation component of the PE GPCI.

In the CY 2011 PFS final rule (75 FR 73256), we acknowledged that we typically update the GPCI cost share weights concurrently with the most recent MEI rebasing and revision, but in consideration of the commenters' concerns in response to the proposed rule, we did not use the revised cost share weights for the CY 2011 GPCIs and instead finalized the implementation of the rebased and revised MEI cost share weights through subsequent rulemaking. We invited comments on the delay in implementation of the MEI cost share weights for purposes of the CY 2023 GPCIs and PFS ratesetting, given the impacts discussed in section VI. of the proposed rule (87 FR 46419 through 46425). We also solicited comments on how best to proceed with implementation of the rebased and revised MEI cost share weights in the future. More specifically, we sought comment on how best to incorporate the MEI cost share weights into the PE GPCI if we were to implement them outside the statutorily required triennial update in which we phase in all aspects of the GPCI update through the previously discussed 2-year (½ in each year) phase-in required by section 1848(e)(1)(C) of the Act. Section 1848(e)(1)(C) of the Act requires that, if more than one year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, specifically, we sought comment on potentially incorporating the rebased and revised MEI cost share weights into the CY 2024 GPCIs. We noted that we would not be required by statute to phase in the adjustment over 2 years as specified in section 1848(e)(1)(C) of the Act because, in CY 2024, no more than one year would have elapsed since the last GPCI adjustment. Therefore, we also sought comment on whether it would be appropriate to use a multi-year transition to incorporate the rebased and revised MEI cost share weights for purposes of the PE GPCI and PFS ratesetting as we have done in the past when incorporating other new data into the PFS payment methodology (for example, the clinical labor update), or if, because the MEI cost share weights only impact the composition of the PE GPCI, such a transition would not be warranted. If we were to instead apply the rebased and revised MEI cost share weights for purposes of the PE GPCI and PFS ratesetting for CY 2025 or later, we would be required under section 1848(e)(1)(C) of the Act to phase in the GPCI adjustments over 2 years. We sought comments on whether, in that case, it would be appropriate to similarly apply a transition to implement the MEI cost share weights for purposes of PFS ratesetting as well, and referred readers to section II.B and VII. of the proposed rule for more

discussion regarding the alternatives considered and impacts of a phase-in of the rebased and revised MEI cost share weights in PFS ratesetting. The final CY 2023 GPCI cost share weights are displayed in Table 25. We note that the finalized rebased and revised cost share weights discussed in detail in section II.M. of this final rule are also displayed in Table 25 for awareness regarding potential future rulemaking and GPCI updates.

TABLE 25: Final GPCI Cost Share Weights for CY 2023

Expense Category	Current GPCI Cost Share Weights	Final CY 2023 GPCI Cost Share Weights	Rebased and Revised Cost Share Weights as Finalized in Section II.M.
Work	50.866%	50.866%	47.522%
Practice Expense	44.839%	44.839%	51.129%
- Employee Compensation	16.553%	16.553%	25.451%
- Office Rent	10.223%	10.223%	5.684%
- Purchased Services	8.095%	8.095%	13.419%
- Equipment, Supplies, Other	9.968%	9.968%	6.575%
Malpractice Insurance	4.295%	4.295%	1.349%
Total	**100.000%**	**100.000%**	**100.000%**

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in Frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be Frontier States. In general, a Frontier State is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a Frontier State, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the States identified as Frontier States for the CY 2023 PFS proposed rule. The qualifying States are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we will apply a 1.0 PE GPCI floor for these States in CY 2023.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-State fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-State locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-State locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality

structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

(1) Proposed Refinement to Number of Unique Fee Schedule Areas in California

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. This refinement would ultimately change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. In light of the foregoing, for CY 2023, we proposed to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. We sought comment on the proposed technical refinements to consolidate unique fee schedule areas and their locality numbers in California, where the unique localities are not operationally necessary. Based on support from commenters, we are finalizing to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. While we believe these changes are appropriate to consolidate fee schedules areas that are no longer operationally necessary, we are unable to operationalize these changes for CY 2023 due to timing constraints relating to the actions and coordination with the various systems maintainers required to effectuate changes to claims processing. Therefore, for CY 2023, there will be no changes to the existing locality numbers 05, 06, 08, 18, or 26. We intend to operationalize these finalized changes for CY 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS.

h. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of the proposed rule, we identified four technical refinements to the methodology that yielded improvements over the current method; these refinements are applicable to the work and MP GPCIs, the employee wage index component of the PE GPCI, and the GAFs. For purposes of the final rule, we are finalizing these changes as proposed.

We conducted a thorough review of the BLS OEWS occupation codes within each of the seven occupation groups used in past updates to track and document the changes over time. As new BLS OEWS data are released, the availability of specific occupation codes is subject to change, and it is possible that new codes can be added, changed, or removed over time; therefore, we believe it is important to periodically review and update the occupation groups and codes based on our review during the GPCI updates. We reviewed the occupation codes and groups used to capture geographic variation in professional wages to assess other potential codes and groups that could be used in addition to the current selections to calculate the work GPCI, with significant consideration given to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). Based on our review, we proposed the addition of two new occupation groups (and their corresponding occupation codes), Management Occupations and Business and Financial Operation Occupations, to the preexisting seven occupation groups for CY 2023, as described in Table 20 in the proposed rule (87 FR 46009) and Table 26 of this final rule.

TABLE 26: Final Additional Occupation Codes in New Occupation Groups for Inclusion in CY 2023 GPCI Update

Occupation Group	Occupation Code	Occupation Title
11-0000 Management Occupation Group	11-1011	Chief Executives
	11-1021	General and Operations Managers
	11-2011	Advertising and Promotions Managers
	11-2021	Marketing Managers
	11-2022	Sales Managers
	11-2031	Public Relations and Fundraising Managers
	11-3011	Administrative Services Managers
	11-3021	Computer and Information Systems Managers
	11-3031	Financial Managers
	11-3051	Industrial Production Managers
	11-3061	Purchasing Managers
	11-3111	Compensation and Benefits Managers
	11-3121	Human Resources Managers
	11-3131	Training and Development Managers
	11-9021	Construction Managers
	11-9031	Education Administrators, Preschool and Childcare Center/Program
	11-9032	Education Administrators, Elementary and Secondary School
	11-9033	Education Administrators, Postsecondary
	11-9039	Education Administrators, All Other
	11-9041	Architectural and Engineering Managers
	11-9111	Medical and Health Services Managers
	11-9121	Natural Sciences Managers
	11-9151	Social and Community Service Managers
	11-9161	Emergency Management Directors
	11-9199	Managers, All Other
13-0000 Business and Financial Operations Group	13-1011	Agents and Business Managers of Artists, Performers, and Athletes
	13-1021	Buyers and Purchasing Agents, Farm Products
	13-1022	Wholesale and Retail Buyers, Except Farm Products
	13-1023	Purchasing Agents, Except Wholesale, Retail, and Farm Products
	13-1041	Compliance Officers
	13-1051	Cost Estimators
	13-1071	Human Resources Specialists
	13-1075	Labor Relations Specialists
	13-1081	Logisticians
	13-1111	Management Analysts
	13-1121	Meeting, Convention, and Event Planners
	13-1131	Fundraisers
	13-1141	Compensation, Benefits, and Job Analysis Specialists
	13-1151	Training and Development Specialists
	13-1161	Market Research Analysts and Marketing Specialists
	13-1199	Business Operations Specialists, All Other
	13-2011	Accountants and Auditors
	13-2021	Appraisers and Assessors of Real Estate
	13-2031	Budget Analysts
	13-2041	Credit Analysts
	13-2051	Financial Analysts
	13-2052	Personal Financial Advisors
	13-2053	Insurance Underwriters
	13-2061	Financial Examiners
	13-2071	Credit Counselors
	13-2072	Loan Officers
	13-2081	Tax Examiners and Collectors, and Revenue Agents
	13-2099	Financial Specialists, All Other

We also proposed to add four occupation codes to the Computer, Mathematical, Life, and Physical Science group, and three occupation codes to the Social Science, Community and Social Service, and Legal group, for

CY 2023, as shown in Table 21 in the proposed rule (87 FR 46010) and Table 27 in this final rule. The practical effect of the inclusion of these occupation groups and codes on the work GPCI is minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but their inclusion adds meaningful data regarding the geographic variation in professional wages for CY 2023.

TABLE 27: Final Additional Occupation Codes in Current Occupation Groups for Inclusion in CY 2023 GPCI Update

Occupation Code	Occupation Title	Common Education Requirement
Group: Computer, Mathematical, Life, and Physical Science		
15-1212	Information Security Analysts	Bachelor degree in a computer- or technology-related field
15-1257	Web Developers and Digital Interface Designers	Sometimes a two-year associate degree, other times a bachelor degree in computer science, programming, or a related field
15-1241	Computer Network Architects	Bachelor degree in computer science, information systems, engineering or related field; sometimes MBA in information systems
19-1099	Life Scientists, All Other	Bachelor's degree in a life science such as biology, chemistry, or genetics
Group: Social Science, Community and Social Service, and Legal		
19-5011	Occupational Health and Safety Specialists	Bachelor's degree
21-1099	Community and Social Service Specialists, All Other	Bachelor's degree, along with coursework in social or behavioral science
23-1012	Judicial Law Clerks	Recent law school graduates, generally, law clerks possess a master's degree in law, a specialized legal master's degree (e.g., public policy or international law), or a Juris Doctor degree

We proposed to modify the list of occupation codes used within the first PE GPCI component, Employee Wages, to conform more closely to the clinical labor categories used in PFS ratesetting. Specifically, six occupation codes listed as sources for clinical labor rates used to establish PE RVUs in PFS ratesetting that were previously inadvertently excluded in the Employee Wage Index calculation are now included in the final CY 2023 Employee Wage Index (29–1126, 29–1124, 19–3031, 29–1031, 29–1181, 29–1127). Lastly, we proposed a technical refinement to the method used to calculate each locality's GAF. The GAFs are calculated as the weighted composite of the three GPCIs (work, PE, and MP), essentially representing the net geographic adjustment that would be made to a theoretical standard service. Instead of the 2006-based MEI cost share weights, which were used to calculate GAFs in previous updates to the GPCIs, we calculated the CY 2023 GAFs using weights that reflect the share of total RVUs that each component (work, PE, and MP) accounts for, based on Medicare utilization data from CY 2020. The GAFs are not used for payment under the PFS but are a useful measure to illustrate the overall effect of geographic adjustments under the PFS across Medicare fee schedule areas. We believe that using the share of RVUs reflected in recent Medicare utilization data as weights when calculating the CY 2023 GAFs results in GAFs that more accurately reflect the composite effect of geographic adjustment on payment, year over year, as compared to the GAFs calculated using the 2006-based MEI cost share weights. This change also allows the use of current Medicare utilization data that are available each year as opposed to the MEI cost share weights that are not updated as frequently. The final weights used to calculate the CY 2023 GAFs are displayed in Table 28.

TABLE 28: Final Weights Used to Calculate the CY 2023 GAFs

Component to Be Weighted	Current Weights (2006-based MEI Cost Share Weights)	CY 2023 Final Weights (CY 2020 Utilization Shares)
Work	50.866%	50.247%
Practice Expense	44.839%	45.556%
Malpractice Insurance	4.295%	4.196%

These four methodological refinements, including changes to: (1) the occupation group; (2) occupation codes; (3) occupation codes used for the Employee Wage Index; and (4) the GAF weighting adjustment, yield improved mathematical precision in the final CY 2023 GPCIs and GAFs by providing for a more accurate, full landscape of occupations that should be accounted for in the work and PE GPCIs, and by aligning the GAF equation weights to

use routinely available data. We are finalizing all four refinements as proposed. Additional information on the GPCI methodology and the refinements are available in the final report, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS'' on our website located under the supporting documents section of the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

i. Alternatives Considered Related to the Use of the American Community Survey (ACS) Data for Office Rent Index

Commenters often express concern about the use of residential rents as a proxy for physician office space costs for purposes of updating the PE GPCIs, and state that CMS should collect commercial rent data and use it either as the basis for measuring geographic differences in physician office rents, or if this is not feasible, use it to validate the residential rents as a proxy for physician office rents. In the past, commenters have requested that CMS provide a specific explanation of the barriers to obtaining better commercial rent data and that we reevaluate existing databases to find or develop a nationwide measure of commercial office rents for use in calculating PE GPCIs. For each GPCI update, we have noted that our efforts are ongoing to identify a publicly-available, robust, nationally representative commercial rent data source that could be made available to CMS for this purpose. We have welcomed opportunities to discuss such data sources with interested parties and to incorporate such data, as appropriate in the GPCI calculation process, through our annual rulemaking process.

Because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires us to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data source that is available on a nationwide basis, that is regularly updated, and retains consistency area-to-area, year-to-year. The ACS is administered by the United States Census Bureau, which is a leading source of national, robust, high quality, publicly available data. We agree that a data source for commercial office rents that provided for adequate representation of urban and rural areas nationally would be preferable to a residential rent data source as a proxy for commercial rents. We have previously discussed in the CY 2005, CY 2008, CY 2011, and CY 2017 (69 FR 66262, 72 FR 66376, 75 FR 73257, and 81 FR 80265, respectively) final rules that we recognize that apartment rents may not be a perfect proxy for physician office rent.

We have conducted searches for commercial rent data sources for consideration as an alternative to the ACS data in the past and have not found or received public comments with suggestions of reliable data sources that meet our needs. As discussed in the proposed rule, for CY 2023, we conducted another search for reliable commercial rent data sources that are publicly available for the CY 2023 update and did not find any reliable data sources that would meet our needs. The principal characteristic of any substitute data source for the ACS data would be that it captures geographic variation in the office space cost for physician practices. We primarily investigated sources that report data on commercial real estate, but we also considered a few residential rent data sources and one data source that reports on a type of property that would be unable to house a physician practice—U.S. Post Office (P.O.) box rentals. Because the underlying property in which the P.O. boxes are located is commercial in nature, the rental rates may reflect the underlying geographic variation in facility cost. Because this source has other features that are important for creating a geographic index, we have included it for consideration. Although interested parties may prefer a database focused on the types of properties that physicians would use for offices (that is, a commercial rent database), the identified potential data alternatives discussed below failed to meet one or more of five criteria that we believe are critical to the creation of an appropriate geographic index.

We used the following five criteria to analyze the potential data sources for this search: (1) applicability to planned use; (2) standardization of the measure; (3) potential bias; (4) geographic scope, distribution, and granularity of the data; and (5) availability, continuity, and price of the data. Our review revealed challenges with the commercial real estate market data in several of these criteria. Under the first criterion, there are two sub-criteria that present problems with the type of real estate data reported when we considered their use for creating a geographic index: (1A) leases versus sales of commercial real estate, and (1B) comparables versus listings versus assessments of commercial real estate. For the first sub-criterion, the commercial and residential real estate markets can be subdivided into markets for leases and sales. Terms for commercial leased properties are often varied and not readily available. Commercial sales, especially of office condominiums, may be more readily available and require less adjustment for use in a geographic index. The availability of different arrangements—leasing versus owning—may vary geographically, affecting the underlying stability and representativeness of an index based on either. Under the second sub-criterion, an important distinction is whether the data in the alternative data source represents closed transactions (known as ''comparables'' or ''comps'') or asking prices (known as ''listings''), regardless of whether the source is reporting data for leased or sales of commercial property. Because asking prices are often aspirational, professional real estate appraisers rely on comparable transactions in order to estimate a price for sale or lease. Therefore, comparables provide the most reliable substitute dataset for consideration for use in creating a geographic index. Assessments are the estimated values of real property set by the tax assessors in each State, which are generally intended to reflect full cash value of the property, though there may be State-specific laws and regulations that interfere (that is, by limiting the percentage increase in a property from year to year if it has not been transferred). Assessments for commercial properties often rely heavily on the ''income method'' of valuation, which capitalizes the net income the property does or could receive if rented. The advantage of assessments for use in creation of a geographic index is their existence for every property in the United States.

The second criterion is that appropriate adjustments need to be made to reduce variation for other factors, or the standardization of the data reported by a considered alternative data source. The primary data adjustment is to standardize the size of the property. For commercial space, conversion to a price per square foot (price/SF) value allows for direct comparison between properties. There are other factors involved in standardizing commercial rents and sale prices. The Building Owners and Managers Association (BOMA) groups buildings into three property classes:

- Class A: Most prestigious buildings competing for premiere office users with rents above market average for the area. These buildings have high quality standard finishes, state of the art building systems and amenities, exceptional accessibility, and a definite market presence.

• Class B: Buildings competing for a wide range of users with rents in the average range for the market. Buildings finishes are good to fair for the area, and systems are adequate but the building does not compete with Class A at the same price.

• Class C: Buildings competing for tenants requiring functional space at rents below average for the market.[109]

A dataset of commercial rentals or sales must include the building class information so properties can be appropriately compared to each other, similar to the way that CMS currently only compares ACS rent data for two-bedroom apartments. For leases, the dataset would also need to specify lease type (Single Net, Double Net, Triple Net, Bondable Net, Full Service Gross, Modified Gross, and or Percentage).[110] The same property rented under a type of Net lease would be expected to have a lower rent than if it were rented under a Full-Service lease because the lessee would pay some amount towards operating expenses. Although a dataset may contain an indication of the type of lease, it may not include the amount of operating expenses paid by the lessee that would be necessary to standardize the rent or other terms that affected the final transaction price. There are often considerable privacy considerations with respect to commercial transactions in order to maintain competitive advantage, so accurate information is often difficult to obtain. Typically, the sale price for a leased property, assuming an arms-length transaction, accounts for the detailed lease terms applicable to the property and likely would not require adjustment for this factor. Another consideration is the effective date of the transaction. Market prices for leases and sales can change rapidly or slowly, and even transactions occurring within the same calendar year may or may not require adjustment in order to be reflective of the market at the intended point in time, and therefore, the transaction date is critical for professional appraisals. Markets are also localized, so even data reported for areas in relatively close proximity may not experience the same price fluctuations.

The third criterion is that potential bias is limited in a considered alternative data source. Our search to date was unable to locate any scientifically designed national survey of commercial property costs. Many of the data sources are intended to facilitate the sale of commercial property and provide listings, rather than comparables. They also may only contain a fraction of the listings on the market and have been selected by brokers to advertise for sale, rather than to represent the entire market, resulting in substantial bias. Even the most comprehensive and detailed data sources for verified transactions are designed to support valuation of individual properties. These databases reflect the mix of properties that are either currently available or have been sold or leased during a defined period. The aggregate data are not intended to produce an unbiased estimate of the average cost per square foot in a particular geographic area, whereas, the ACS is a scientifically designed and implemented national housing survey created by the U.S. Census Bureau that has been designed to reduce bias in the statistics it creates.

The fourth criterion is that the alternate data source would need to be national in scope and sufficiently granular to capture the characteristics of highly localized real estate markets. The ACS data have been consistently available in each year for the majority of counties in the nation. Although some of the commercial data sources may range nationwide and provide property-level data, there may be a much higher proportion of areas with missing data. An important consideration for the office rent index is that it sufficiently captures data in both urban and rural areas. Rural areas may have a less active commercial real estate market than urban areas, in which case there may be few transactions to use in a geographic index.

Lastly, the fifth criterion is that the data source be publicly available, consistently available for CMS' GPCI update years, and/or reasonably priced in order to facilitate transparency and administrative efficiency. Proprietary databases can only be accessed by those who sign up for the service, and use of the data is governed by Terms of Service (TOS) that may preclude its use in derivative works, such as the creation of a geographic index, or dissemination of the data. Public databases are more likely to be accessible and able to be used for derivative work, such as the creation of the GPCIs. Any change in the data source we use in the creation of the index is likely to cause changes in index values, and possibly invoke critique if the resulting changes are significant. If CMS were to consider a change in data source, the change would need to be sustainable over time, and therefore, the data must be consistently accessible for subsequent GPCI updates, and data sources must maintain consistency over time in order to avoid any potential dramatic changes and/or the need to refine the adjustments to a dataset each update year, which would introduce unnecessary variation in the index. If the data source changes or discontinues the dataset, CMS would need to find a replacement data source, possibly within a short time period. This would likely introduce the possibility of dramatic changes and variation in the index that does not reflect the real geographic changes between update years—stemming from the use of different data sources. Additionally, the price to obtain and make necessary adjustments to the data discussed above may be prohibitive for use in the GPCIs.

The Federal Government already paid for the construction of the ACS, the ACS provides the data in a very usable form, CMS can consistently and freely access the data, and relatively minor processing is required to turn it into an index. Every proprietary database is likely to charge substantial amounts to access the data as it is currently provided, which will be geared to uses very different from the creation of an office rent index. There may be substantial work required to gather and process the data and TOS conditions imposed by the database owners may not allow even free data to be used for the intended purpose. In all cases, it is likely that CMS would need to negotiate the terms for utilizing any proprietary sources.

We identified eight data sources for analysis as potential alternatives to the ACS, but all failed to meet one or more of the five key criteria discussed above that would allow us to better reflect geographic cost variation for the office rent component of the PE GPCI that is currently measured using the ACS. We specifically identified the following potential data sources: (1) REIS® Real Estate Solutions by Moody's Analytics®; (2) CompStak; (3) CoStar™; (4) Zillow® Assessor and Real Estate Database (ZTRAX); (5) U.S. Postal Service (USPS®) P.O. Box Rental; (6) GSA® Lease Inventory; (7) Reonomy®; and (8) SMR Research. Three of the eight data sources had substantial costs associated with obtaining the data, and we were unable to obtain pricing information for an additional two of the eight without extensive discussions with a sales representative. Two of the eight sources lacked necessary building class information, and many of the eight sources presented challenges with TOS restrictions, representativeness of rural areas, small or undisclosed sample sizes, sample sizes that differed from

[109] *https://www.boma.org/BOMA/Research-Resources/Industry_Resources/BuildingClassDefinitions.aspx.*

[110] *https://www.reonomy.com/blog/post/commercial-lease-types.*

year to year, and/or a large number of geographic areas with missing data.

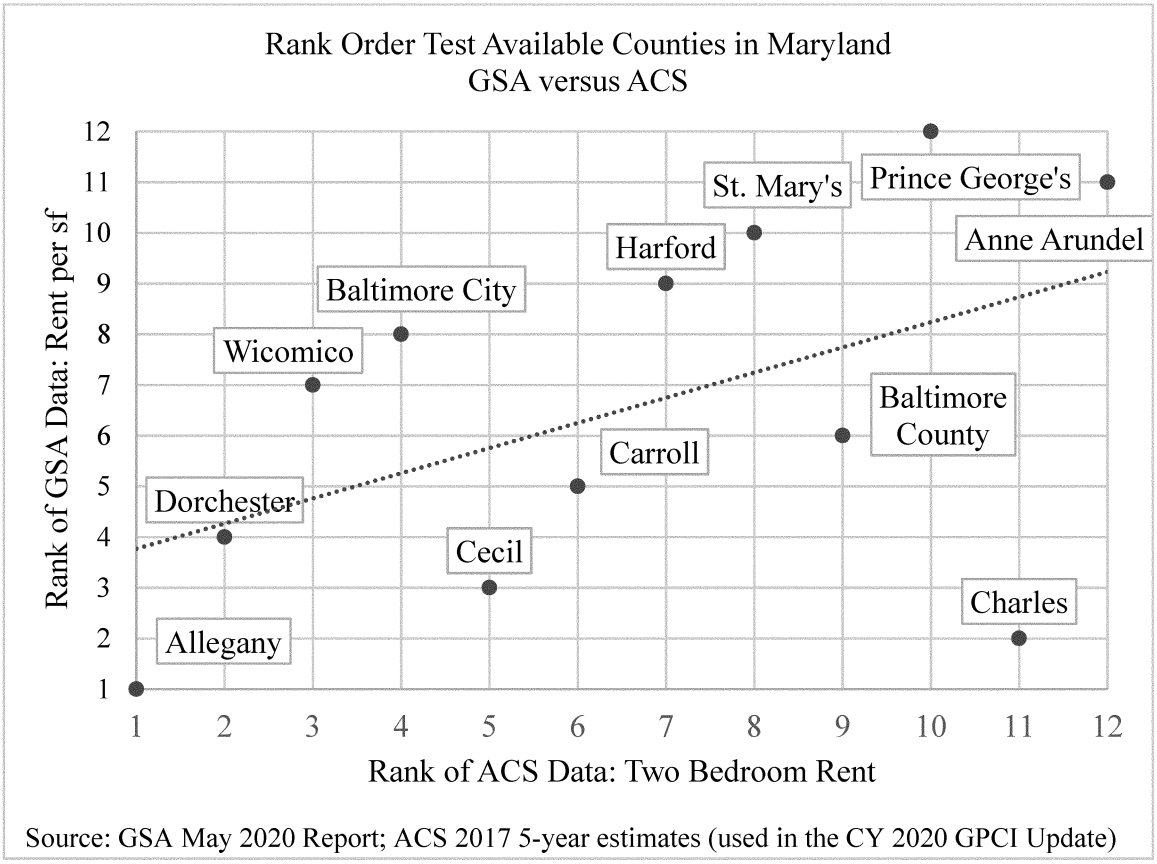
While we determined that none of these data sources are appropriate substitutes for the ACS data we currently use, based on their failure to meet one or more of the five key criteria discussed above, some of the sources possess useful qualities that allowed for further preliminary research into the correlation between commercial and residential rent that fell within the confines of our contractual restrictions. To investigate whether the use of ACS residential rents captures geographic variation in office rents, as discussed above, we identified a few data alternatives above for further research and examined their correlation with the ACS residential rent data in effort to evaluate the validity of the ACS data as a proxy for determining geographic variation in office rents. Overall, our ongoing analysis shows that the ACS residential rent data are highly correlated with commercial rents across areas. Therefore, we have concluded that the continued use of the ACS data for the office rent component of the PE GPCI is appropriate. We considered the use of USPS P.O. Box Rental data for preliminary analysis, as it is free, publicly available, and national in scope (in all zip codes where P.O. Boxes are available), but resource and time constraints limited us from considering this for the CY 2023 update. P.O. Box rent data is available online, but it is not formatted in an easy-to-use dataset that we could readily analyze without conducting resource-intensive data extraction and preparation. Considering that the P.O. Box rent data would have required significant resources, and that expending such resources was not feasible for the CY 2023 proposed rule, we identified the GSA Lease Inventory data source as the next best alternative data source to use to evaluate the correlation between residential and commercial rents because it is publicly available, free, and accessible in an easy-to-use format that required limited adjustments to allow analysis. To get a comparative sense of the rents per square foot that would be suggested for a specific geographic area, we chose to compare the GSA Lease Inventory data and the ACS data for available counties in the State of Maryland. As shown in Table 29, the GSA Lease Inventory data are missing for approximately half of the counties in Maryland. For those counties with available GSA data, the rent per square foot of the GSA leased facilities is shown in Table 29 and can be compared to the corresponding ACS residential rent data for that county.

TABLE 29: Comparing GSA Lease Inventory and ACS Data for Counties in Maryland

		GSA Data				ACS Data		
County	**Population**	**Freq**	**Rent per sf ($)**	**Unweighted Index**	**Population Weighted Index**	**Two Bedroom Rent ($)**	**Unweighted Index**	**Population Weighted Index**
Allegany	73,060	4	17.54	0.651	0.540	670	0.588	0.532
Anne Arundel	559,737	23	32.98	1.224	1.015	1,543	1.354	1.225
Baltimore City	621,000	29	27.63	1.025	0.850	1,053	0.924	0.836
Baltimore County	825,666	18	24.44	0.907	0.752	1,233	1.082	0.979
Carroll	167,535	3	24.28	0.901	0.747	1,102	0.967	0.875
Cecil	102,175	3	19.98	0.742	0.615	1,062	0.932	0.843
Charles	154,357	1	18.70	0.694	0.575	1,487	1.305	1.180
Dorchester	32,451	3	22.37	0.830	0.688	828	0.727	0.657
Harford	249,776	5	28.05	1.041	0.863	1,152	1.011	0.914
Prince George's	897,693	52	52.36	1.944	1.610	1,401	1.229	1.112
St Marys	110,675	3	29.58	1.098	0.910	1,174	1.030	0.932
Wicomico	101,527	8	25.35	0.941	0.780	970	0.851	0.770
Garrett	29,677	Not available in GSA Lease Inventory data				596	n/a	n/a
Somerset	25,899					687	n/a	n/a
Caroline	32,653					849	n/a	n/a
Washington	149,571					856	n/a	n/a
Worcester	51,441					920	n/a	n/a
Kent	19,819					927	n/a	n/a
Talbot	37,668					1,071	n/a	n/a
Frederick	243,465					1,277	n/a	n/a
Queen Anne's	48,712					1,290	n/a	n/a
Calvert	90,527					1,321	n/a	n/a
Howard	308,447					1,686	n/a	n/a
Montgomery	1,026,371					1,711	n/a	n/a
Unweighted Average			**26.94**	**1.000**		**1,140**	**1.000**	
Weighted Average			**32.51**		**1.000**	**1,260**		**1.000**

Figure 1 shows a rank order test for the counties in Maryland where both GSA Lease Inventory data and ACS data are available. Allegany County has the lowest rent per square foot in the GSA Lease Inventory data and the lowest residential rent in the ACS data. Anne Arundel County has the highest residential rent data and the second highest GSA Lease Inventory data. Analysis shows that the rank order of the available counties in the GSA Lease Inventory data follow a relatively similar pattern (positive, linear relationship) to the same counties in the ACS data.

FIGURE 1: Rank Order Test for Counties with Both GSA and ACS Data in Maryland



Source: GSA May 2020 Report; ACS 2017 5-year estimates (used in the CY 2020 GPCI Update)

We expanded the comparison of the GSA Lease Inventory data with the ACS residential rent data from available counties in Maryland to all available counties nationwide by creating a rent per square foot measure for all GSA Lease Inventory records using the January 2017 GSA Leased Inventory data. The comparison was done by condensing the GSA Lease data to the county level, merging it with the ACS data (for counties where GSA data were available), and aggregating it to the Medicare locality level, weighting by county population. We performed two rank order tests for both ACS (median two-bedroom rent) and GSA (rent per SF) measures in all available localities where at least 50 percent, and 75 percent, subsequently, of the locality population was represented in the county-level GSA data file. Similar to our findings from the initial analysis of Maryland counties, the expanded comparisons generally show a positive, linear relationship between rank of ACS (median two-bedroom rent) and rank of GSA (rent per SF) measures. Because the GSA Lease Inventory data are not geographically complete, our analyses were limited. GSA Lease Inventory data are sparse or nonexistent in some counties, therefore, we calculated the percent of the locality population and only included localities in our analysis with county-level data where at least 50 percent (and 75 percent for the second analysis) of the locality population was represented in the county-level GSA data file. For example, Locality A includes county 1 and county 2. If the GSA data includes county 1 (with a population of 1,000), but not county 2 (population of 50), we included Locality A in the analysis, as it met the 50 percent and 75 percent thresholds. In contrast, if the GSA data includes county 2 (population of 50), but not county 1 (population of 1,000), we did not perform analysis on Locality A. The January 2017 GSA data file includes information on approximately 8,200 GSA leases across the country, which were then aggregated to the county level, and then to the Medicare locality level for our analysis. After these two aggregations, we had enough GSA Lease Inventory data to perform two rank order tests on 52 Medicare localities, one rank order test for counties where at least 50 percent of the locality population was represented and a second rank order test for counties where 75 percent of the locality population was represented. We further analyzed the outlier localities (where the ACS rank differs from the GSA rank by ±30 ranks) and found that when the population threshold increased from 50 percent to 75 percent, we see a reduction in outliers from 13 to only two localities, indicating that more

complete data (that is, 75 percent of the locality population represented in GSA lease data) yields higher correlation between the median two-bedroom rent in the ACS data and the rent per square foot in the GSA data. This correlative effect supports the continued use of ACS data in the GPCI update for CY 2023, as it indicates that GSA lease data (a commercial rent data source) and ACS residential rents varied similarly across geographic areas.

It is important to note that we use the ACS data to create an index to measure cost differences, and not as a direct proxy for commercial office rents. Rather, the ACS data are used to measure geographic variation in residential rents, which is used as a proxy for the geographic variation in commercial office rent. Based on our limited analyses comparing the GSA and ACS data, which showed that commercial and residential rents varied similarly across geographic areas, and the lack of any identified alternative data source that meets all five of the criteria discussed above, we believe that it is appropriate to continue use of the ACS data.

With regard to the suggestion that CMS should collect commercial rent data, we note that we discussed this issue in the CY 2012 PFS final rule with comment period (76 FR 73088) and stated that the development and implementation of a survey could take several years if CMS were to survey physicians directly to gather data to compute the office rent index. Additionally, we have historically not sought direct survey data from physicians related to the GPCI to avoid issues of circularity and self-reporting bias. In the CY 2011 PFS final rule with comment period (75 FR 73259), we solicited public comments regarding the benefits of utilizing physician cost reports to potentially achieve greater precision in measuring the relative cost difference among Medicare localities. We also asked for comments regarding the administrative burden of requiring physicians to routinely complete these cost reports and whether this should be mandatory for physicians' practices. We did not receive any feedback related to that comment solicitation during the open public comment period for the CY 2011 PFS final rule with comment period.

We reiterate that the GPCIs are not an absolute measure of practice costs. Rather they are a measure of the relative cost differences for each of the three GPCI components. The U.S. Census Bureau is a Federal agency that specializes in data collection, accuracy, and reliability, and we continue to believe that where such a publicly available resource exists that can provide useful data to assess geographic cost differences in office rent, even though it is a proxy for the exact data we seek, that we should utilize that available resource. In addition to reviewing alternative data sources, we also explored whether there are alternative ways of using the ACS data that could improve geographic representation or improve interested parties' confidence in it as a reasonable way to capture geographic variation in office rent, including consideration of alternative ways to handle counties where we are missing ACS data, as well as using alternative variables within the ACS data to assess whether there are other similar variables that have more complete data than median gross rent for two-bedroom residences. Our research indicates that using alternatives within the ACS would likely result in minimal changes to the resulting index and would likely not address commenters' concerns regarding use of residential rent data as a proxy for office rent. Our research also suggests that the variation captured by the two-bedroom measure is highly correlated with the geographic variation in one-bedroom and three-bedroom units. The high correlation coefficient strengthens the support for using the ACS two-bedroom measure to capture office rent variation across areas. We explored the continued use of the ACS data to see if there are other available variables that have a lower count of missing observations. The data includes variables on the median gross rent for no bedrooms, one bedroom, two bedrooms, three bedrooms, four bedrooms, five or more bedrooms, and the total median gross rent. Table 30 shows the number of observations that are missing for each of the median gross rent variables in the 2017 5-year ACS data.

TABLE 30: Number of Missing Observations for ACS Residential Rent Variables

Total Number of Missing Observations	Frequency	Percent
Median gross rent -- - Total:	1	0.03
Median gross rent -- - Total: - No bedroom	1310	40.68
Median gross rent -- - Total: - 1 bedroom	164	5.09
Median gross rent -- - Total: - 2 bedrooms	31	0.96
Median gross rent -- - Total: - 3 bedrooms	21	0.65
Median gross rent -- - Total: - 4 bedrooms	367	11.4
Median gross rent -- - Total: - 5 or more bedrooms	1553	48.23

Source: 2017 ACS 5-Year Estimates

Based on the 2017 5-year ACS data, total median gross rent and median gross rent for three bedrooms are two available alternative variables that have fewer missing county-level ACS data than the currently used median gross rent for two bedrooms. However, it is important to note that the number of missing observations for each variable could change over time. While the median gross rent for two bedrooms has a relatively low count for missing observations, it could be substituted with the total median gross rent, which has the smallest count of missing observations. In future years of ACS data, there could be more or fewer missing observations for this list of variables. Moving to use of the median gross rent for three bedrooms would result in slightly fewer missing observations in the 2017 ACS 5-Year Estimates, but this may not be the case for all update years.

There are also alternative ways of handling counties that are missing data. In the CY 2020 update, we imputed county-level rent estimates using the average value for a given county's MSA. Other options include using the average value for contiguous counties, using an average value for the county's State or removing the missing observation from

the calculation. However, we note that the current method of handling counties that are missing data is a reasonable approach and any alternative would not likely affect the calculation materially. Additionally, since there are so few counties that are missing data (less than one percent), these alternatives (even if we had reason to prefer one of them) would likely have no impact on the resulting index. Table 31 shows the correlation coefficients between the available residential rent variables in the ACS. The variation captured by the two-bedroom measure is highly correlated with the geographic variation in one-bedroom and three-bedroom units (approximately 0.9). This relationship is similar, but not quite as prominent for the other residential measures. The correlation coefficient between three-bedroom and four-bedroom rent measures is also approximately 0.9. Based on our research, the geographic variation in residential rents is consistent regardless of specific measure used, and therefore, a change in the ACS variable used or a change in the way of handling counties that are missing data would likely result in minimal changes to the resulting index.

TABLE 31: Correlation Coefficient Between ACS Residential Rent Variables

ACS Residential Rent Variables	Correlation Coefficient	N (max 3,220)
0 vs. 1 bedroom	0.55	1,895
1 vs. 2 bedrooms	0.89	3,043
2 vs. 3 bedrooms	0.92	3,172
3 vs. 4 bedrooms	0.87	2,850
4 vs. 5 bedrooms	0.77	1,645
Total vs. 2 bedrooms	0.95	3,189

Source: 2017 ACS 5-Year Estimates

Given its national representation, reliability, high response rate and frequent updates, and based on the rank order comparison of GSA and ACS data and high correlation coefficients for the ACS residential rent variables discussed above, we continue to believe the ACS residential rent data is the most appropriate data source available at this time for the purposes of calculating the rent index of the PE GPCI. We undertook a comprehensive analysis of alternatives to the ACS data and concluded that there is still no acceptable national data source available for physician office or other comparable commercial rents, and therefore, we proposed to continue to use county-level residential rent data from the ACS as a proxy for the relative cost differences in commercial office rents for the proposed CY 2023 update, and have done so in calculating the CY 2023 final GPCIs.

j. GPCI Update Summary

As explained in the Background section above, section 1848(e)(1)(C) of the Act mandates the periodic review and adjustment of GPCIs. For each periodic review and adjustment, we publish the proposed GPCIs in the PFS proposed rule to provide an opportunity for public notice and comment, and allow us to consider whether any revisions in response to comments are warranted prior to implementation. The CY 2023 updated GPCIs for the first and second year of the 2-year phase-in, along with the GAFs, are displayed in Addenda D and E to this final rule available on our website under the supporting documents section of the CY 2023 PFS final rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

The following is a summary of the public comments received on the proposed revisions to the CY 2023 GPCIs and our responses:

Comment: Some commenters expressed support for the proposed methodological refinements to the GAF calculation and the refinement to the number of unique fee schedule areas in California.

Response: We thank the commenters for the support of our proposed methodological refinements to both the GAF calculation and the number of unique fee schedule areas in California. As noted above, we are finalizing to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. As noted above, there will be no changes to the existing locality numbers 05, 06, 08, 18, or 26 for CY 2023 due to timing constraints relating to the operationalization of these changes. As noted above, we intend to operationalize these finalized changes for CY 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS.

Comment: Some commenters urged CMS to apply the locality RVUs rather than the national RVUs when calculating the GAFs. One commenter stated that this adjustment to the proposed GAF calculation methodology would provide the most precise information at the locality level. In doing so, the commenter stated that calculating a locality's GAF * Total RVUs * Conversion Factor would more accurately reflect locality payments.

Response: We remind commenters that the GAFs are a weighted composite of each PFS locality's work, PE and MP expense GPCIs, which were previously calculated using the national GPCI cost share weights. For CY 2023, we proposed to update the GAF calculation to weight each component by total RVUs that each component accounts for, based on Medicare utilization data from CY 2020. We reiterate that we believe using the share of RVUs reflected in recent Medicare utilization data as weights when calculating the CY 2023 GAFs results in GAFs that more accurately reflect the composite effect of geographic adjustment on payment, year over year, as compared to the GAFs calculated using the 2006-based MEI cost share weights. In the proposed rule, we noted that this change, if finalized, would allow the use of current Medicare utilization data that are available each year as opposed to the MEI cost share weights that are not updated as frequently. We note that the difference between the GAFs, when calculated using the current calculation methodology and the proposed calculation methodology is very minimal, differing only by a maximum of 0.717 percent. We also remind

commenters that we do not actually use GAFs in computing the fee schedule payment for a specific service; rather, the GAFs are useful in comparing overall costs and payments among fee schedule areas. Therefore, we disagree with the commenter that utilizing the locality RVUs when calculating the GAFs would more accurately reflect locality payments, as we do not utilize the GAFs to calculate payment under the PFS. We also note that because the GAFs were previously calculated using the national GPCI cost share weights, we believe that it would be more appropriate to use the national RVUs, rather than locality RVUs as suggested by commenters, to aid transparency between update years. We are finalizing the adjustment to the proposed GAF calculation methodology as proposed.

Comment: Some commenters stated that our proposed methodologic changes to the work GPCI occupation groups and codes create unnecessary complexity and limited transparency. The commenters stated that CMS did not provide an impact analysis or criteria for inclusion (that is, how well it correlated as a proxy) other than significant consideration to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). The commenters stated that, without further explanation, two additional occupation groups were added to the previous seven occupation groups, which increased the greater than 100 current occupation codes by 60. One commenter believes that it is unlikely that the cumulation of so many professions will accurately reflect the relative difference in work of a single profession such as a physician; the commenter stated that, if one were to compare the BLS OEWS data file used for the work GPCI with that of the healthcare provider dataset, there is a discordance. The commenters agreed that the healthcare provider dataset should not be used for developing the work GPCI due to circularity, but believe it can be used to validate the proposed work GPCIs and to identify a much smaller subset of professions that would act as more reliable proxies than what was proposed. The commenters urged CMS to apply a smaller number of professions to the work GPCI, as they thought that doing so would result in a more reliable and accurate proxy for physician work, and provide more information about the correlation between physician work and the proxy professions to allow the public to verify its accuracy.

Response: As noted in the final report, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*, we conducted a thorough review of the BLS OEWS occupation codes within each of the seven occupation groups used in past updates to track and document the changes over time for the CY 2023 GPCI update. As new BLS OEWS data are released, the availability of specific occupation codes is subject to change, and it is possible that new codes can be added, changed, or removed from the BLS OEWS data over time; therefore, we believe it is important to periodically review and update the occupation groups and codes that are included in our triennial GPCI updates based on our review. This review of the BLS OEWS occupation codes is consistent with previous updates. We use the most updated resource cost data in each area to better adjust PFS payments for geographic cost differences compared to national average costs, therefore, we continue to believe that as updated, more complete BLS OEWS data becomes available, we should incorporate that data into our methodologies as appropriate.

We note that the seven proxy professional wage categories span several different industries, including pharmacists and registered nurses, which demonstrates that the healthcare industry is represented in those proxy wage categories. We also remind commenters that the work GPCI captures the relative cost of physician and non-physician practitioner labor across Medicare payment localities, not absolute costs. In other words, the proxy professional wages from the BLS OEWS data are not a proxy for physician *wages,* but rather, the geographic variation in proxy professional wages is used as a proxy for the geographic *variation* in physician wages. The work GPCI reflects differences in living and other costs faced by practitioners in different areas, since other similarly educated professionals face similar costs. Regarding the commenter's statement that information regarding correlation should be provided, we note that including physician wage data in the work GPCI would potentially introduce some circularity, therefore we remind commenters that, consistent with our longstanding practice, a set of proxy occupation groups representing a variety of highly educated professionals are used in the work GPCI calculation. As discussed in previous rulemaking in response to commenters' concerns with the use of unrelated proxy data for physician wages, specifically that MedPAC studies have confirmed that the data sources currently relied upon for geographic adjustment bear no correlation to physician earnings, we have stated that we will continue to consider the possibility of establishing a physician cost report and requiring a sufficiently large sample of physicians in each locality to report data on actual costs incurred (81 FR 80264). However, we also stated that we believed that a physician cost report could take years to develop and implement, and could be prohibitively expensive (75 FR 73259). We solicited public comment regarding the potential benefits to be gained from establishing a physician cost report and whether this approach is appropriate to achieve potentially greater precision in measuring the relative cost differences in physicians' practices among PFS localities. We also solicited public comments on the potential administrative burden of requiring physicians to routinely complete and submit a cost report. We did not receive any feedback specifically related to that comment solicitation (76 FR 73088). We note that we do not claim the proxy professions themselves, or the absolute wages of the proxy professionals are correlated to physician wages, but rather, that the geographic variation in proxy professional wages is similar to the geographic variation in physician wages.

We believe that there would be similar geographic variation if one were to compare the BLS OEWS data used for the work GPCI with data from a healthcare provider dataset, as we continue to believe in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals across an array of industries vary. Further, we welcome opportunities to discuss data sources that can be used to validate the work GPCIs, similar to the analysis that we performed for residential and commercial rent data used for the office rent index.

Comment: One commenter stated that they agree with the use of more recent wage data, but encouraged CMS to consider the potential effects of the COVID–19 pandemic on the GPCIs given that the timeframe of the BLS OEWS data is pre-pandemic and wages have increased drastically since the start of the pandemic.

Response: We reiterate that the work GPCI captures the relative cost of physician and non-physician practitioner labor across Medicare

payment localities, not absolute costs. We note that overall nationwide wage changes would not be reflected in the work GPCI, but rather, the geographic variation compared to the national average would be reflected. We note that we did not use the Census Bureau's 2020 ACS data in the office rent index for the proposed CY 2023 GPCI update due to potential COVID–19 pandemic impacts on data, as previously discussed in the proposed rule. We noted in the proposed rule that we would analyze the ACS data collected in 2020 and subsequent years that occurred during the COVID–19 pandemic, and consider using those data for the next GPCI update after we better understand their integrity and validity for our purposes. Similarly, we understand that the BLS OEWS data could be impacted by conditions during the COVID–19 pandemic, therefore, we will perform similar analyses on the BLS OWES data for the next GPCI update.

Comment: A few commenters stated that the GPCIs for Hawaii do not account for the unique costs of providing medical services in Hawaii and that this will lead to an accelerating shortage of health care providers across the state of Hawaii. The commenter stated that the 1.5 work GPCI floor for Alaska, and the 1.0 PE GPCI floor for the Frontier States should serve as a basis for reevaluating the cost of providing medical services in Hawaii. The commenter stated that the GPCIs should be adjusted to reflect a factor at least equal to Alaska's work GPCI. Another commenter requested that Hawaii's GPCIs be increased for the cost of rent and supplies in Hawaii. One commenter stated that Hawaii's unique geography makes providing care more expensive and that the cost of living ranks amongst the highest in the nation, and the data used by CMS do not reflect the cost of living.

Response: We reiterate that the GPCIs, in particular the work GPCI and the PE GPCI to which the commenters refer, are based on nationally-representative and publicly-available wage data from the BLS OEWS for the work GPCI and employee wage and purchased services components of the PE GPCI, and the Census Bureau's ACS data for the rent index component of the PE GPCI. The GPCIs are a measure of relative resource cost differences among localities compared to the national average as informed by the data (not a measure of absolute costs). We remind commenters that the work GPCI value for Alaska is not based on the data for that State, instead section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for Alaska. Similarly, section 1848(e)(1)(I) of the Act sets a permanent PE GPCI floor of 1.0 for the Frontier States.

Comment: One commenter stated that it disputes the claim that the equipment, supplies, and miscellaneous expenses component of the PE GPCI do not vary by geographic area. The commenter states that small specialty practices in rural communities do not have the volume to negotiate with the national suppliers, particularly for specialty testing, for which there are only a few places to get the specialty supplies. The commenter states that prices are typically presented by the supplier based on volume, and suppliers rarely compromise on order minimums for rural providers. The commenter also noted that many medical supplies have expiration dates, and rural areas struggle to utilize the supplies prior to their expiration dates because of lower volume and large supply shipments based on a supplier's order minimum. The commenter expressed concern with access to urgent and direct patient care services because the national corporations and laboratories will not provide these low paying services in rural areas.

Response: With regard to the supplies, equipment, and miscellaneous expense cost index component of the PE GPCIs, we note that we made no proposals regarding our current policy for this component of the PE GPCI. We have stated that we believe there is a national market for these items and there is not significant geographic variation in those costs, and as such we assign a value of 1.00 for this component for each locality, consistent with the national average. The commenter did not provide any data or information to quantify the variation of costs of supplies, the amount of supplies lost to expiration dates, or national suppliers' order minimums in contrast to a rural specialty practice's demand for these supplies. We encourage the commenter and other interested parties to submit data supporting their assertions for consideration in future rulemaking; specifically, we would be interested in information regarding potential data sources for shipping costs and the costs of medical equipment and supplies for different geographic regions. Ideally, the potential data sources are accessible to the public, available on a national basis for both urban and rural areas, and updated regularly. Similarly, we have previously attempted to locate data sources specific to geographic variation in shipping costs, and we found no comprehensive national data source for this information, and therefore, we have not been able to quantify variation in costs specific to islands or rural communities.

Comment: A few commenters stated that they do not believe that local taxes are accounted for in the GPCIs, such as a general excise tax that is applied to medical services provided in a State.

Response: We note that costs associated with practicing in a particular locality are accounted for in the data that underpin the GPCI calculations. Therefore, we disagree with the commenter's statement that the GPCIs do not account for geographic differences in taxes.

Comment: Two commenters stated that there is a lack of transparency into the GPCI data and methodology used to derive the GPCIs. One commenter stated that they cannot accurately validate CMS' GPCI calculations because there is little transparency and access to the data and methods used. The commenter stated that they submitted a comment on the CY 2022 Physician Fee Schedule proposed rule urging CMS to provide more transparency into the GPCI calculations in general, including a more detailed description of the step-by-step methodology and the specific data files used to derive the GPCIs. In addition to making the RVUs by county available, the commenters urged CMS to make available the source data for the work GPCI by county, the source data for each component of the practice expense GPCI, and all budget neutrality adjustments and calculations.

The commenters stated that CMS provided these data prior to 2020 and that they used it to reproduce and validate the CMS methodology for calculating the GPCIs each year. One commenter stated that they have identified substantial errors in previous proposed rules which CMS has swiftly corrected. The commenters stated that it is important that CMS provide more detailed information related to this critical component of the PFS in the proposed rule in order for the public to reproduce and validate the GPCIs. The commenters stated that the information should be published with the proposed rule just as CMS provides the practice expense RVUs, but with the specific data files.

Response: We refer readers to the step-by-step instructions provided in the final report, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* We also refer readers to Table 4.A.1: Summary of Elements Required for GPCI Calculation

in the final report, and the previous discussion, for the data sources used for the work GPCI and each component of the practice expense GPCI. As noted in the proposed rule, and as previously stated in this final rule, we discuss the years and timeframes of data used from each source. We note that we provide web links to the publicly-available data sources used in this GPCI update, the methodological parameters, as well as an overview of how we develop each GPCI component in the final report. This practice is consistent with previous updates. We also note that the budget neutrality adjustment and statutory floors applied after the budget neutrality adjustment are detailed in the note, ''CY 2023 GPCI Update Note_County_Data,'' on our website located under the supporting documents section for the CY 2023 PFS proposed and final rules at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

Regarding the interested parties' comment on the CY 2022 proposed rule urging CMS to provide more transparency on the GPCI calculations, including a more detailed description of the step-by-step methodology and the specific data used to derive the GPCIs, we note that we did not make any proposals relating to the GPCIs in the CY 2022 proposed rule, so did not solicit or respond to public comments on that rule regarding GPCIs. However, we remind commenters that, in response to the commenters' concerns expressed in rulemaking for the CY 2020 GPCI update, we included more detailed steps in the final report, ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Phys Fee Sched_v19Feb2020'', which is available on the CMS website under the downloads section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-forService-Payment/PhysicianFeeSched/index.html*, to assist interested parties in navigating these data. Additionally, as part of our ongoing commitment to transparency, we post the county-level data that we use to develop the proposed GPCIs, which allows interested parties to further examine and replicate our GPCI methodology. This file is available on the CMS website on our website under the Downloads section, titled ''CY 2023 Proposed Rule GPCI County-Level Data File.'' We believe that we sufficiently addressed previous commenters concerns for the CY 2023 GPCI update in the proposed rule and aforementioned CY 2020 and CY 2023 interim and final reports.

Comment: Some commenters that addressed the proposed rebased and revised MEI supported the proposed delayed implementation of the updated MEI in the PE GPCI and PFS ratesetting for CY 2023, but we note that most commenters specifically commented on the data and methodologies proposed in section II.M. of the proposed rule, rather than the proposed delayed implementation, as proposed in sections II.B. and II.G. of the proposed rule. One commenter expressed concern with the geographic redistribution that could potentially occur with implementation of the rebased and revised MEI cost share weights used in the PE GPCI. The commenter stated that when CMS proposes to modify the weights of the practice expense categories (employee compensation, office rent, purchased services and equipment/supplies/other) within the practice expense GPCI, a significant reduction in the weight of office rent could lead to reductions in the payment to urban sites and increases to payment in rural areas and states with a single GPCI. The commenter urged CMS to also consider the impact of implementation of the rebased and revised MEI cost share weights for geographical areas with relatively high malpractice premiums, given the decreased weight of PLI in the proposed rebased and revised MEI.

Response: We thank the commenters for the support of our proposed delayed implementation of the rebased and revised MEI weights for the GPCIs and PFS ratesetting for CY 2023. We note that we address specific comments regarding the rebased and revised MEI in section II.M. of this final rule. We also note that we provided alternate Addenda D and E to show the CY 2023 GPCIs and summarized GAFs if the rebased and revised MEI cost share weights proposed in section II.M. of the proposed rule were incorporated to weight the proposed CY 2023 PE GPCIs (for comparison to Addenda D and E with the proposal to maintain the current 2006-based MEI cost share weights for the PE GPCIs). We refer readers to the discussion of the impacts of the alternative considered (to implement the proposed rebased and revised MEI in the proposed CY 2023 PE GPCI) in section VI. (2. Alternatives Considered for the Practice Expense (PE) Geographic Practice Cost Index (GPCI)) of the proposed rule. We remind commenters that the implementation of the proposed rebased and revised MEI would only impact the PE GPCI (and GAFs, as the PE GPCI factors into the calculation of the GAF), as the MEI cost share weights are only used in the GPCIs to weight the four components of the PE GPCI. Therefore, the implementation of the rebased and revised MEI would not impact the work or MP GPCIs. We refer readers to the discussion of the impacts of the alternative considered (to implement the proposed rebased and revised MEI in CY 2023 ratesetting) in section VI. (1. Alternatives Considered for Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)) of the proposed rule for impacts of decreased PLI weight in the proposed rebased and revised MEI on PFS ratesetting.

Comment: One commenter expressed appreciation for CMS' efforts to analyze the commercial rent data sources as alternatives considered for the residential rent data used in the practice expense GPCI. The commenter stated that they believe the criteria applied to evaluate alternative sources of rent data were appropriate and encouraged CMS to continue this ongoing effort.

Response: We thank the commenters for the support of our efforts and encourage commenters to submit information regarding potential data sources for our consideration in future rulemaking. We note that our efforts are ongoing to identify a publicly-available, robust, nationally representative commercial rent data source that could be made available to CMS for this purpose. Further, we welcome opportunities to discuss such data sources with interested parties and to incorporate such data, as appropriate, in the GPCI calculation process.

After considering the public comments, we are finalizing the CY 2023 GPCI update, and the methodological refinements, as proposed. As discussed previously in this section of the final rule, we are finalizing to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. As noted above, there will be no changes to the existing locality numbers 05, 06, 08, 18, or 26 for CY 2023 due to timing constraints relating to the operationalization of these changes. As noted above, we intend to operationalize these finalized changes for CY 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS. As a result, the final CY 2023 GPCIs and summarized GAFs in Addenda D and E to this final rule do not reflect the California locality changes as finalized, as there will be no

changes to the existing locality numbers 05, 06, 08, 18, or 26 for CY 2023, and note that the changes will be reflected in Addenda D and E for CY 2024 when the finalized changes are operationalized.

H. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that valuations for each service under the PFS be composed of three components: work, practice expense (PE), and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period (79 FR 67591 through 67596), we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs, see the CY 2015 PFS proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596). In the CY 2018 PFS proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors, used in the calculation of MP RVUs, prior to the next required 5-year update (CY 2020), using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however, the proposal was ultimately not finalized for CY 2018.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor (RF) was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. In the CY 2020 PFS final rule with comment period, we implemented the fourth review and update of MP RVUs, and we also conducted the statutorily required 3-year review of the GPCIs. For a comprehensive discussion of the fourth review and update of MP RVUs, see the CY 2020 PFS proposed rule (84 FR 40504 through 40510) and final rule with comment period (84 FR 62606 through 62615). The MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Therefore, for the CY 2020 update of MP RVUs we finalized a policy to align the update of MP premium data with the update to the MP GPCIs to increase efficiency. Effective beginning in CY 2020, our policy is to review, and if necessary update, the MP RVUs at least every 3 years, similar to our review and update of the GPCIs.

2. Methodology for the Revision of Resource-Based Malpractice (MP) RVUs

a. General Discussion

As discussed in the CY 2023 PFS proposed rule (87 FR 46016), we calculated the MP RVUs that we proposed for CY 2023 using updated MP premium data obtained from State insurance rate filings. We used a calculation methodology for the CY 2023 review and update of resource-based MP RVUs that largely parallels the process used in the CY 2020 update; however, we proposed to incorporate some methodological refinements, which we described in the proposed rule. The MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors (RFs) for the various specialties that furnish a particular service. Because MP premiums vary by State and specialty, the MP premium information must be weighted geographically and by specialty. The MP RVUs that we proposed were calculated using four data sources:

- MP premium data presumed to be in effect as of December 31, 2020;
- CY 2020 Medicare payment and utilization data;
- Higher of the CY 2022 final work RVUs or the clinical labor portion of the direct PE RVUs; and
- CY 2022 MP GPCIs.

We used the higher of the CY 2022 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2023 proposed MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2020 update, the proposed MP RVUs were calculated using specialty-specific MP premium data because they represent the expense incurred by practitioners to obtain MP insurance as reported by insurers. For CY 2023, the most current MP premium data available, with a presumed effective date of no later than December 31, 2020, were obtained from insurers with the largest market share in each State. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) market share report. This annual

report provides State-level market share for entities that provide premium liability insurance (PLI) in a State. Premium data were downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating States. For non-SERFF States, data were downloaded from the State-specific website (if available online) or obtained directly from the State's alternate access to filings. For SERFF States and non-SERFF States with online access to filings, the 2020 market share report was used to select companies. These were the most current data available during the data collection and acquisition process.

MP insurance premium data were collected from all 50 States, and the District of Columbia. Efforts were made to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection, and therefore, filings from the previous update were used. Consistent with the CY 2020 update, no filings were collected for the other U.S. territories: American Samoa; Guam; Virgin Islands; or Northern Mariana Islands. MP premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. Adjustments were made to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the State's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in States where participation in such funds is mandatory.

Premium data were included for all physician and nonphysician practitioner (NPP) specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all States, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all States. In the CY 2020 PFS final rule (84 FR 62607 through 62610), we finalized methodological improvements that expanded the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

b. Methodological Refinements

For the CY 2023 update, we proposed the following methodological improvements to the development of MP premium data:

(1) Improving our current imputation strategy to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names or do not include all CMS specialties.

In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, we finalized in the CY 2020 final rule (84 FR 62607 through 62610) to use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there were no data corresponding to a CMS specialty in the filing, we finalized a policy to use total imputation to establish premiums for that specialty. We proposed to further refine our strategy for imputing risk factor values for specialties that have incomplete data during the data collection process by using rates mapped from the more commonly reported specialty within risk class as opposed to excluding underrepresented filing data.

For example, Hospice and Palliative Care is typically assigned the same risk class as Internal medicine. Rather than excluding Hospice and Palliative Care because there is insufficient filing data, we would use Internal Medicine rates in filings that did not explicitly report Hospice and Palliative Care. For the CY 2020 update, commenters requested that we continue to improve our data collection process to ensure that as much specialty-specific data as possible are used to calculate risk factors. Therefore, we proposed to utilize this small improvement for collecting risk value input data in the future, as this retains as much data as possible and maps specialties more intentionally.

(2) Creation of a risk index for the calculation of MP RVUs.

We proposed to utilize a true MP risk index as opposed to derived risk factors when calculating MP RVUs. Historically, we have used risk factors, which is a ratio of a specialty's national average premium to a single referent specialty's national average premium. This denominator has typically been based on the national average premium for the Allergy/Immunology specialty, which has had the lowest average premium for 2017 and 2020. As proposed, the risk index would be calculated as a ratio of the specialty's national average premium to the volume-weighted national average premium across all specialties. We discussed that we believe the change would increase consistency with the calculation of MP RVUs, so that changes in the MP risk index reflect changes in payment, as opposed to changes relative only to the specialty with the lowest national average premium. We noted that we believe that this definitional change to risk index does not impact the pricing of services in the PFS since it does not change relative risk across specialties, and MP RVUs are rescaled for purposes of budget neutrality to be equal to the overall pool of MP RVUs. Readers can refer to the section of the proposed rule entitled, ''Application of BN to Adjustments of RVUs'' for a discussion of our budget neutrality process.

c. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 PFS final rule with comment period (79 FR 67591), along with the proposed methodological improvements. The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk index of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area MP premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2015–2019 American Community Survey (ACS) 5-year estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We referred readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic

variation so that the locality cost differences (as reflected by the 2022 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of MP claims if they occur. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated a distinct risk index for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty. These methods are discussed below.

Developing Distinct Service Risk Groups: We determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 17 specialties (there were 15 such specialties in the CY 2020 update). These specialties are listed in Table 26. The CY 2023 update uses the same structure of specialty/service risk group as the previous update except that Unknown Physician Specialty (99) is now divided into surgery and non-surgery groups. We were able to collect an expanded amount of premium data for this specialty relative to the previous update, and this service risk group structure change is reflective of the patterns observed in the most current premium data. For all other specialties (those that are not listed in Table 32) that typically do not distinguish premiums as described above, a single risk index value was calculated, and that specialty risk index value was applied to all services performed by those specialties. For further discussion of the information contained in Table 26, refer to ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule'' Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

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TABLE 32: Specialties Subdivided into Service Risk Groups

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Cardiac Electrophysiology (21), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93) Unknown Physician Specialty (99)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step (3): Calculate a risk index for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk index. These risk index values are calculated by dividing the national average premium for each specialty by the volume-weighted national average premium across all specialties. For specialties with sufficient surgical and non-surgical premium data, we calculated both a surgical and non-surgical risk index value. Similarly, for specialties with rate filings that distinguished surgical premiums with obstetrics, we recognized that service-risk subgroup of the specialty and calculated a separate surgical with obstetrics risk index value.

Table 33 shows the risk index values by specialty type and service risk group.

TABLE 33: CY 2023 Risk Index by Specialty and Service Risk Group

Medicare Specialty Code and Name	2023 Service Risk Group	2023 Risk Index
01-General practice	NO SURG	0.704
01-General practice	SURG	1.475
01-General practice	OB	1.637
02-General surgery	ALL	2.927
03-Allergy/immunology	ALL	0.430
04-Otolaryngology	NO SURG	0.682
04-Otolaryngology	SURG	1.659
05-Anesthesiology	ALL	0.933
06-Cardiology	NO SURG	0.777
06-Cardiology	SURG	2.628
07-Dermatology	NO SURG	0.491
07-Dermatology	SURG	1.192
08-Family practice	NO SURG	0.715
08-Family practice	SURG	1.534
08-Family practice	OB	1.636
09-Interventional Pain Management	ALL	1.202
10-Gastroenterology	NO SURG	0.786
10-Gastroenterology	SURG	1.353
11-Internal medicine	ALL	0.757
12-Osteopathic manipulative therapy	ALL	0.434
13-Neurology	NO SURG	0.936
13-Neurology	SURG	4.726
14-Neurosurgery	ALL	4.726
15-Speech Language Pathology	ALL	0.276*
16-Obstetrics/gynecology	NO SURG	0.669
16-Obstetrics/gynecology	SURG	1.925
16-Obstetrics/gynecology	OB	3.485
17-Hospice & Palliative Care	ALL	0.747
18-Ophthalmology	NO SURG	0.493
18-Ophthalmology	SURG	0.894
19-Oral surgery (dental only)	ALL	1.099
20-Orthopedic surgery	ALL	2.349
21-Cardiac Electrophysiology	NO SURG	0.777
21-Cardiac Electrophysiology	SURG	2.626
22-Pathology	ALL	0.636
23-Sports Medicine	ALL	0.732
24-Plastic and reconstructive surgery	ALL	2.103
25-Physical medicine and rehabilitation	ALL	0.608
26-Psychiatry	ALL	0.460
27-Geriatric Psychiatry	ALL	0.460
28-Colorectal surgery	ALL	1.546
29-Pulmonary disease	ALL	0.896
30-Diagnostic radiology	ALL	1.011
31-Intensive Cardiac Rehab	ALL	0.777
32-Anesthesiologist assistants	ALL	0.272
33-Thoracic surgery	ALL	2.809
34-Urology	NO SURG	0.817
34-Urology	SURG	1.388
35-Chiropractic	ALL	0.147
36-Nuclear medicine	ALL	0.570
37-Pediatric medicine	ALL	0.782
38-Geriatric medicine	NO SURG	0.656
38-Geriatric medicine	SURG	1.549
39-Nephrology	NO SURG	0.684

Medicare Specialty Code and Name	2023 Service Risk Group	2023 Risk Index
39-Nephrology	SURG	1.162
40-Hand surgery	ALL	1.959
41-Optometry	ALL	0.048*
42-Certified nurse midwife	ALL	0.914
43-CRNA	ALL	0.276
44-Infectious disease	ALL	0.870
45-Mammography screening center	ALL	0.276*
46-Endocrinology	NO SURG	0.661
46-Endocrinology	SURG	1.285
47-Independent Diagnostic Testing Facility	ALL	0.276*
48-Podiatry	NO SURG	0.495
48-Podiatry	SURG	0.902
62-Psychologist	ALL	0.276*
63-Portable X-ray supplier	ALL	0.276*
64-Audiologist	ALL	0.276*
65-Physical therapist	ALL	0.276*
66-Rheumatology	ALL	0.667
67-Occupational therapist	ALL	0.276*
68-Clinical psychologist	ALL	0.276*
69-Clinical laboratory	ALL	0.276*
70-Multispecialty clinic or group practice	ALL	0.686
71-Registered Dietician/Nutrition Professional	ALL	0.276*
72-Pain management	ALL	1.008
75-Slide Preparation Facilities	ALL	0.276*
76-Peripheral vascular disease	ALL	2.83
77-Vascular surgery	ALL	2.830
78-Cardiac surgery	ALL	2.628
79-Addiction medicine	ALL	0.449
80-Licensed clinical social worker	ALL	0.276*
81-Critical care (intensivists)	ALL	1.126
82-Hematology	ALL	0.725
83-Hematology/oncology	ALL	0.743
84-Preventive medicine	ALL	0.580
85-Maxillofacial surgery	ALL	1.170
86-Neuropsychiatry	ALL	0.460
90-Medical oncology	ALL	0.737
91-Surgical oncology	ALL	2.777
92-Radiation oncology	ALL	0.907
93-Emergency medicine	NO SURG	1.252
93-Emergency medicine	SURG	2.446
94-Interventional radiology	ALL	1.407
98-Gynecologist/oncologist	ALL	2.777
99-Unknown physician specialty	NO SURG	0.686
99-Unknown physician specialty	SURG	1.166
C0-Sleep Medicine	ALL	0.889
C3-Interventional Cardiology	ALL	2.589
C6-Hospitalist	ALL	0.841
C7-Advanced Heart Failure & Transplant Cardiology	ALL	1.756
C8-Medical toxicology	ALL	1.252
C9-Hematopoietic cell transplantation and cellular therapy	ALL	0.780

*Specialty impacted by the phase-in and the 2023 Risk Index value without the phase-in applied.

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Step (4): Calculate MP RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This

percentage was then multiplied by each respective specialty's risk index value as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk index reflecting the weighted MP costs across all specialties furnishing that procedure. The service specific risk index was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

Impacts of expanded data collection: As we discussed in the proposed rule, we proposed important methodological improvements to our process for calculating MP RVUs. The improvements were in response to comments from interested parties suggesting that we continue to improve data collection to ensure that we use as much specialty-specific data as possible to reflect the most accurate trends in malpractice premiums. When we do not have sufficient premium data for a specialty, our practice has been to use the data from the specialty with the lowest premium. As discussed in the proposed rule, we now have specialty-specific data for many more specialties. However, although the newly captured specialty-specific premium data are more accurate, the new data produce premiums and risk index values that are significantly lower for some specialties than the ones we applied in the absence of sufficient specialty-specific data.

We acknowledged that this reduction in premiums and risk index value is expected to negatively impact payment for services furnished by those specialties that are affected by the improved data collection process. Based on our analyses of the new risk index data, we identified an impact threshold to guide how we could integrate the new information into our calculations and minimize the impact on affected specialties. Specifically, we identified a reduction of approximately ⅓ to the risk index calculated for specialties based on the new specialty-specific premium data compared to the information we had previously used. To mitigate the negative impact on affected specialties, promote payment stability, and prevent potential reductions in access to services for beneficiaries, for specialties for which the use of newly available premium data would result in a 30 percent or greater reduction in the risk index for CY 2023 as compared to the current risk index value for CY 2022, we proposed to phase in the reduction in MP RVUs over the 3 years that precedes the next update, by ⅓ of the change in MP RVUs for those specialties in each year that have a 30 percent or more threshold reduction in risk index value as a result of the update. For a detailed explanation of how the phase-in will be applied per specialty, a file is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* As proposed, the phase-in is similar to the 2-year phase-in required under section 1848(e)(1)(C) of the Act for changes to the GPCIs when it has been more than one year since the last changes. We proposed to phase in the reduction in MP RVUs over 3 years rather than 2 years because the MP risk index values are updated every 3 years. The list of specialties that would be subject to the phase-in under the proposed policy, and the corresponding risk index values for each specialty is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Low volume service codes: As we discussed in the proposed rule, for low volume service codes, we used the list of expected specialties who may perform a service instead of the claims-based specialty mix when calculating MP RVUs. We finalized this approach in the CY 2018 PFS final rule to address concerns from interested parties about the year-to-year variability in PE and MP RVUs for low volume services (which also includes no volume services). (82 FR 53000 through 53006). Low volume codes are codes that have 100 or fewer allowed services for a year. These service-level overrides are used to determine the expected specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2023, we solicited public comment on the list of expected specialties. As noted in the proposed rule, the proposed list of codes and expected specialties was made available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on the list of expected specialties. The following is a summary of the comments we received and our responses.

Comment: Commenters suggested additional CPT codes to be added to the Expected Specialty Overrides for Low Volume Service Codes list.

Response: We appreciate commenters' suggested additions of low volume service CPT codes to the Expected Specialty Overrides for Low Volume Service Codes list. We refer readers to the PE RVU Methodology section of this final rule for a discussion regarding the expected specialties list and the suggested additions for CY 2023.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource-based MP RVUs are equal to the total current resource-based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of the proposed rule, Determination of Practice Expense Relative Value Units, we discussed specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We proposed to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We noted that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we proposed to also exclude for the purpose of calculating MP RVUs is available in section II.B. of the proposed rule, Determination of Practice Expense Relative Value Units. The resource-based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2023 PFS final rule at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type is detailed in section VII. of the proposed rule, the Regulatory Impact Analysis.

Additional information on our methodology for updating the MP RVUs is available in the ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' was made available on the CMS website under the downloads section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*.

The following is a summary of the public comments received on the proposed revisions to the Determination of Malpractice RVUs and our responses:

Comment: The majority of commenters are in support of the proposed methodological improvements to our imputation strategy and expanded data collection efforts to create a risk index rather than risk factors. In particular, most commenters are pleased with the expanded data collection efforts that have resulted in increased accuracy for non-physician practitioner's premium data and a risk index system that is volume-weighted to the national average premium across all specialties, rather than allergy/immunology. One commenter requested that CMS not implement the update to the 2023 MP RVUs, as proposed, due to concern for an increase in professional liability costs over the next few years. The commenter noted there could be an increase in malpractice claims caused by the public health emergency, and therefore, any negative impacts would be exacerbated.

Response: We thank commenters for their feedback and overall support. We believe that the negative impacts of this MP update are relatively modest and we agree with the majority of commenters that believe that the impacts do not outweigh the benefit of updated and expanded premium data that yield more accurate professional liability insurance costs across all specialties. Therefore, we are finalizing our methodological improvements as proposed.

Comment: A few commenters requested that CMS not implement the proposed phase-in of risk index values that have decreased by 30 percent or more as a result of the expanded data collection efforts. These commenters requested that we implement the risk index values in their entirety for 2023 and noted that there has been a request for expanded data collection efforts and, therefore, more accurate premium data for several years. The commenters stated that these changes to risk index values were anticipated as a result of expanded data collection, and are relatively minor. Additionally, some commenters noted that in previous updates to the MP RVU data, CMS has not implemented a phase-in in response to dramatic reductions in premiums for a few specialties. One commenter was appreciative of the phase-in and requested that it be implemented as proposed.

Response: We acknowledge that, for previous MP RVU updates, reductions in risk index values have not always been phased-in over time when there is a significant impact to a specific specialty. We also acknowledge commenters' opinions that changes to risk index values are anticipated when there are expanded data collection efforts. However, we remain committed to reducing burdens on practitioners by maintaining stability in Medicare payment and removing barriers to access for beneficiaries that could occur as a result of impacts from a reduction in payment to practitioners. Therefore, we believe it is important to implement a phase-in for those specialties for which we observed a large reduction in risk index value. We are finalizing our MP RVU phase-in strategy as proposed.

Comment: One commenter suggested that CMS make changes to the specialty data source for a few specialties that they believe are incorrectly mapped for purposes of data imputation. The commenter also noted that they would like us to further improve our imputation methodologies by publishing impacts for all CMS specialties instead of mapping to related specialties in the regulatory impact table included in all PFS **Federal Register** notices. Additionally, the commenter stated that they would like CMS to work with the RUC to better identify appropriate cross-walks when necessary. The commenter's requested changes to mappings are as follows: 19-Oral Surgery (dental only) (ALL) to Other, 13-Neurology (SURG) to Other, 14- Neurosurgery (ALL) to Other, 72-Pain Management (ALL) to 11- Internal Medicine, 98-Gynecologist/oncologist (ALL) to 91-Surgical oncology (ALL), C0-Sleep medicine (ALL) to 13-Neurology (NO SURG), C7-Advanced heart failure and transplant cardiology (ALL) to 06-Cardiology (NO SURG), 71-Registered Dietician to Other, and 42-Certified Nurse Midwife to Other.

Response: We appreciate the commenter's mapping suggestions for some specialties that require imputation of premium data. We would also like to reiterate that we will continue to work with all interested parties to improve the data used for calculating risk index values. We continue to believe that the regulatory impact table (Table 8.A CMS Specialty Map into Impact Specialty) of the ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule'' is a useful tool to assist us with mapping premium data when specialty specific premium data are not included in a filing. However, as we discussed in the proposed rule and above, we have adopted policies to improve our data imputation and employ partial imputation based on available data to approximate the premiums when we do not have complete specialty specific premium data, as reflected in Table 8.C (Source Specialty/Service Risk Group for Imputation for Updated PLI Premium Data) of the ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule.''. In particular, 71-Registered Dietician, (for purposes of impacts) is mapped to Other in Table 8.A. 42- Certified Nurse Midwife is also mapped to Obstetrics/Gynecology. However, we were able to collect sufficient premium data such that partial imputation was not required and we were able to use the actual premium data to formulate a risk index value for both specialties. Therefore, we disagree with commenters and will not re-map Registered Dietician or Certified Nurse Mid-wife in Table 8.A (CMS Specialty Map into Impact Specialty), as no mapping for premium data was required. We believe that the expanded premium data collected is an accurate representation of those specialty's premiums for this update. Therefore, they are also not required to be listed in Table 8.C. for specialties that require partial imputation. Additionally, 19-

Oral Surgery (dental only) is mapped to Maxillofacial surgery for purposes of data imputation. We note that when collecting premium data, Oral Surgery frequently appears together with Maxillofacial surgery. Without additional information to change this mapping and in consideration of their frequency of reporting together, we do not believe it is appropriate to change the mapping for this update. Additionally, without additional information to support a change in mapping, we do not believe it is necessary to change the mapping for 13-Neurology (SURG) and 14-Neurosurgery (ALL). We note that 13- Neurology (SURG) and 14-Neurosurgery (ALL) have had the same risk value for the last two updates of the MP RVUs. For the other requested re-mappings listed above, after further review and consideration of the commenters requests, we are finalizing a change for the following specialties for purposes of partial imputation as reflected in Table 8.C.: 72- Pain Management (ALL) to 11-Internal Medicine (ALL), 98-Gynecologist/oncologist (ALL) to 91-Surgical oncology (ALL), C0-Sleep medicine (ALL) to 13-Neurology (NO SURG), and C7- Advanced heart failure and transplant cardiology (ALL) to 06-Cardiology (NO SURG).

Comment: Several commenters alerted CMS to a technical ratesetting error for technical component (TC)-only services. Commenters were concerned about the ratesetting error causing an inappropriate redistribution effect within the technical component (TC) and professional component (26) such that the relationship became inverted with MP RVUs being drawn away from the 26 services and added to the TC services. Commenters stated that they believe that this error was caused by the change to a risk index and an error within ratesetting to map TC-only services to a 1.00 risk value. Commenters requested that CMS correct the error or delay implementation of the MP RVU update.

Response: We appreciate commenters bringing to our attention the error in calculating the proposed MP RVUs for TC-only services. We agree with commenters that a technical error in our ratesetting system that mapped all TC-only services to a 1.00 risk value resulted in the TC and 26 MP RVU distribution error. For the CY 2020 update of the MP RVUs (84 FR 62606 through 62615), we finalized that we would assign a risk factor of 1.00, which was the lowest physician specialty risk factor (allergy/immunology), to TC-only services due to a lack of sufficient professional liability premium data. For the proposed CY 2023 update of the MP RVUs (87 FR 46016), we stated that, ''When we do not have sufficient premium data for a specialty, our practice has been to use the data from the specialty with the lowest premium. We now have specialty-specific data for many more specialties.'' Our expanded data collection efforts resulted in sufficient premium data such that we could directly assign a risk value for TC-only services without the need for mapping. However, due to a technical error, we continued to assign a 1.0 risk factor for all TC-only services which resulted in an incorrect calculation of the proposed MP RVUs for TC-only services. In consideration of commenters asking us to find a way to resolve the inappropriate distribution or delay implementation, we are finalizing a correction to the ratesetting error for the 2023 update of the MP RVUs. The correction will again map TC-only services to allergy/immunology for this update, which is a risk index value of 0.430. We believe that using this risk value will correct the identified error, while also maintaining as much stability as possible for TC-only services so that there is not a major shift in value from current MP RVUs for the TC and 26 components. We will continue to re-evaluate the MP RVU methodology for TC-only services for future updates.

Additional information on our methodology for updating the MP RVUs is available in the ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*.

After consideration of the comments, we are finalizing the CY 2023 update as proposed with a modification to address an error with respect to the risk values for TC-only services, as indicated above. We are finalizing our proposal to implement a risk index rather than risk factors and improve upon our data imputation strategy by mapping to service risk group/class. We are also implementing a 3-year phase-in for specialties with a reduction in risk value of 30 percent or more to reduce burden, maintain stability in reimbursement for practitioners, and maintain access to services for beneficiaries.

I. Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services

Remote Therapeutic Monitoring (RTM) is a family of five codes created by the CPT Editorial Panel in October 2020, valued by the RUC at its January 2021 meeting, and finalized for Medicare payment in the CY 2022 PFS final rule (86 FR 65114 through 65117). The RTM codes include three PE-only codes and two professional work, treatment management codes.

In the CY 2022 PFS final rule, we finalized refinements to payment for the three PE-only RTM codes: CPT code 98975 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*); CPT code 98976 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*); and CPT code 98977 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*). We valued the three PE-only codes by: (1) cross-walking CPT code 98975 to the PE RVU value of CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate*), *initial; set-up and patient education on use of equipment*); and by (2) cross-walking CPT codes 98976 and 98977 to the PE RVU of comparable CPT code 99454 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*), a code that includes payment for the medical device used to collect and transmit data.

For the two RTM treatment management codes, we finalized the RUC-recommended work RVU of 0.62 for CPT code 98980 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes*) and the RUC-recommended work RVU of 0.61 for its add-on code, CPT code 98981 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the*

patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)).

We also finalized the RUC-recommended direct PE inputs for the two treatment management codes without refinement. The direct PE for these two codes includes clinical labor. According to the supporting materials in the RUC recommendations that we accepted, CPT code 98980 includes 40 minutes of activities performed by clinical staff while CPT code 98981 includes 20 minutes of activities performed by clinical staff as direct practice expenses (PE). The RUC materials describe the activities of clinical staff who perform the clinical labor involved in each of these codes as including: communicating with the patient throughout the month, resolving technology or data transmission concerns, reviewing data with the billing practitioner, updating and modifying care plans, and addressing lack of patient improvement. These activities performed by clinical staff of the billing practitioner would be considered services provided incident to the services of the billing practitioner. For more information about ''incident to'' services, see § 410.26.

We expressed concern in the CY 2022 PFS final rule (86 FR 65116) about the treatment management codes as described by the CPT and RUC. In particular, we expressed concern about the inclusion of clinical labor in codes that could be billed by qualified nonphysician healthcare professionals because Medicare Part B does not include a benefit for services furnished ''incident to'' the services of some types of qualified nonphysician healthcare professionals including CSWs, CRNAs, PTs, OTs, and SLPs. Commenters on the CY 2022 PFS proposed rule (86 FR 65116) agreed with our assessment and suggested that we consider developing new coding to resolve the issue. In the CY 2022 PFS final rule, we finalized a policy that permitted therapists and other qualified healthcare practitioners to bill the RTM codes. We stated that where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the services described by the codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the billing PT's or OT's supervision.

The commenters also expressed concern about another issue with the RTM coding that also relates to the clinical labor in the direct PE for the two treatment management codes (86 FR 65116). The commenters acknowledged that the clinical labor involved in these codes, that is, the portion of these services performed by clinical staff incident to the services of the billing clinician, requires direct supervision by the billing practitioner. The commenters stated that direct supervision of clinical staff performing these activities was burdensome, and suggested that physicians and nonphysician practitioners who can bill for ''incident to'' services would be unlikely to use the codes if direct supervision were required. The commenters suggested that we designate CPT codes 98980 and 98981 as care management services or alternatively, that we develop HCPCS G codes that would allow the ''incident to'' clinical labor portions of the services to be furnished under general supervision of the billing physician or nonphysician practitioner.

Since the CY 2022 PFS final rule was issued, we have remained in communication with interested parties. Conversations continue to revolve around the two concerns detailed above related to the clinical labor in the direct PE for the two RTM treatment management codes, CPT codes 98980 and 98981. Thus, for CY 2023 we proposed to create four new HCPCS G codes with one pair of codes aimed at increasing patient access to remote therapeutic monitoring services and the second pair aimed at reducing physician and NPP supervisory burden.

In the proposed rule, we noted that we also considered requests from interested parties to develop a generic device code for RTM, and that we had decided to wait to develop a generic RTM device code. We explained that we would seek comment to inform any new coding relating to devices. Thus, we sought comment about RTM devices that are used to deliver services that meet the ''reasonable and necessary'' standard under section 1862(a)(1)(A) of the Act. We sought information related to the types of data collected using RTM devices, how the data that are collected solve specific health conditions and what those health conditions are, the costs associated with RTM devices that are available to collect RTM data, how long the typical episode of care by condition type might last, and the potential number of beneficiaries for whom an RTM device might be used by the health condition type.

Summary of the proposal to develop two HCPCS G codes that allow certain qualified nonphysician healthcare professionals to furnish RTM services. As discussed in the proposed rule, we have heard that a primary reason for developing the RTM codes was to increase beneficiary access to remote monitoring services by allowing the services to be furnished by a broad array of qualified nonphysician healthcare professionals (87 FR 46023 and 46024). However, concerns with the CPT coding structure related to the inclusion of clinical labor integral to the professional services have complicated the achievement of those goals. In the CY 2022 PFS final rule, we finalized a policy that permitted therapists and other qualified healthcare practitioners to bill the RTM codes, though we expressed some concerns about the ability of therapists to bill for these codes because the Medicare benefit does not include services provided incident to the services of a therapist (86 FR 65116). We stated that where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the services described by the codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the billing PT's or OT's supervision. We stated that these practitioners could bill CPT codes 98980 and 98981 even when the practitioner's Medicare benefit category did not include services furnished incident to their professional services as long as the services were furnished directly by the billing practitioner.

In this year's proposed rule, as a means of increasing beneficiary access to RTM services, as well as to more clearly define the services of RTM for qualified nonphysician healthcare practitioners whose Medicare benefit category does not include services provided incident to their own services, we proposed to create two new codes that would expressly facilitate RTM services furnished by qualified nonphysician healthcare professionals who cannot bill under Medicare Part B for services furnished incident to their professional services. These codes would not include ''incident to'' activities in the PE. Neither of the two proposed new codes included clinical labor inputs in the direct PE. We also proposed to make the current CPT codes 98980 and 98981 codes non-payable by Medicare.

We proposed the following two HCPCS G codes:

- GRTM3 (*Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month*).
- GRTM4 (*Remote therapeutic monitoring treatment assessment*

services, additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month (List separately in addition to code for primary procedure)).

For CY 2023, we proposed a work RVU of 0.62 for the base code, HCPCS code GRTM3, which is the RUC-recommended work RVU we established for CPT code 98980 in the CY 2022 PFS final rule. Similarly, for the add-on code, HCPCS code GRTM4, we proposed a work RVU of 0.61, which is the RUC-recommended value we established for CPT code 98981. We proposed to remove the clinical labor inputs in the direct PE for both codes, which will facilitate the use of these codes by qualified nonphysician healthcare practitioners who cannot bill under Medicare Part B for services furnished incident to their professional services. See Table 34: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services for more detailed information about the codes.

Additionally, we noted that all the RTM codes including proposed HCPCS codes GRTM3 and GRTM4 would be designated as ''sometimes therapy'' codes, which means that the services could be billed outside a therapy plan of care by physicians and certain NPPs. We noted that when the services described by proposed HCPCS codes GRTM3 and GRTM4 are furnished by PTs, OTs, or SLPs, the services would always need to be furnished under a therapy plan of care. We reminded readers that RTM services that relate to devices specific to therapy services should always be furnished under a therapy plan of care *regardless of who provides them.* See the Medicare Benefit Policy Manual Chapter 15, Section 230 for more information about the practice of PT, OT, and SLP.

Summary of the proposal to develop two HCPCS G codes allowing general supervision of auxiliary personnel. As we described in the proposed rule, since the CY 2022 PFS final rule was published, we have continued to hear concerns from interested parties that, as for most ''incident to'' services, the clinical labor activities described in the direct PE of CPT codes 98980 and 98981 must be furnished under the direct supervision of the billing practitioner, which imposes burden on physicians and NPPs who are delivering services to other patients. Thus, for CY 2023, we proposed to create two HCPCS G codes, one base code and one add-on code, that include clinical labor activities (that is, incident to services such as communicating with the patient, resolving technology concerns, reviewing data, updating and modifying care plans, and addressing lack of patient improvement) that can be furnished by auxiliary personnel under general supervision. These two new G codes, GRTM1 and GRTM2, include physician work and direct PE inputs as currently described in CPT codes 98980 and 98981 but allow general supervision of the clinical labor found in the direct PE inputs. See Table 34: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services for more detailed information about the codes and use of the codes.

We proposed the following two HCPCS G codes:

- HCPCS code GRTM1 (*Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes of evaluation and management services*).
- HCPCS code GRTM2 (*Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver over a calendar month; each additional 20 minutes of evaluation and management services during the calendar month (List separately in additional to code for primary procedure*).

For CY 2023, we proposed a work RVU of 0.62 for HCPCS code GRTM1, which reflects the work RVU for CPT code 98980 that we finalized in the CY 2022 PFS final rule. For HCPCS code GRTM2, we proposed a work RVU of 0.61, which is the RUC-recommended value we finalized for the similar CPT code 98981. We proposed the direct PE inputs associated with CPT codes 98980 and 98981 without refinement for HCPCS codes GRTM1 and GRTM2, respectively. As stated previously, we proposed to make the current CPT codes 98980 and 98981 codes non-payable by Medicare.

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TABLE 34: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services

HCPCS Code	Code Descriptor	Global Period	Work RVU Recommendation
GRTM1	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes (Report GRTM1 once each 30 days, regardless of the number of parameters remotely monitored) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2) (At least 16 days of data must be reported) (Do not report GRTM1 for services less than 20 minutes) (Do not report GRTM1 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM3, GRTM4) (Do not report GRTM1 in the same calendar month as 99473, 99474)	XXX	0.62
GRTM2	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure) (Use GRTM2 in conjunction with GRTM1) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2) (Do not report GRTM2 for services less than of 20 minutes) (Do not report GRTM2 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM3, GRTM4)	ZZZ	0.61

HCPCS Code	Code Descriptor	Global Period	Work RVU Recommendation
GRTM3	Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (Report GRTM3 once each 30 days, regardless of the number of parameters remotely monitored) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM3 and GRTM4) (At least 16 days of data must be reported) (Do not report GRTM3 for services less than 20 minutes) (Do not report GRTM3 in conjunction with 93264, 99457, 99458. 98980, 98981, GRTM1, GRTM2) (Do not report GRTM3 in the same month as 99473, 99474)	XXX	0.62
GRTM4	Remote therapeutic monitoring treatment assessment services, each additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (List separately in addition to code for primary procedure) (Use GRTM4 in conjunction with GRTM3) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM3 and GRTM4) (Do not report GRTM4 for services less than 20 minutes) (Do not report GRTM4 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM1, GRTM2)	ZZZ	0.61

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Review of New RTM Device Code: Cognitive Behavioral Therapy Monitoring (CPT Code 989X6)

During its October 2021 meeting, the CPT Editorial Panel replaced two Category III codes: 0702T (*Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days*) and 0703T (*Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional per calendar month*) (*e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response*) with the Category 1 CPT code 989X6, Cognitive Behavioral Therapy Monitoring (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response); initial set-up and patient education on use of equipment; device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*). The CPT Editorial Panel created 989X6 for CY 2023 and deleted Codes 0702T and 0703T.

Also, during the October 2021 meeting, the CPT Editorial Panel revised the code descriptors for the PE-only RTM codes (that is, CPT codes 98975, 98976, and 98977) that CMS finalized in the CY 2022 PFS final rule (86 FR 65114 through 65117) to include ''cognitive behavioral therapy'' as another example of the type of service described by the coding. The RUC indicated that it considered this revision to be editorial.

During the January 2022 RUC review, the definition of new CPT code 989X6 was further refined to read *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily)*

recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days). During the RUC review of CPT code 989X6, specialty societies indicated that the technologies for this service are still evolving. As a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. In response, the RUC recommended that CPT code 989X6 be contractor priced.

Given the anticipatory nature of this code, we agreed with the RUC recommendation that this new code should be contractor priced until we learn more about the devices being used to furnish the service. Thus, we proposed to accept the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. There is no professional work associated with the code. We noted that we would work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the new cognitive behavioral monitoring code, CPT code 989X6.

We thanked last year's commenters and the many others who have contacted us with their questions and ideas. We noted that we appreciated the continuing dialogue about the remote monitoring codes and welcomed comments including any additional information that the medical community and other members of the public believe may provide further clarity on how remote patient monitoring services are used in clinical practice, and how they would be most appropriately coded, billed and valued under the Medicare PFS.

The following is a summary of the public comments received on the proposed revisions to the Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services and our responses:

Comment: A number of commenters provided specific feedback about our discussion of the purpose and intent of the proposed new codes, GRTM1–4. In particular, commenters noted that if finalized, the aims of increasing access to RTM services while reducing burden associated with use of the codes may not manifest. In particular, some questioned whether our proposals would result in appropriate levels of payment that reflect the burden of supervision and coordination of different levels of clinical staff and skills, including use of auxiliary personnel, required to furnish RTM services. Some commenters noted that creating G codes as a means to address various different levels of effort of clinical staff involved in rendering these services would possibly create confusion and increase burden; these commenters also responded that various types of clinical staff activities are already accounted for in the existing RTM codes. One commenter cited our finalized policies from last year, expressed confusion about the complexity and utility of creating a new set of codes, and stated that CMS should instead modify the level of supervision required for the existing codes because the supervision requirements are themselves within our specific delegated authority to adjust.

Response: We thank commenters for the feedback on our proposed GRTM codes, and note that our response here is consistent with our discussion of the existing code set in previous rulemaking. In our CY 2022 final rule, we noted that despite our concerns about the construction of the codes, we believe the services RTM described by the codes are important to beneficiaries. (86 FR 65116). In this year's rulemaking, we find similar themes. Commenters remain supportive of our efforts to enhance access to RTM and RPM services, yet commenters also continue to raise concerns similar to feedback received on last year's proposals for RTM. Our proposals for GRTM1–4 drew concern from various perspectives.

As commenters noted, the existing RTM codes do reflect a broad range of clinical activities, and use of various levels and involvement of auxiliary staff. To this point, in the CY 2022 PFS final rule (86 FR 65114 through 65117), we discussed and finalized a policy that permits therapists and other qualified healthcare professionals to bill the RTM codes. As noted, the billing rules for the current family of RTM codes do allow a broader range of clinical activities and varied levels and involvement of auxiliary staff. We refer readers to our discussion in the CY 2022 PFS final rule that addresses the RTM family of codes: the initial set-up and patient education services (CPT code 98975), as well as the device codes (CPT codes 98976 and 98977), as well as the treatment management codes (CPT codes 98980 and 98981). There we explained our thinking and experience with the RTM code family which led us to this year's proposed G-codes. We reiterate that the general feedback we have received for RTM codes suggested two possible paths forward. One path was reflected in the proposal that appeared in this year's proposed rule; another path is an alternative that we described in response to comments in the CY 2022 PFS final rule. The alternative to the creation of new G-codes as we proposed was to instead modify our supervision policy for services furnished incident to a practitioner's professional service to require a general level of supervision, rather than direct supervision, for the existing RTM codes (CPT codes 98975, 98976, 98977, 98980, and 98981) as we have done for certain designated care management services. We thank commenters for continuing to provide feedback, and agree with commenters who noted that the current CPT code descriptions for RTM treatment management encompass a broad range of practitioners and clinical staff activities. We refer readers to our discussion in last year's final rule for background on the valuation of CPT codes 98980 and 98981 (86 FR 65116).

However, we acknowledge that our proposals may have generated confusion among some interested parties. Based on some of the comments received, we believe some interested parties may have misinterpreted our proposed valuation of the G-codes, GTRM–3 and GTRM–4. Specifically, we received comments that misunderstood our proposed valuation for GTRM–3 and GTRM–4 to mean that we proposed an across-the-board cut to payment for all Medicare Part B payment for certain types of non-physician practitioners that current may bill the RTM treatment management codes (CPT codes 98980 and 98981). Based on public comments, we agree that confusion remains about how the new G-codes, if finalized, would or would not possibly create a chilling effect on the availability of RTM services.

Comment: Some commenters submitted general feedback regarding the RTM codes rather than our specific proposals, and stated that individual practitioners or their employers would not engage in further investment of time and resources that would be required to implement, maintain, and support RTM services without better clarity on three main aspects of our RTM policy. In brief, these comments focused concerns about the burden associated with maintaining direct supervision for all auxiliary staff involved in furnishing RTM services, the difficulty of navigating ambiguity as to the data that must be kept and maintained for recordkeeping and care coordination, and uncertainty about whether certain devices would or could be used in light of the first two issues regarding supervision and recordkeeping requirements. We received feedback that generally questioned how practitioners should navigate furnishing RTM services when the requirements

appeared to create a risk of later needing to return payments after potential future CMS audits. Some commenters also suggested that CMS would ''claw back'' payment for these services if an individual beneficiary received concurrent RTM services from two different clinicians engaged in separate episodes of care that involved provision of RTM services for the same beneficiary during the same month, which is not allowed under current policy. Some commenters also shared anecdotal evidence that suggests RTM services do or will improve health equity, and were concerned that our imposition of limitations or burdensome requirements, or possible payment denials or recovery of overpayments, may create disincentives that reduce beneficiary access to RTM services.

Response: We believe that our goals have remained consistent throughout our efforts to shape RTM and RPM coding and payment policy, and refer to our CY 2020 (84 FR 62697 through 62698), CY 2021 (85 FR 84542 through 84546), and CY 2022 (86 FR 65114 through 65116) rules for further background discussion of these goals. In the CY 2023 PFS proposed rule, we included proposals to address specific issues relating to the CPT code set for RTM services, and in particular the RTM treatment management codes (CPT codes 98980 and 98981). We recognize and appreciate the more generalized concerns raised by these commenters and will take these comments into consideration for possible future rulemaking.

Comment: Many commenters requested that CMS reconsider the proposals because the burden of the proposed GRTM codes would involve a requirement that certain supply codes (CPT codes 98975 and 98976 or 98977) must be billed prior to furnishing the services reflected in GRTM1–4. This feedback came from various interested parties, which included a diverse set of perspectives and roles across the medical community, various trade associations, many professional societies, and health IT vendors. In summary, the commenters suggest that the timing and sequence of proposed requirements for the proposed GRTM codes would possibly create gaps in care, or delays in access to care.

Some commenters expressed concern about initiating an episode of RTM services without necessary claims data available to know whether an existing and overlapping RTM service is being billed for the same beneficiary for a different episode of care initiated by a different practitioner in any given month. We received comments from healthcare providers and vendors that support medical practices expressing concern about the need to avoid situations where a practitioner may furnish RTM services, and later be expected to return Medicare payment, if CMS were to determine that all applicable requirements were not met. These commenters suggested that such scenarios could result in unstable or uncertain financial liability. Vendors requested more clarity about the structure and form of data that would need to be available at the point-of-care, including claims history that would be necessary to track a beneficiary's current use of RTM services and assess whether the beneficiary would be eligible to begin any additional RTM service. Some in the clinical community suggested that it would be difficult or impossible to track the necessary information to know whether a beneficiary is eligible for RTM services.

Commenters who raised these concerns explained that CMS' proposals may cause delays in delivery of necessary care, or unduly limit access. Further, commenters reiterated feedback we had received in previous rulemaking that CMS should allow multiple, concurrent RTM services for an individual beneficiary, which would not be permitted under existing policies or under our proposed policy changes, if finalized.

Response: We thank the commenters for sharing their views and appreciate the questions and concerns they presented. We continue to gather information and experience with coding and payment policies for RTM services. We will continue our discussions with healthcare providers and MACs to understand opportunities and challenges related to our policies and claims processing for RTM codes, and consider the need for further guidance, practitioner education, program instructions, or further rulemaking regarding these services.

Comment: Commenters who responded to our request for feedback on the possible future development of a generic RTM device code noted that a generic RTM device code would allow a broader range of types of remote therapy monitoring, beyond the existing codes that allow payment for services that address respiratory system status, musculoskeletal status, and therapy adherence, or therapy response. Some commenters stated that a path forward is unclear because certain approved devices monitor conditions that presently have no available RTM code (for example, specific neurological conditions), and requested that we consider establishing in the future a mechanism to submit data on these types of devices and conditions that any clinical specialty. Commenters generally supported the concept of a generic RTM device code, and offered a wide variety of possible use cases, where FDA approved devices already exist for the purpose of monitoring various conditions that do not meet the current scope of the existing RTM codes. These included monitoring during episodes of care for various neurological conditions, and others.

Response: We thank the many commenters who suggested ways we could consider implementation of a possible future generic device code for RTM. We note that it remains unclear whether a generic device code would be administrable as a permanent policy, for many reasons. We refer readers to last year's discussion of valuations of supplies and equipment for RTM services (86 FR 39173). Comments received in response to the CY 2023 PFS proposed rule seem to reinforce that it may be difficult to establish an appropriate valuation for a single device code that would reflect the myriad of possible applicable devices.

We note that the valuation of a generic device code would require some consensus on the mix and balance of costs for these devices, which would be difficult to develop when there such wide variability in the devices themselves and in how the devices support delivery of RTM services. Further, we note that a generic device code would require covering many more clinical topics than exist under our current policies. Our current policies allow payment using the RTM codes for services that support an episode of therapy where the clinical issue ties to musculoskeletal, or respiratory, or medication adherence/response.

Commenters noted the varied ways that an individual device is costed and priced for use on the market. Vendors also make available a broad array of pricing models that clinical practices could consider in making technology investments to furnish RPM and RTM services. For example, vendors may offer discounts, or waivers of licensing fees, or reduced fees for licensing of a device when used with other, unrelated products; all of these influence the cost of a given device.

We reiterate our clarification included in previous rulemaking (85 FR 84545) that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and

that the services must be reasonable and necessary.

We continue to weigh the possible tradeoffs that would be necessary to further reduce coding and billing complexity for RTM, and increase care delivery flexibility and retain appropriate beneficiary access to RTM services. As noted in the CPT codebook, at page 843, RTM services, ''...represent the review and monitoring of data related to signs, symptoms, and functions of a therapeutic response. These data may represent objective device-generated data or subjective inputs reported by a patient. These data are reflective of therapeutic responses that provide a functionally integrative representation of patient status.'' We will look to evidence-based peer-reviewed sources, as well as clinical practice guidelines, in addition to engaging with interested parties, to inform any decisions about whether it would be practicable to establish a generic RTM device code that is potentially agnostic to the specific body system involved (that is, musculoskeletal, respiratory) or therapy type (that is, medication therapy response) that the device monitors, in future rulemaking. However, we note that the CPT codebook makes clear that RTM services must be ordered by a physician or other qualified health care professional, and that any device used must be a medical device as defined by the FDA, and that CPT codes 98980 and 98981 (RTM treatment management codes) should not be used for time that can be reported using codes for more specific monitoring services. (CPT codebook, at page 843). Informed by our experience with RPM payment policy refinements, and in light of possible forthcoming changes to CPT coding for both RPM and RTM, it remains unclear whether generic device codes would undermine or stall progress toward a wider set of specific codes that would provide less ambiguity. As such, we appreciate the commenters' views on this topic and the continuing dialogue on these important issues around coding and payment policies for RTM services.

Comment: Some commenters suggested that the indirect PE allocations for the proposed GRTM codes do not adequately consider the costs of the included use of various computer software, and stated that certain types of software are incorrectly categorized within the PFS; or that the concepts related to software, and devices themselves, should not be addressed as categorical questions specific to RTM. Among these comments, some also expressed concern about the definition of ''device'' in the RTM codes. One commenter noted that CMS does include specific software costs as supplies within direct PE for other codes, and suggested that this should be a basis for both reconsidering our GRTM proposals and the current RPM valuations. Other commenters requested more clarity about what specific devices would be appropriate for purposes of RTM services. Many commenters recommended that we separately consider Software as a Medical Device (SaMD), use of artificial intelligence (AI)/machine learning algorithms (ML), and related topics as part of a standalone RFI which would later inform updates to specific codes because the influence of these topics have impacts far beyond the RTM codes alone.

Response: Historically, we have considered most computer software and associated licensing fees to be indirect costs. We refer readers to our previous discussions of this topic in our CY 2019 final rule. (83 FR 59577). Further, we continue to believe that licensing fees that would not be allocated to the use of a specific piece of software/equipment/device for an individual patient for an individual service, are better understood as forms of indirect costs similar to office rent or administrative expenses. Refer to our discussion of this aspect of licensing specifically in our CY 2019 proposed rule (83 FR 35771). As we noted in section II.B. of this final rule (the RFI for Updates to PE Methodology section), interested parties have routinely expressed concerns with allocations of indirect costs, especially for evolving technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware. We continue to engage in discussions and conduct further research into these topics of AI, SaMD, and other related evolving technologies, to understand ways that we may refine our allocations of cost for software and licensing.

We remind readers that in finalizing valuations for the current family of RTM codes, we have considered the RUC-recommended inputs for the codes, and in doing so, considered all elements of RTM described by the AMA in CPT code descriptors. For more detail on this discussion, refer to last year's proposed rule (86 FR 39173). Within the RTM family of codes, the structure of the code set relies on use of device codes (PE only) that are used in conjunction with the remainder of the RTM codes. CPT code 98976 and 98977 are intended to report a 30-day device supply with scheduled recordings or program alert transmission to monitor the respiratory system (98976) or musculoskeletal system (98977). In the CY 2022 PFS final rule, we finalized refinements to payment for the three PE-only RTM codes: CPT code 98975 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*); CPT code 98976 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*); and CPT code 98977 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*).

We refer readers to the publicly available FDA guidance and explanations for medical devices, including explanations of SaMD. As SaMD, as a broader topic, is outside the scope of our proposed policies, we are not issuing any specific guidance. FDA guidance on SaMD is available at *https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd.* Additionally, we refer readers to CPT Appendix S: *AI taxonomy for medical services & procedures* (available at *https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures*). We note that our proposals do not include a specific RTM device list, nor specific examples of RTM devices that would be appropriate for use when furnishing RTM services. We believe that a possible unintended consequence of express reference to a device, or list of devices, may include a preference or shift toward use of one device or class of device simply because of its inclusion on a list. We believe that the pace of innovation and evidence-based clinical decision-making inherent to use of the devices that support furnishing RTM services calls for medical and behavioral health professionals, groups of behavioral health and medical professionals, or professional societies, each to study carefully the needs of the populations under their care, and identify guidelines that shape selection and use of any specific device in clinical practice.

Comment: A number of commenters expressed concerns with the duration of data collection required to meet

reporting minimums for these codes. Various commenters gave examples of monitoring requirements for individual clinical needs that would not require a full 16 days of data. Examples provided addressed use of standardized screening tools, such as electronically-reported Patient-Reported Outcomes (e-PRO) tools, which may be collected through SaMD. A beneficiary using these tools self-reports clinically relevant information by responding to prompts, based on recall over shorter periods of time (for example, over the past day, or 7 days). Other commenters explained that it was ambiguous whether the act of data collection must occur at least 16 days per month, or if data collection less than 16 times in a 30-day period would satisfy the requirement when these data are representative of 16 or more days of clinically relevant transmittable information.

Some commenters suggested that our proposals would create unintended consequences of overtreatment to satisfy data collection minimums, when therapeutic benefit would otherwise be possible in far fewer therapy sessions or discrete uses of the RTM device. Other commenters explained that facilitating patient self-management through tracking adherence, and symptom and trigger logging via a mobile app all represent collection of data that would be useful to provide practitioners better insight into clinically meaningful events; commenters provided examples, such as the use of a remote therapy monitoring device that connects a patient to an as-needed means to track potential side-effects of an ongoing, current medication therapy regimen. In these examples, commenters stated that when a frequency of use requirement is set in place by the practitioner to satisfy billing requirements, the requirement represents unnecessary burden for the beneficiary and may degrade the validity of patient-reported data.

Response: We thank commenters for the feedback on our minimum data requirements for reporting RTM. Readers should also refer to our discussion of these requirements in previous rulemaking. (85 FR 84544). We believe a restatement of our current policies, which points to existing resources that are publicly available, and were available to the public when we finalized our existing RTM requirements, would assist readers in easier access to resources that may inform individual clinical and beneficiary choices. To avoid possible interference with clinical decision-making and shared decision-making, at this time, as discussed in the response immediately above, we are not issuing specific examples of devices that might be used in the delivery of RTM services because we believe that to do so could generate further confusion, as well as have the possible unintended consequence of implying our approval or endorsement of a specific tool, device, use of a device, or shift by practitioners toward use of a specific device when offering RTM services. However, we would be supportive of the clinical community offering such examples in the context of clinical practice guidelines, preferably generated with a patient-centered focus and an emphasis on health equity considerations.

For more background on our earlier development of payment policies for the related RPM family of codes, refer to the discussion in the CY 2019 FR (83 FR 53015). We believe that as with RPM policy development, this year's finalized policies may not mitigate the need for further revisions to coding and payment policies for RTM services, which would be addressed in future rulemaking, in order to account for some of the concerns raised by commenters regarding the broad nature of codes that describe professional collection and interpretation of stored patient data. Further, also similar to the trajectory of the RPM policies we developed and refined over the last 5 years, we continue our efforts to understand better how CPT code revisions that are expected soon, or planned for future years, would possibly address certain concerns, and in the specific case of minimum reporting specifications, the CPT Editorial Committee's consideration of new codes that would require less than 16 days of data collection.

After considering all of the public comments received on our RTM proposals this year, we are not finalizing the proposed creation of 4 new G-codes, (GRTM–1–4). Instead, for CY 2023, we are maintaining our current policies for the RTM treatment management CPT codes 98980 and 98981, with exceptions as noted below. Commenters expressed many perspectives, views, and general support for remote therapeutic monitoring services. Yet, the totality of the circumstances and broad range of interests and priorities presented by commenters leads us to believe that there should be continued discussion on these topics before CMS finalizes changes to the current RTM coding and payment policies that go beyond refinements to our supervision and documentation requirements for RTM. We continue to engage with the public, and assess the landscape of RTM devices and services, and will consider addressing the RTM codes and associated payment policies in future rulemaking that will aim to build on progress in this area, while mitigating commenters' concerns.

We are not finalizing our proposal to create 4 new G-codes, (GRTM–1–4) which we proposed to address various issues relating to incident-to services, inclusions of clinical staff time, and supervision levels. CMS proposed to establish a general level of supervision for the two G codes (GRTM–1 and GRTM–2) that include services incident-to services of physicians and NPPS, but not for the other G codes (GRTM–3 and GRTM–4). Commenters recommended that CMS instead permit general supervision of incident-to services described by the two treatment management CPT codes (98980, and 98981). With that said, in this final rule, we are issuing a clarification and finalizing a new policy regarding the billing requirements for the current RTM codes: CPT codes 98975, 98976, 98977, 98980, and 98981. Beginning January 1, 2023, below modifications to our existing RTM policies take effect:

- *General supervision for all RTM services.* Any RTM service may be furnished under our general supervision requirements.
- *Cognitive behavioral therapy monitoring device.* We are finalizing our proposal to accept the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. There is no professional work associated with the code. We will work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the new cognitive behavioral monitoring code, CPT code 989X6.

Therapy KX Modifier Threshold Amounts

The KX modifier thresholds, formerly referred to as therapy caps, were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest $10.00.

For CY 2023, we proposed to rebase and revise the MEI to a 2017-base year as discussed in section II.M. of this final rule, and we are finalizing the 2017-

based MEI for CY 2023, with technical modifications based on public comments. Therefore, we are increasing the CY 2022 KX modifier threshold amount of $2,150 by the CY 2023 MEI of 3.8 percent and rounding to the nearest $10.00, which results in a CY 2023 KX threshold amount of $2,230 for PT and SLP services combined and $2,230 for OT services.

Section 1833(g)(7)(B) of the Act was also added by section 50202 of the BBA of 2018 and it retains the targeted medical review process, but at a lower threshold amount of $3,000 (until CY 2028 when it is updated by the MEI). Accordingly, for CY 2023, the MR threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Under the established targeted review process, some, but not all, claims exceeding the MR threshold amount are subject to review. Information on the targeted manual medical review process is available at *https://www.cms.gov/ResearchStatistics-Data-and-Systems/MonitoringPrograms/Medicare-FFSCompliancePrograms/Medical-Review/TherapyCap.html*.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services.

We apply the same PFS-rate accrual process noted above to outpatient therapy services furnished by critical access hospitals (CAHs), even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014).

When the expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. By using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

J. Payment for Skin Substitutes

1. Background

In the CY 2022 PFS final rule, in order to address the need to establish a payment mechanism for synthetic skin substitutes in the physician office setting and to be responsive to feedback received from commenters, we finalized an approach for payment of each of 10 synthetic skin substitutes in the physician office setting for which we had received a HCPCS Level II coding application, and we finalized that those products would be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them. The ten products are as follows: NovoSorb® SynPath™, Restrata® Wound Matrix, Symphony™, InnovaMatrix™ AC, Mirragen® Advanced Wound Matrix, bio-ConneKt® Wound Matrix, TheraGenesis®, XCelliStem®, Microlyte® Matrix, and Apis® (86 FR 65121). After the CY 2022 PFS Final rule was released, we deleted the ''A'' code that was established for bio-ConneKt Wound Matrix after subsequent determination that a HCPCS Level II code, Q4161, was already established for this product. We note that since we issued the CY 2022 PFS final rule, we have received additional HCPCS Level II coding applications for similarly situated 510(k) cleared wound care management products. HCPCS ''A'' codes have been issued that described those products and are payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them.

We also received several comments in response to our finalized policies expressing concern about potential inconsistencies in our policies for synthetic and non-synthetic skin substitutes. We indicated we would take these concerns into future consideration.

2. Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

We outlined our HCPCS Level II coding and payment policy objectives in section III.N. of the CY 2023 PFS proposed rule (87 FR 46249) because we believed it would be beneficial for interested parties to understand our priorities as we work to create a consistent approach for the suite of products we have referred to as skin substitutes. As discussed in the CY 2023 PFS proposed rule, we have a number of objectives related to refining our Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the physician office setting; however, interested parties have also indicated that further alignment of our policies across the physician office and hospital outpatient department settings would reduce confusion.

In past years, interested parties have suggested that all skin substitutes, regardless of the inclusion of human, animal, or synthetic material in the product, should be treated as drugs and biological products. Furthermore, they believe all skin substitute products should receive product-specific ''Q'' codes and receive separate payment under the ASP+6 methodology. They have expressed confusion regarding our assignment of HCPCS Level II ''A'' codes to 9 [111] skin substitute products referenced in the CY 2022 PFS final rule, which are codes we typically assign to identify ambulance services and medical supplies, instead of ''Q'' codes, which we typically assign to identify drugs and biologicals. They have indicated that the use of HCPCS Level II ''A'' codes has caused confusion, not only for interested parties, but also for the A/B MACs. The interested parties assert that the A/B MACs have inconsistently processed submitted claims in part because the products are assigned HCPCS ''A'' codes are treated as supplies and are subject to contractor pricing under the PFS. Additionally, interested parties have expressed concern that physicians and practitioners are hesitant to use the products associated with ''A'' codes because they are unsure what they will be paid when using those products. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased approach over the next 1 to 5 years that allows CMS sufficient time to consider input

[111] As explained above, we deleted the A code for one product after determining that it had already been assigned a Q code.

from interested parties on coding and policy changes, primarily through our rulemaking process, with the goal of ensuring access to medically necessary care involving the use of these products.

We welcomed comment on our policy objectives for creating a consistent approach for treatment of the suite of products we have referred to as skin substitutes. Additionally, we welcomed feedback on the phased approach and associated timeline. To achieve our objective of creating a consistent approach for paying for skin substitutes across the physician office and hospital outpatient department setting, we included similar proposed changes in the CY 2023 OPPS proposed rule.

Comment: A few commenters stated that they appreciate CMS' efforts to improve and clarify policies and procedures and expressed support for the key objectives and roadmap outlined by CMS for the consistent treatment of skin substitutes.

Response: We appreciate the commenters' support of our key objectives and roadmap.

Comment: One commenter suggested that CMS should also consider a fifth objective to guide decision making with regards to skin substitutes. Specifically, the commenter suggested that CMS should aim to provide broad access to these products by Medicare beneficiaries who would benefit from their use, regardless of wound size, wound type, or geographic location.

Response: We appreciate this feedback from the commenter and note that we are interested in health equity for all Medicare beneficiaries. We will consider potential additional objectives in future rulemaking.

3. Changing the Terminology of Skin Substitutes

In the CY 2023 PFS proposed rule (87 FR 46028), we stated that as we work to clarify our policies for these products, we believe that the existing terminology of ''skin substitutes'' is an overly broad misnomer. In the CY 2021 OPPS/ASC final rule with comment period, we revised our description of skin substitutes to refer to a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers (85 FR 86605). We noted that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that within the hospital outpatient department, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. (85 FR 86066).

While this description has been updated to provide clarity that synthetic products typically regulated as devices by the FDA are considered to be skin substitutes, there is still confusion with the usage of the term skin substitutes because as noted in the discussion above, these skin substitute products are technically not a substitute for skin, but rather, a wound covering. We have used the current term ''skin substitutes'' to describe the suite of products that are currently referred to as skin substitutes. Additionally, the term ''skin substitutes'' is used within the Current Procedural Terminology (CPT®) code series 15271–8 as maintained by the American Medical Association. Also, skin substitute products are generally regulated by the FDA as medical devices under section 510(k) of the Federal Food, Drug and Cosmetic (FD&C) Act and implementing regulations per 21 CFR part 807, or as HCT/Ps solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. The FDA approves new drugs through the New Drug Application (NDA) pathway, and approves biological products through the Biologics License Application (BLA) pathway.

We believe that improving how we reference these products by using a more accurate and meaningful term will help address confusion among interested parties about how we describe these products, and further, how we pay for them. We proposed to replace the term ''skin substitutes'' with the term ''wound care management'' or ''wound care management products.'' We explained that we believe this new term more accurately describes the suite of products that are currently referred to as skin substitutes while providing enough specificity to not include bandages or standard dressings, which as noted above, are not considered skin substitutes. We noted that we understand that the proposed terms contain the words ''care management'' which could be construed to implicate the care management series of AMA CPT codes (for example, 99424–99427, 99437, 99439, 99487, 99489, 99490–99491) that are commonly used by healthcare professionals. We also explained that we understand that the use of the word ''management'' in the proposed terms might be construed by some to implicate AMA CPT Evaluation or Assessment and Management (E/M) codes. We clarified that the proposed terms, ''wound care management'' and ''wound care management products,'' would not implicate the care management series of AMA CPT codes (for example, 99424–99427, 99437, 99439, 99487, 99489, 99490–99491), or our own G-codes that describe care management services. Nor would our proposed terms relate to the AMA CPT E/M codes. Unlike ''care management'' or ''evaluation and management'' codes and services, the proposed terms would describe a category of items or products, not a type of services. Lastly, we noted that we also considered alternate terms such as wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds but believe the proposed terms are more technically accurate and descriptive for how these products are used than the alternatives considered.

We solicited comment on the proposal to change the terminology we use for the suite of products referred to as ''skin substitutes'' to instead use the term ''wound care management'' or ''wound care management products,'' and on the alternative terms we considered including wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds. We noted that we were particularly interested in how these products are referenced in current CPT coding and would appreciate feedback from the CPT Editorial Panel and other interested parties on how to address the challenges we discuss above. We also requested comment on other possible terms that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes.

Comment: A few commenters agreed with the proposed terminology change to wound care management products.

Response: We thank the commenters for their feedback and support.

Comment: Several commenters disagreed with the proposed terminology change, as well as with all of the alternative terms we considered; and suggested that we should retain the term skin substitute. Some commenters stated that the CPT Editorial Panel was purposeful in creation of the skin substitutes application codes (CPT codes 15271–15278) to specifically describe instances that are, and are not, appropriate to report as the application of skin substitutes. In contrast, the CPT procedure codes associated with wound care management are distinctly different in both purpose and products used in their delivery. A few commenters stated that it is clear that skin substitutes are very specific and separately reportable from wound dressings, and changing the

terminology to wound management would differ from CPT nomenclature and cause confusion and inconsistent reporting. A few commenters stated that changing the terminology to wound care management products would conflate skin substitute products with other products like wound care dressings or bandages. The commenters stated that the proposed terminology incorrectly suggests that the skin substitute products are not technically a substitute for skin, but rather, a wound covering that is used to promote healing. The commenters stated that this is not accurate, as the application of skin substitutes serves a specific purpose of temporary or permanent coverage of open skin wounds. Therefore, the commenters stated that the assumption that a skin substitute is just a wound covering is inaccurate. They stated that the application of the product is part of the recovery process, and indicated that the product does function similarly to skin as it is not always removed. The commenters stated that whether the product is applied temporarily and later removed, or is placed and not removed, the skin substitute is allowing for the construction of natural dermis which goes above and beyond a ''wound covering.'' The commenters further pointed out that the CPT coding guidelines specifically outline the application of skin substitutes grafts as non-autologous human skin grafts, non-human skin substitute grafts, and biological products that form a sheet scaffolding for skin growth. The commenters asserted that there is a possibility that as technology evolves, new categories of wound care may become available; however, the CPT guidelines and reporting for skin substitutes are clear and they do not include the application of non-graft wound dressings (for example, powder, ointment, foam, liquid) or injected skin substitutes, and those items should not be lumped together in a catch-all terminology such as wound management. Some commenters stated that the proposed terminology is not necessarily more accurate or meaningful than the existing term. A few commenters suggested that CMS work directly with the CPT Editorial Panel, relevant medical specialty societies, and industry representatives to determine the optimal approach to updating skin substitutes terminology.

Response: While we continue to believe that the term skin substitutes is an overly broad misnomer, and believe that improving how we reference these products by using a more accurate and meaningful term will help to address confusion about how we describe these products, we also believe that it is important to adopt the most appropriate terminology to more accurately capture the full suite of products. After considering the public comments, we believe that additional dialogue will be beneficial before finalizing new terminology. The feedback received through the public comments process has been helpful and informative, and we would like to further engage with stakeholders prior to adopting any new terminology in future rulemaking. As such, we are not finalizing changes to the terminology at this time. We will continue to carefully consider the comments that were received in response to this proposed rule, and welcome additional input from interested parties. Additionally, we intend to hold a Town Hall in early 2023, prior to CY 2024 rulemaking, to have additional discussions in an effort to further understand the concerns interested parties have about potential new terminology we could consider and any other alternative terms not yet considered.

Comment: Several commenters agreed that the term skin substitute is not accurate and stated that it does not reflect the entry of synthetics in the marketplace, but disagree with the proposed terminology.

Response: As indicated above, though we still intend to change the terminology to more accurately capture the full suite of products, we are not finalizing a change in terminology at this time. We intend to discuss this issue further in a Town Hall and anticipate addressing it in future rulemaking.

Comment: A few commenters suggested alternatives including: Cellular and/or Synthetic Grafts for Surgical Wound Management; Bioengineered, Cellular or Tissue-Based Products; Skin Matrix/Matrices; and Ulcer/Wound Care Products. Several commenters supported use of one of the alternative terms we considered, Cellular and/or tissue-based products (CTPs) for skin wounds, and stated that it was consistent with the American Society for Standards and Materials (ASTM) definition of skin substitutes, and is nomenclature used by wound care clinicians; one commenter also indicated that CTPs is inclusive of both current and future technology.

Response: We appreciate the support from commenters for one of the alternative terms we considered. We intend to have more discussion about appropriate changes to the terminology for skin substitutes as indicated above. We expect to hold a Town Hall early next year before CY 2024 rulemaking to provide an opportunity to further engage interested parties on this matter and provide a forum for additional discussion as we seek to identify the most reasonable approach going forward.

Comment: One commenter stated that changing the terminology to wound care management products does not align with FDA guidance on permitted use of HCT/Ps for reconstruction, repair, or replacement under 21 CFR 1271.3(f)(1), and therefore, HCT/Ps which are a subset of CTPs should not be considered as equivalent to other wound care management products and considering HCT/Ps as equivalent to other wound care management products would create confusion.

Response: We appreciate the feedback from the commenter. As previously indicated, we are not finalizing changes to the terminology at this time, and intend to further engage interested parties on this matter.

Comment: One commenter expressed support for CMS's efforts to more accurately describe skin substitute products amid an evolving wound care environment, but disagreed with the proposed name change and recommended that we continue with the term skin substitute which they believe accurately reflects this category. The commenter stated that while skin substitutes are not a term under the FDA, the terminology has been used for some time in medical vernacular. The commenter stated that the proposal to change the terminology will in effect diminish the time, resources, and cost that goes into manufacturing and applying these products.

Response: We disagree that the term skin substitute is the best term to reflect this suite of products despite the longstanding use of the term in the industry. We continue to believe that improving how we reference these products by using a more accurate and meaningful term will be beneficial as we work to create a consistent approach for treatment of these products across settings. As previously indicated, we are not finalizing changes to the terminology at this time, and intend to further engage interested parties on this matter.

Comment: One commenter stated that they support the goal of replacing old terminology, but stated that purely synthetic products should not be included within the classification. The commenter also stated that excluding synthetics is consistent with the industry standards including ASTM which defines CTPs. The commenter recommended that we exclude all 100

percent synthetic products. Another commenter stated that CTPs is an outdated misnomer because the term explicitly excludes synthetic skin substitutes since it only refers to a subset of skin substitutes (those comprised of animal or human cells or tissues).

Response: As stated in the proposed rule, one of our key objectives in creating a consistent coding and payment approach for the suite of products currently referred to as skin substitutes is to address concerns regarding differential treatment for clinically similar products (as an example, animal-based, and synthetic skin products). Additionally, we note that the Standard Guide for Categories and Terminology of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds (ASTM F3163–22) available on ASTM's website (*https://www.astm.org/f3163–22.html*), states that CTPs may include synthetic components.

Comment: A commenter stated that changing the terminology would create confusion and coding challenges because the AMA has already published the 2023 CPT Codebook, and applications for changes to the CY 2024 CPT Codebook may no longer be made. Therefore, a change to the terminology contained in the CPT code set for the codes that describe product application procedures could not take effect until CY 2025. The commenter stated that creating a discrepancy between the way CMS refers to such products and CPT describes the application procedures in the CPT code set would create burdensome disruptions to providing wound care services.

Response: We note that as we navigate our roadmap, we anticipate that there will likely be some transition time, in which the industry would potentially need to clarify or adopt new terminology more broadly; however, as previously indicated, we are not finalizing a change in terminology at this time to allow an opportunity for additional discussions and input from interested parties.

Comment: One commenter stated that CMS should treat powder skin substitute products the same as sheet products under the PFS. The commenter stated that powder skin substitutes are not bandages or simple wound dressings and that when applied to a wound, powder products have demonstrated the same ability to form a sheet scaffolding for wound healing as sheet products.

Response: We did not make any specific proposals regarding the treatment of powder skin substitute products. Therefore, this comment is outside the scope of the proposals in the proposed rule. We thank the commenter for the suggestions.

4. Revising Payment for Skin Substitutes

In 2003, the Medicare Modernization Act established the Average Sales Price (ASP) approach for drugs and biologicals as described under section 1847A of the Act. We generally considered skin substitute products to be biologicals in our initial implementation of the ASP methodology. However, with the introduction of synthetic skin substitute products over the last several years, we are reviewing our categorization of these products, especially as we work to establish payment policies for these products across the various care settings. As explained above, we announced in the CY 2022 PFS final rule that we would establish HCPCS Level II codes for certain products for which we had received a HCPCS Level II coding application. We also finalized that these products would be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them (86 FR 65120). After we issued the CY 2022 PFS final rule, we assigned nine HCPCS ''A'' codes for the synthetic skin substitute products that were addressed in the rule.

In the CY 2022 PFS final rule, we stated that we recognized there was no payment mechanism for synthetic skin substitute products within the PFS, and we acknowledged the need to reconcile the gap in payment for synthetic products in the physician office setting without delay (86 FR 65121). Additionally, as we described in the CY 2022 PFS final rule, a commenter stated that skin substitutes are a heterogenous group and there is an increasing intersection between biological, bioengineered, and synthetic components. This highlights that the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements. The increasing overlap of both synthetic and non-synthetic skin substitute products emphasizes the importance of treating all skin substitute products in a similar manner in terms of coding and payment.

After further review, we agree with interested party recommendations that the suite of products referred to as skin substitutes should be treated in a uniform manner across different outpatient care settings. In terms of payment for these products within the office setting, we acknowledge the current variation between contractor pricing for synthetic skin substitute products and payment based on ASP+6% for non-synthetic skin substitute products; and also, the challenges to the clear categorization of products as synthetic or non-synthetic. We believe establishing a consistent framework for how these products are treated within the physician office and hospital outpatient settings will help ensure equitable access and appropriate payment for these services.

In order to ensure we treat skin substitutes consistently in terms of coverage, coding, and payment, we proposed that skin substitute products that are commonly furnished in the physician office setting be considered as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act, effective January 1, 2024. ''Incident-to supplies'' refers to supplies that are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness (§ 410.26). As proposed, in the office setting, we would no longer pay separately for skin substitute products under the ASP+6% payment methodology.

We proposed that as we are categorizing skin substitute products that are furnished in the office setting as incident-to supplies, we would consider the cost of the supply used in furnishing a physicians' service through the PFS practice expense (PE) methodology. Treating these products as incident-to supplies would mean that the resource costs for these products would be included in establishing PE relative value units (RVUs) for the associated physicians' service with which they would be furnished. For example, for CPT Code 15271 (application of skin substitute graft, leg or ankle), we establish the PE RVU by considering three separate categories of PE resource costs involved in furnishing the service: clinical labor, supplies, and equipment. Together, these costs are the total direct PE resource inputs. When considering these skin substitute products as a supply, we would add their associated cost to the direct PE inputs for the service with which the product is furnished. For a more detailed description of the PE RVU methodology, please refer to section II.B. of this final rule, Determination of Practice Expense Relative Value Units in the rule.

We acknowledged that the proposed change to consider skin substitute products furnished in the office setting as incident-to supplies would not be implemented immediately in CY 2023. Rather, we explained that we would need to transition toward consistent

coding and payment for these products. We referred readers to section III.N. of the proposed rule for the proposed changes to our process for assigning HCPCS Level II codes to wound care management products.

We discussed that we believe it is necessary to establish an effective date of January 1, 2024, for the proposed payment of skin substitutes in the non-facility setting as incident-to supplies in order to align with the HCPCS Level II coding proposals for wound care management products as described in section III.N. of the proposed rule, to ensure all interested parties have the same opportunity to effectively transition toward the coding and payment changes. Additionally, we noted that we intend to engage with interested parties via an open-door forum/listening session to receive additional feedback.

To summarize, we proposed to treat skin substitutes (including synthetic skin substitutes) as incident-to supplies as described under section 1861(s)(2)(A) of the Act when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024. The proposal would mean skin substitutes are treated in the same manner for purposes of payment when furnished in non-facility settings, and would be consistently contractor priced through CY 2024. Given these changes, we believe maintaining the current treatment of these products for purposes of payment during CY 2023 will ensure a smooth transition. We also proposed to discontinue the use of the term skin substitutes beginning January 1, 2024 and to instead refer to this suite of products as ''wound care management products.'' We solicited feedback on the proposals.

The following is a summary of the public comments received on the proposed revisions to the Payment for Skin Substitutes and our responses:

Comment: Many commenters stated that the proposal to revise payment for skin substitutes does not provide enough information about how these skin substitute products will be packaged and paid for if finalized in the CY 2023 final rule to be effective for CY 2024. More specifically, several commenters requested clarification on cost information used to establish contractor pricing for skin substitute products, how skin substitute products will be incorporated in the PE RVU methodology, and the dollar amount that would be included in the bundle for these skin substitute products. Additionally, these commenters mentioned that our proposal lacks sufficient time for interested parties to effectively transition products that were previously assigned Q codes to shift to A codes in order to meet the proposed changes to incident-to supply effective CY 2024. As a result, these commenters stated that they could not provide meaningful comment on these significant policy changes and urged CMS to delay the implementation of this proposal until these necessary details are addressed.

Response: We appreciate all of the public comments on the proposal, especially questions and comments received regarding how we intend to achieve our policy goals. To clarify several significant questions, for CY 2023, CMS did not propose to make any changes to the existing payment methodology under the PFS associated with the proposed change to pay for skin substitute products as incident-to supplies. Rather, our proposal was to pay for these products beginning for CY 2024 as incident-to supplies in the same way that we pay for other incident-to supplies.

Based on our review of the comments received, we understand that it would be beneficial to provide interested parties more opportunity to comment on the specific details of changes in coding and payment mechanisms prior to finalizing a specific date when the transition to more appropriate and consistent payment and coding for these products will be completed. While we continue to believe that the current, transitory situation where like products are not being paid and treated consistently is unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice, we believe additional opportunity for information sharing and subsequent rulemaking is necessary before the transitory policies can be retired. In consideration of the comments and in the interest of ensuring appropriate payment and access in accordance with our above outlined policy objectives for creating a consistent payment approach across payment systems, benefit categories, and coding for treatment of the suite of products we have referred to as skin substitutes, we are going to conduct a Town Hall in early CY 2023 that will be open to interested parties in order to provide additional opportunity for discussion to address these concerns as well as discuss potential approaches to the methodology for payment of skin substitute products under the PFS. We will take into account the comments we received in response to CY 2023 rulemaking and feedback from the Town Hall in order to strengthen proposed policies for skin substitutes in future rulemaking.

Comment: Some commenters stated that the proposal to revise payment for skin substitute products under the PFS is concerning because the proposal did not include an impact analysis.

Response: Since the proposal to categorize skin substitute products as incident to supplies does not take effect until CY 2024, any corresponding impact analysis would be included as part of rulemaking for CY 2024. However, as stated above, we recognize the need to ensure more opportunity for information sharing, notice, and comment rulemaking prior to completing the transition to equitable payment for like products. As a result, we will further discuss approaches towards a consistent payment mechanism for skin substitute products at the Town Hall with interested parties.

Comment: Many commenters disagreed with bundling the payment of skin substitute products into the payment for the procedures that use the products under the PFS. These commenters raised the concern that packaging payment of skin substitute products in non-facility settings will cut payment for the products and pose financial burden to providers, which would limit or eliminate the options of skin substitute products offered to patients. Commenters also stated that cutting payment rates for skin substitutes would stifle innovation for these products that are necessary to effectively treat a vulnerable patient population. Additionally, some commenters stated that if CMS were to bundle skin substitute products similar to the bundling of policies under the OPPS for services furnished in the hospital outpatient department, then large wounds would not be treated any longer in the physician office setting due to the excessive cost and low payment for the supplies, thus, redirecting these patients toward more costly inpatient hospital settings. Furthermore, commenters stated that the PE RVU methodology referenced in the proposed rule should not be used as a payment methodology for skin substitute products since these products are expensive, and absorbing them into the PE would cause a decrease in PE payment for other areas due to the PE RVU's budget neutrality requirements.

Response: We thank commenters for their feedback and concerns regarding bundling payment and using the PE RVU methodology for skin substitute products under the PFS. In response to

these and other similar comments, and as previously stated, we are not finalizing the proposed payment methodology for skin substitute products under the PFS.

Comment: Many commenters disagree with the proposal to recategorize all skin substitute products as incident-to supplies. Commenters stated that biological skin substitute products should be a category of its own due to the complexity of biological skin substitutes and the certain preparation and procedural codes that are required for biological skin substitutes. Thus, commenters stated that they believe that grouping the biological and synthetic skin substitute products together disregards how these products are treated clinically. Commenters also stated that skin substitutes are incorporated into the wound bed to aid healing and have certain regulatory requirements unique to skin substitutes. Due to these issues, commenters emphasized that skin substitutes are vastly different from other supplies such as wound dressings/bandages, which fall within the incident-to supply category. Furthermore, these commenters reiterated similar concerns to other commenters about bundling payment for skin substitutes with payment for the procedures in which they are used, which would also accompany recategorizing these products as incident-to supply.

Response: As mentioned previously, we plan to hold additional discussions with interested parties during a Town Hall session to discuss potential alternative approaches for equitable payment and treatment of skin substitute products in the physician office setting. This will ensure ongoing dialogue to address concerns around bundling payment (which is typically the approach for incident-to supplies) for all skin substitute products.

Additionally, we noted in the proposed rule that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. We also clarified that our definition of skin substitutes does not include bandages or standard dressings (87 FR 46028). As highlighted in the proposed rule, skin substitutes are a heterogenous group and there is an increasing intersection between biological, bioengineered, and synthetic components. This highlights that the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements (87 FR 46028). Therefore, prompting us to recognize the need to achieve a standardized approach to pay for these products.

Comment: Some commenters presented a few concerns that our proposal to treat all skin substitute products as incident-to supplies is contrary to current statute. Specifically, these commenters were concerned that categorizing skin substitute products as incident-to supplies in the physician office setting would be inconsistent with the applicable payment framework for biologicals provided in a physician clinic, as set out in sections 1842 and 1847A in the Act. Another commenter also stated that the products approved through a drug or biological pathway like a BLA or NDA are vastly different compared to products approved as 510(k) devices or regulated as HCT/Ps; therefore, the commenter believes NDA/BLA skin substitute products should remain separate and paid as a drug/biological. Lastly, one commenter stated that the lack of any impact analysis or evidence that supports our proposal is contrary to Administrative Law.

Response: As mentioned previously, we recognize the importance of information sharing and notice, which we look forward to addressing with interested parties at the Town Hall.

Comment: Several commenters suggested various alternative payment approaches. For example, one commenter suggested that CMS should separately identify and pay for high-cost disposable supplies priced more than $500 using appropriate HCPCS codes, where the pricing would be based on a transparent and annual review process under the PFS. Another commenter suggested that we create five unique A-codes that would cover all skin substitutes based on composition-based categories. Then, the skin substitute approved products would be paid separately at the same rate per square centimeter in order to ensure there are no gaps in care for large wounds.

Response: We thank commenters for their feedback and look forward to ongoing discussions regarding alternative payment approaches for skin substitutes.

Comment: Several commenters expressed concern about what they viewed as a payment disadvantage for synthetic skin substitute products, if biological skin substitute products are paid using the ASP+6% payment methodology, whereas synthetic skin substitute products are contractor priced under the PFS. Overall, these commenters supported our proposal to treat all skin substitute products as incident-to supplies, since it ensures consistency for all skin substitute products in terms of payment, across multiple settings.

Response: We thank the commenters for their support. As noted in the CY 2023 PFS Proposed Rule, we acknowledged the current variation between contractor pricing for synthetic skin substitutes and payment based on ASP+6% for biological skin substitute products. As a result, we believe achieving a consistent payment mechanism is important and look forward to discussing ways in which to achieve this with interested parties at the Town Hall.

Comment: A few commenters stated that they support a multi-year phased approach consistent with the five-year timeline to improve clarity and consistency of payment policies for skin substitutes, but expressed confusion regarding the longer-term road map given the stated implementation date of CY 2024.

Response: We appreciate the commenters' support for our phased approach, and clarify that we anticipate addressing various considerations over the next few years through rulemaking. As indicated above, we are delaying changes to the terminology to allow for additional discussions with, and input from interested parties. Additionally, we will consider payment approaches in future rulemaking.

After consideration of the public comments, we are not finalizing our proposal to change the terminology for skin substitutes at this time, and intend to further engage interested parties and allow an additional opportunity for input regarding the most appropriate term that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes. We intend to revisit the change in terminology in future rulemaking as early as next year. Further, after considering the issues raised in public comments, we are not finalizing the payment approach outlined in the proposed rule where we considered establishing payment under our typical approach for incident- to supplies using our PE RVU methodology. Instead, we intend to conduct a Town Hall with interested parties in early CY 2023 to discuss alternative potential payment approaches for skin substitute products prior to CY 2024 rulemaking in order to achieve a transition to equitable payment for like products; we will also use this Town Hall as an opportunity to discuss the aforementioned change to the terminology.

K. Provision To Allow Audiologists To Furnish Certain Diagnostic Tests Without a Physician Order

Audiologists are recognized under Medicare Part B to provide certain diagnostic audiology services as defined at section 1861(ll)(3) of the Act. Specifically, the statute describes audiology services that include such hearing and balance assessment services as the audiologist is legally authorized to perform under State law, as would otherwise be covered if the services were furnished by a physician. The definition of qualified audiologist appears at section 1861(ll)(4)(B) of the Act. Currently, the only other provision in the Medicare statute that relates to audiology services is found at section 1862(a)(7) of the Act, which excludes payment for hearing aids and related examinations. This exclusion is codified at § 411.15(d)(1), which precludes payment for hearing aids or examinations for the purpose of prescription, fitting, and changing hearing aids. There are no other Medicare statutory provisions addressing audiologists or audiology services. Diagnostic tests are included as a Medicare Part B benefit under section 1861(s)(3) of the Act.

For many diagnostic testing services, payment under the PFS can be made in two separate components of the service when parts of the services are furnished by two different physicians, practitioners, or other suppliers: the technical component (TC) and the professional component (PC). The TC is the portion of the service that involves the collection of information from the patient—for example, a sample, specimen, radiological image, or interrogatory study. When the TC is furnished separately, the ''TC'' modifier is used with the relevant HCPCS code to bill for the service under the PFS. The PC of a diagnostic test is the portion of the service involving the interpretation of the collected information by a physician or other practitioner. When the PC is furnished separately, the service is coded with modifier ''26''. When the same physician or practitioner furnishes both the TC and PC of the service, the relevant HCPCS code (known as the ''global'') is billed without a modifier. We have established general requirements for furnishing and billing diagnostic tests at § 410.32.

In the CY 1997 PFS final rule, we established in regulations at § 410.32(a), based on long-standing manual provisions, that all diagnostic tests, including audiology tests, must be ordered by the physician who is treating the beneficiary who will use the results to manage the beneficiary's care. We believed this requirement was necessary to ensure that the physician had a relationship with the beneficiary, and would ensure the tests were reasonable and medically necessary, as well as prevent patterns of abuse. At the same time, we finalized a regulatory provision at § 410.32(c) (later redesignated to § 410.32(a)(2)) to recognize as the treating practitioner for the purpose of ordering diagnostic tests certain nonphysician practitioners (NPPs) who are authorized under the statute to provide services that would be physician services if furnished by a physician when they are operating within the scope of their State license. The NPPs who can serve as the treating practitioner for purposes of ordering diagnostic tests include physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) (defined in sections 1861(s)(2)(K)(i) and (ii) of the Act, respectively), certified nurse-midwives (defined in section 1861(gg) of the Act), qualified psychologists (defined in section 1861(ii) of the Act), and social workers (defined in section 1861(hh) of the Act)) (61 FR 59497 through 59498). We note that all of these NPPs are included as practitioners who must accept Medicare payment on an assignment-related basis under section 1842(b)(18)(C) of the Act. As such, these NPPs can only collect any applicable cost-sharing from the patient, and cannot balance bill the patient for additional amounts above the Medicare payment amount. The regulation reflecting the ordering requirements for diagnostic tests has not been substantively amended since that time, except to add an exception to the treating practitioner ordering requirement for screening mammography and, in response to the PHE for COVID–19, to add a limited exception for a single, otherwise-covered COVID–19 diagnostic test (and one otherwise covered diagnostic laboratory test for flu or similar respiratory condition needed to diagnose COVID–19) per patient per year during the PHE.

In the CY 1998 final rule (62 FR 59057 through 59070), we also amended § 410.32(a) to clarify that the ordering requirement is based on the exclusion in section 1862(a)(1)(A) of the Act and contained in § 411.15(k)(1); that is, diagnostic testing services that do not meet the ordering requirements in § 410.32(a) are considered not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. We explained that we found tests not demonstrably reasonable and medically necessary if they are not ordered by the beneficiary's treating physician or practitioner who will use the test results to manage the beneficiary's condition or symptom. Also in the CY 1998 PFS final rule, while we continued to require physician supervision for most diagnostic tests, we amended our regulation to except diagnostic tests personally furnished by audiologists (as well as psychologists and certain physical therapists board-certified in electrophysiology) from the physician supervision requirement.

As explained above, all of the NPPs that we recognize as treating practitioners in § 410.32(a)(2) for purposes of the diagnostic test order requirement who must accept Medicare payment on an assignment-related basis can only collect any applicable cost-sharing from the patient and cannot balance bill the patient for additional amounts. Audiologists are not NPPs as defined by the statute (that is, they are not listed at section 1842(b)(18)(C) of the Act). However, beginning in 2008, we allowed audiologists to enroll in the Medicare program so that they could independently bill for their audiology services rather than relying on physicians or other enrolled practitioners to bill on their behalf. As such, audiologists are not required to accept payment on an assignment-related basis.

Over the past several years, interested parties have requested that CMS eliminate the treating physician or other practitioner order requirement for the hearing and balance assessment services furnished by audiologists. They have suggested that CMS has the administrative authority to eliminate the order requirement for audiology services via notice and comment rulemaking, and that doing so would enable greater access to these important services. The interested parties believe that an order from the treating physician or practitioner is not required by the statute, and that audiology services are covered unless they are otherwise excluded, such as because they are not reasonable and necessary in a particular circumstance. To support their points, these interested parties shared with us a report prepared in 2020 by a consultant concluding that removal of the treating physician or practitioner ordering requirement for audiology hearing and balance assessment services would result in an estimated savings to Medicare over a 10-year period of approximately $108 million, which includes a savings of $36 million in

beneficiary copayments. These savings estimates are based on projected Medicare payments and beneficiary copayments that would not occur if Medicare beneficiaries directly accessed the audiology hearing and balance services furnished by an audiologist without the order of a treating physician or other practitioner. In addition, we have heard from interested parties that an order is not required for audiology services by certain other public or private health insurers including Medicare Advantage plans, Medicaid, plans under the Federal Health Benefit Program, and the Veterans Administration. We do not know the scope of services that are covered by these plans or insurers when furnished by audiologists, including whether these health insurers cover only hearing and balance assessment services (as the Medicare program does in accordance with the statute) or also hearing aid examinations for the prescription, fitting, and programming of hearing aids or other services excluded from payment under Medicare Part B and/or whether only some or all of the plans allow payment directly to audiologists for some or all of the covered services without a physician/NPP order. Additionally, we note that some of these health insurance programs involve closed systems with greater levels of interprofessional communication and control (for example, within certain accountable care organizations (ACOs), managed care plan networks, or through various Veterans Affairs medical centers). In contrast, the physicians and practitioners furnishing care under the fee-for-service Medicare Part B program often practice independently from each other, which can pose barriers to communication and coordination of care between health care professionals such as audiologists and the treating physicians or other practitioners.

In addition, the nature of audiology services personally furnished by audiologists is such that these services are often billed based on the audiologist's reassignment of billing rights by an entity other than the furnishing audiologist, so we are currently unable to determine the number of audiologists furnishing these services or the full scope of beneficiary utilization of these services in those settings.

While we believe that CMS has the administrative authority to remove the treating physician or practitioner order requirement for audiology hearing and balance assessment services via notice and comment rulemaking, we do not agree with the suggestions of interested parties that audiologists should be considered in the same way as the NPPs we recognized as treating practitioners for purposes of the order requirement under § 410.32(a)(2). Specifically, we allowed the NPPs (including PAs, NPs, and CNSs) to order diagnostic tests for the beneficiaries they treat, and we continued to require that the results of the tests be used in the management of the patient's specific medical problem. In these cases, the relationship of the patient to the NPP who orders diagnostic tests and uses the results in managing the beneficiary's medical condition serves to provide assurance that the services are medically necessary. In contrast, audiologists are not recognized under Medicare Part B to treat or manage patients. We consider audiologists' services to be more specialized than those of other physicians and NPPs who provide diagnostic services. That is, their diagnostic tests are more limited and focused in scope than others furnishing services under the Medicare Part B benefit for diagnostic tests at section 1861(s)(3) of the Act. Unlike PAs, NPs or CNSs who may bill for E/M services, and for whom Medicare Part B covers services and supplies incident to their own professional services as provided in the regulation at § 410.26, the scope of audiology services under the Medicare Part B statute includes only diagnostic hearing and balance assessment services. We are concerned that removal of the order requirement for hearing and balance services furnished by audiologists could lead to the furnishing and payment of services that are not used by a treating physician or practitioner in the management of the patient's medical condition, and thus, not medically necessary. We are also concerned about patient safety if Medicare beneficiaries seek hearing and balance services directly from audiologists without the involvement of a treating physician or practitioner. For example, the beneficiary could have an acute condition or symptom such as acute sensorineural hearing loss resulting from a viral neuronitis that needs to be diagnosed and treated by a physician or practitioner on an emergent basis, and that care could be delayed if the beneficiary first sought care directly from an audiologist. As an additional example, disequilibrium has many possible causes, including potentially life threatening cardiologic (for example, arrythmias, heart attack, or cardiac ischemia) and neurologic etiologies (for example, migraines, TIAs (transient ischemic attacks), strokes). The wide variety of possible causes of disequilibrium with some of these in both categories being potentially life threatening (for example, stroke, heart attack, arrythmias) speaks to the importance of a physician or NPP being involved in the initial patient assessment. Such an assessment would include a careful history, a physical examination, and immediate office-based testing (for example, EKG) to look for some of the more critical possible causes of disequilibrium, and the physician or NPP would determine the plan for the progression of the outpatient workup. That is to say, the physician or NPP would decide, given the history and clinical exam, whether the evaluation should continue along cardiologic, neurologic, or vestibular perspectives—the latter of which could possibly result in an order/referral to an audiologist for balance assessments using the vestibular dysfunction testing codes. For these reasons, we believe patients with disequilibrium would be best served by seeing a physician or NPP before being referred to an audiologist as appropriate. Furthermore, as previously noted, audiologists are not required to accept Medicare payment on an assignment-related basis, and therefore, can balance bill the beneficiary. We are concerned that the removal of the treating physician or practitioner ordering requirement, and potentially increased volume of audiology services, could lead to unnecessary costs to beneficiaries. In addition, in the absence of a required order of the treating physician or practitioner, we are concerned that the direct access to audiologists might incentivize changes in behavior and practice patterns among audiologists that could lead to overutilization of audiology services.

We have carefully considered the interested parties' requests to remove the treating physician or practitioner order requirement for diagnostic audiology hearing and balance assessment services. We believe it would be appropriate to provide a limited exception to the order requirement for diagnostic hearing testing services furnished by audiologists in order to broaden patient access to these services. In response to the requests of interested parties, we proposed to amend our regulation by adding a paragraph at § 410.32(a)(4) to remove the order requirement under certain circumstances for certain audiology services furnished personally by an audiologist for non-acute hearing conditions. These non-acute hearing conditions would not include balance assessments that are used for patients with disequilibrium, because as we

explained above, the physician/NPP needs to first evaluate the patient clinically due to the many serious medical conditions the beneficiary might have, and ensure the patient is cleared medically before setting them on track to receive vestibular function tests, possibly from an audiologist. The list of audiology services for which Medicare payment can be made when an audiologist personally performs them on the order of the treating physician or NPP can be found on the Medicare physician fee schedule web page under the link titled ''Audiology Services'' at *https://www.cms.gov/medicare/medicare-Fee-for-Service-Payment/Physicianfeesched.* We proposed to permit the services described by the codes listed in Table 35 to be furnished under the proposed exception without the order of the treating physician or NPP. We noted that Table 35 does not include the codes for vestibular function tests in the CPT code ranges of 92517–92519 and 92537–92549 because, as discussed above, we believe it is in the clinical interest of the beneficiary to be assessed by a treating physician or NPP for potentially serious medical implications of disequilibrium symptoms, including cardiologic and neurologic etiologies before they can be cleared and referred for vestibular function tests.

BILLING CODE 4150–28–P

TABLE 35: Proposed Codes for Tests that can be Encompassed by HCPCS Code GAUDX that Audiologists can Provide without a Physician or NPP Order/Referral

CPT Code	Short Descriptor
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92562	Loudness balance test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92571	Filtered speech hearing test
92572	Staggered spondaic word test
92575	Sensorineural acuity test
92576	Synthetic sentence test
92577	Stenger test speech
92579	Visual audiometry (vra)
92582	Conditioning play audiometry
92583	Select picture audiometry
92584	Electrocochleography
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92602	Reprogram cochlear implt <7
92603	Cochlear implt f/up exam 7/>
92604	Reprogram cochlear implt 7/>
92620	Auditory function 60 min
92621	Auditory function + 15 min
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92640	Aud brainstem implt programg
92561	Aep hearing status deter i&r
92562	Aep thrshld est mlt freq i&r
92563	Aep neurodiagnostic i&r

BILLING CODE 4150–28–C

We proposed to create HCPCS code GAUDX (*Audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids; (service may be performed once every 12 months)* to describe these audiology services furnished personally

by an audiologist without the order of the treating physician or other practitioner. We noted that we believe that limiting the audiology services that can be furnished without an order to include only hearing conditions that are non-acute in onset and balance services (patients with disequilibrium symptoms) by removing the CPT codes for vestibular dysfunction would be appropriate to address our patient safety concerns. We also proposed to specify in the code descriptor for HCPCS code GAUDX that the audiology services can be performed only once every 12 months. We noted that we believe this limitation is appropriate to avoid potential program integrity issues, such as audiologists billing for GAUDX with a greater frequency, or providing services that are not reasonable and necessary for the treatment of the patient's illness or injury. We selected once every 12 months, rather than every 6 months, for two reasons. The first is because 6 months did not seem long enough for a new, non-acute hearing condition to arise, and if an acute hearing condition were to onset, it would necessitate an evaluation with a physician/NPP. The second reason is that, at any time, the beneficiary may always elect to see their physician/NPP for any hearing conditions—acute or non-acute—or for conditions with disequilibrium symptoms.

As proposed, an audiologist would be able to bill code GAUDX once every 12 months for a beneficiary. The GAUDX code would include and be used to bill for any number of audiology services furnished in that particular encounter with the beneficiary. Since the proposed GAUDX code is generic, the tests provided could include those that are split into PC/TC and those that are not. As with all services, the actual tests provided and their results would need to be documented in the medical record, for purposes of medical review. Further, we proposed that no more than one unit of code GAUDX could be billed—that means ''1'' is inserted in the ''days or units'' block 24G on the CMS 1500 professional claim form. We noted concerns that beneficiaries may receive services billed as code GAUDX from more than one audiologist in the 12-month period and/or be mistaken or misled into thinking that code GAUDX represents a screening/preventive service which Medicare does not cover. To avoid the potential for inappropriate use of HCPCS code GAUDX, we explained that we plan to establish system edits through our usual change management process to ensure that GAUDX is only paid once every 12 months, per each beneficiary. We noted that the code descriptor proposed for GAUDX could be billed for patients seeking care for non-acute hearing conditions, and that the furnished audiology services would still have to be medically necessary. As proposed, after receiving audiology services from an audiologist accessed directly without the order of a treating physician or practitioner, the beneficiary would have to wait a full 12 months before receiving additional diagnostic tests from an audiologist without a physician/NPP order. The beneficiary would remain free to seek care from a treating physician (or/NPP) if needed, and that care could potentially include a referral with an order for further diagnostic testing furnished by an audiologist.

To value HCPCS code GAUDX, we proposed to use the combined values of CPT codes 92557 (*Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined))* and 92567 (*Tympanometry (impedance testing)*), which we believe would represent a typical service provided by audiologists. We explained that we chose CPT Codes 92557 and 92567 as typical because they make up 72 percent of all billings for audiologists; and, when all physician and practitioner specialties are considered, including audiologists, CPT code 92557 is billed with CPT code 92567 over 60 percent of the time and CPT code 92567 is billed with CPT code 92557 over 83 percent of the time in the same clinical encounter, according to Medicare claims data.

Thus, we proposed a total work RVU of 0.8 for GAUDX, calculated by combining the 0.60 work RVU for CPT code 92557 and 0.20 work RVU for CPT code 92567. We proposed to establish the PE value for GAUDX by combining the unduplicated PE of CPT codes 92557 and 92567. Specifically, we proposed to include the following direct practice expense (PE) inputs for supply items: two SD046 (Ear tip, tympanometry probe), two SJ053 (Swab pad, alcohol), one SM0251 (Specula tips, otoscope), one (SK059) sheet of recording paper, and two SD047 (Ear tip insert with sound tube); and the following direct PE inputs for equipment: EQ054 (*Audiometric soundproof booth (exam and control room))* for 20 minutes, EQ053 *(Audiometer, clinical, diagnostic)* for 20 minutes, and EQ244 *(Tympanometer with printer)* for 4 minutes. We also proposed to apply the same provisions for code GAUDX as those set for CPT codes 92557 and 92567 (for example, PC/TC indicator, bilateral indicator, physician supervision indicator, etc.), as they now appear in the PFS Relative Value file found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files*.

We discussed in the proposed rule that we believe that proposed HCPCS code GAUDX, if finalized, will allow us to better understand the scope of beneficiary access to these services with or without the order requirement. We also noted that we believe that proposed HCPCS code GAUDX, if finalized, will allow us to better assess possible burdens to the beneficiary when attempting to access these services. We noted that, given the makeup and intended use of proposed code GAUDX, we would like to increase our understanding about how and where these audiology services would be provided without the order of a treating physician or practitioner. We requested comments from interested parties about what settings might represent the typical places of service and which institutional providers might bill for HCPCS code GAUDX.

The following is a summary of the public comments received on the Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order and our responses:

Comment: One commenter informed us that the final three codes listed in Table 29 of the proposed rule (Proposed Codes for Tests that can be Encompassed by HCPCS Code GAUDX . . .) were transcribed incorrectly as CPT codes 92561, 92562, and 92563. However, the correct codes related to auditory evoked potential (AEP) testing are CPT codes 92651, 92652, 92653.

Response: We agree that we included the incorrect codes in Table 29 of the proposed rule. We have corrected our error, and the correct AEP testing codes now appear below in Table 36 as part of our final policy.

Comment: Several commenters supported the proposal to provide a limited list of codes that could be provided without the treating physician/NPP order. However, many of these commenters did not support the use of the HCPCS code GAUDX, recommending that the existing CPT codes should be billed and paid at the PFS rate. A few commenters (including the RUC) specifically disagreed with our proposed G-code valuation process, telling us that it would not preserve relativity with other codes in the family, and does not reflect the clinical input and expertise of the audiologists that furnish the services.

Response: We appreciate that interested parties supported our

proposal for a limited code set that would allow for direct access to audiologists, without a physician/NPP order, for non-acute hearing assessments unrelated to disequilibrium. We also appreciate hearing the commenters' thoughts about the valuation of code GAUDX, as well as the commenters' recommendations to use the CPT codes to bill for these services, instead of the proposed GAUDX code. We agree with the commenters about the usefulness of the CPT codes listed in Table 36, as we detail in our final policy below.

Comment: We heard from several commenters who opposed our proposal to provide for limited direct access to audiologists without a physician/NPP order, and most of these commenters asked us to reverse our proposal. A few commenters explained that they opposed the proposal because physicians have more education and training than audiologists, and this additional training enabled them to treat patients holistically, yielding a better ability to treat and diagnose the serious medical conditions associated with hearing loss. Most of these commenters noted that there are negative consequences of removing physicians from the care team. One commenter stated they would conditionally support our proposal as long as we did not revise our current safeguards (that is, direct access to audiologists for nonacute hearing assessments unrelated to disequilibrium), because they have consistently stood against a ''blanket'' direct access to audiologist services without the order of a physician or practitioner, believing that such broadly available direct access will generate considerable patient safety and cost consequences without yielding significant improvements to access to care. This commenter also suggested that CMS should make payment to audiologists using the CPT codes based on the valuations CMS adopts after review through the RUC process, rather than using the proposed CMS-valued GAUDX code. Further, the commenter requested that CPT code 92640 (for programming of an auditory brainstem implant (ABI)) be removed from the list of 36 codes that are permitted without an order. The commenter stated that because this service carries risk of stimulating part of the brainstem and associated cardiac events, a physician should supervise the first activation provided by the audiologist.

Response: We appreciate the commenters' views, but we do not agree that we should withdraw our proposal. As we noted above, we believe it would be appropriate to provide a limited exception to the order requirement for diagnostic hearing testing services furnished by audiologists in order to broaden patient access to these services. We appreciate the commenter that expressed their conditional support for limited direct access to audiology services without a physician or NPP order with the proposed safeguards that are built into the GAUDX long descriptor. We further explain these safeguards below in the discussion of our final policy. We also appreciate the commenter's recommendation to remove the initial episode of CPT code 92640 (for ABI programming) from the set of codes for services that could be furnished without a physician or NPP order under the proposed policy, and remind the commenter that the presence of a code on the list does not preclude a physician (including the ABI surgeon) or NPP from writing an order for this service. Moreover, we anticipate that most physicians will write an order for the initial ABI programming upon discharge from this brainstem surgery. We plan to gather data about audiologists' use of CPT code 92640 without a physician or NPP order, and will consider this recommendation in future rulemaking.

Comment: Several commenters disagreed with the safety concerns we discussed in the proposed rule. Several commenters stated that audiology malpractice insurance is very low, and that, if there were safety risks, it would be higher than what they currently pay, which is around $500 each year. A few commenters noted that delaying care until the patient can obtain an order from a physician/NPP could inadvertently have harmful consequences—noting that untreated hearing loss over time can increase the likelihood of falls, social isolation, and accelerated cognitive decline. Another commenter stated that audiologists are qualified to identify, diagnose, manage, and treat disorders of hearing and balance and have the training and knowledge to recognize conditions needing medical treatment, as well as an ethical obligation to refer patients that require medical services.

Response: The patient safety concerns discussed in the proposed rule were related to the lack of involvement of a treating physician or NPP with Medicare beneficiaries seeking hearing and balance services directly from audiologists. There may be certain acute conditions and/or symptoms that need to be medically diagnosed and treated on an emergent basis by a physician or NPP. We continue to believe that beneficiaries with acute hearing loss and disequilibrium symptoms need to be medically managed, due to the potential for serious underlying pathology, such as strokes or heart attacks, if such appropriate identification and care are delayed. As we gain experience and information under the direct access policy we are finalizing, we may consider these issues further in future rulemaking.

Comment: Several audiologist commenters stated that, while they appreciated CMS' proposal to remove physician/NPP order requirements as a first step, they otherwise found the proposed HCPCS code GAUDX to be impracticable, and thought that it would limit beneficiary access to care and add a significant administrative burden to audiologists. These commenters suggested that CMS should recognize the vestibular codes as part of the direct access proposal allowing audiologists to provide service(s) without a physician/NPP order, allow direct access for both acute and nonacute hearing and balance conditions, and remove the requirement that the services described by HCPCS code GAUDX only be furnished to a beneficiary once every 12 months. These commenters disapproved of the valuation of GAUDX, and its use as an umbrella code to encompass the 36 different codes, as it would sometimes overpay for the services provided and underpay for other services. One commenter noted the GAUDX value is approximate $30-$100 less than the value of each cochlear implant-related service, and asked that these codes be removed from the GAUDX umbrella, because the cochlear implant centers would be disproportionately financially impacted. Instead, many commenters requested that some or all of the CPT codes proposed for inclusion in the GAUDX code be used together with a new modifier that could be used for services personally provided by an audiologist without a physician/NPP order. A few of these commenters suggested that the GAUDX code should encompass a smaller subset of codes than the codes listed in Table 29 of the proposed rule, so that more codes would be paid at CPT code-specific rates, even if they require a physician order. One commenter suggested that CMS consider the use of a modifier for even a smaller subset of the existing CPT codes for services provided by an audiologist without an order, rather than finalizing the GAUDX code (even if this reduces access to audiologists without an order), if the full list of 36 codes was unworkable for CMS. Another commenter submitted a suggested list of 7 codes that audiologists would provide without a referral that could be billed with a

modifier in place of the GAUDX code, and another list of 7 codes for services specific to a cochlear implant, auditory osseointegrated implant (AOI), or ABI (but the commenter was unclear as to the requirements for each list). Several commenters also submitted a list of CPT codes that are specific to the services surrounding cochlear implants, AOIs, and ABIs, such as evaluation to determine candidacy for an implanted hearing device and post-surgical evaluation of performance (for example, cochlear, AOI, or ABI implants), as well as for diagnostic analysis and subsequent reprogramming of the cochlear implant, AOI or ABI. The commenters suggested that these codes could be billed with the potential modifier for direct access to an audiologist, noted that the clinical standard of care for some of these services requires them to be repeated more often than once every 12 months. The commenters explained that the audiologist does not need an order from a physician or NPP for these services because the patient's physician and implanting surgeon are involved with these patients and, suggested that the order requirement presents a nuisance for the audiologist, physician or surgeon, and beneficiary.

Response: We thank the commenters for their suggestions. We are struck by the number of commenters that requested that we use a modifier with the CPT codes rather than the proposed GAUDX code, so that audiologists could bill more accurately for the specific tests they furnished and could be paid at the CPT code-specific PFS rates, instead of at the single rate for code GAUDX (which bundled 36 services of varying payment rates together). We also appreciate the suggestions of some commenters to reduce the scope of services/codes that would have been bundled under the GAUDX code, which would also allow them to more specifically bill for the services furnished and be paid at rates valued at the established value for those services. We note that several commenters recommending that fewer services be included in the proposed GAUDX code, even if it meant that a physician/NPP order would be required for more services. We agree with commenters' overwhelmingly consistent recommendations to use a modifier instead of the proposed HCPCS code GAUDX, as explained in the description of our final policy that follows. We would like to point out that a given modifier would only have one descriptor and uniform rules/restrictions, but it would allow for greater specificity in billing and payment for services as suggested by commenters. All of the commenters that supported the use of the modifier generally disfavored the proposed GAUDX code because, as we noted above, the valuation of GAUDX would potentially overpay for some services and underpay for others. We agree that appending a modifier to the specific CPT code for the service furnished will more accurately pay for the specific service furnished. Additionally, the use of a modifier with the specific CPT codes for services furnished by audiologists without an order will allow CMS to track the actual services that are being by audiologists without the physician or NPP order. We also believe that use of a modifier will reduce burden for audiologists as compared to using a new code, because audiologists are familiar with the code set and are currently using these codes to bill for services. Using a modifier allows audiologists to more specifically identify and bill be paid for the services they furnish, as opposed to billing using one code that is paid at the proposed bundled rate across the 36 codes, and allows CMS to have more detailed information on which services are furnished through direct access to audiologists without an order.

Comment: Several audiologist commenters questioned how to handle situations in cases where patients directly access an audiologist, but may be uncertain whether they have seen a different audiologist without an order of their physician or NPP in the past 12 months. They questioned whether billing GAUDX more frequently than once every 12 months requires an Advanced Beneficiary Notice (ABN) where there is no physician or NPP order, to transfer financial responsibility to the beneficiary. Another commenter asked whether they need to keep a voluntary or mandatory ABN on file in case the GAUDX claim is rejected to avoid the financial responsibility themselves. Several commenters noted that a CMS-developed, real-time, online tool should be made available for them to ascertain the needed eligibility information, so that an ABN can be administered to the beneficiary when necessary.

Response: We appreciate these comments and plan to communicate how audiologists can best prepare for and handle these types of situations through healthcare provider education vehicles and other guidance.

Comment: Some commenters requested more context surrounding the nonacute terminology and how it applies to nonacute hearing assessments that are unrelated to disequilibrium.

Response: For purposes of the audiology direct access policy, including all the 36 codes listed in Table 36, acute hearing loss involves a sudden onset in one or both ears—and is a perceived change in hearing by a beneficiary that is not consistent with the progressive loss of hearing over many years that is typical with the aging process. A nonacute hearing loss is a more gradual hearing loss that one may experience with advancing age, known as presbycusis, which the National Institute on Deafness and Other Communication Disorders defines as: ''Age-related hearing loss (presbycusis) is the loss of hearing that gradually occurs in most of us as we grow older. Age-related hearing loss most often occurs in both ears, affecting them equally.'' Audiologists can furnish services among those listed in Table 36, the results of which can provide essential information for them to recommend, for example, further testing or a medical referral to the patient's treating physician or NPP. It is for these nonacute types of gradual hearing loss and for hearing loss that is treated via surgically implanted hearing devices such as cochlear implants, AOIs, and auditory brainstem implants (discussed above) that beneficiaries may be seen by the audiologist without a physician/NPP order.

TABLE 36: Codes for Tests that Audiologists can Bill with the AB Modifier for Nonacute Hearing Conditions without a Physician or NPP Order/Referral

CPT Code	Short Descriptor
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92562	Loudness balance test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92571	Filtered speech hearing test
92572	Staggered spondaic word test
92575	Sensorineural acuity test
92576	Synthetic sentence test
92577	Stenger test speech
92579	Visual audiometry (vra)
92582	Conditioning play audiometry
92583	Select picture audiometry
92584	Electrocochleography
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92602	Reprogram cochlear implt <7
92603	Cochlear implt f/up exam 7/>
92604	Reprogram cochlear implt 7/>
92620	Auditory function 60 min
92621	Auditory function + 15 min
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92640	Aud brainstem implt programg
92651	Aep hearing status deter i&r
92652	Aep thrshld est mlt freq i&r
92653	Aep neurodiagnostic i&r

After consideration of public comments received, we are finalizing amendments to the regulation at § 410.32(a)(4) with modifications effective for services furnished on or after January 1, 2023. We proposed to allow audiologists to furnish the services included on a list of 36 services without a physician order (as listed in Table 36 (which we corrected to identify CPT codes, 92651, 92652, and 92653). We are finalizing our proposal that these services can be covered and paid when furnished without the order of the treating physician or NPP for non-acute hearing assessment unrelated to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids (in alignment with statutory and regulatory restrictions); that the services may be performed once every 12 months per beneficiary. We are not finalizing our proposal to create G-code (GAUDX) for use to bill for audiology services furnished without the order of a physician or NPP. Instead, audiologists are to use the individual CPT codes to identify the services they furnish without the order of a physician or NPP, within the list of 36 allowed services (Table 36), and append a new modifier we will create (modifier AB). We were persuaded by comments from interested parties to use the modifier approach, which allows us to better identify which services are actually furnished (as opposed to the bundled GAUDX code) and reduces burden for audiologists, who already are familiar with the relevant CPT codes. In the last sentence of § 410.32(a)(4), we are replacing the proposed term ''code'' with the term ''modifier'' so that the final sentence of § 410.32(a)(4) will now state that audiology services furnished without an order from the treating physician or NPP are billed using a modifier CMS designates for this purpose.

The AB modifier will be used together with the 36 CPT codes on Table 36 (which has been updated from Table 35 to reflect the corrected CPT code numbers—92651, 92652, and 92653—as

discussed above), to indicate that the service/test was provided on a single treatment day, without an order from the physician/NPP treating the patient. We continue to believe that the patient safety, medical necessity, and program integrity safeguards we proposed are appropriate. Therefore, we are finalizing our proposal to limit direct access to audiology services without the order of the treating physician or NPP to non-acute hearing services to services listed in Table 36, and to establish a once per 12-month frequency limitation. These limitations on audiology services furnished without the order of the treating physician or NPP, which were proposed for HCPCS code GAUDX, will be reflected in the descriptor for the new AB modifier. Additionally, to align our final policy to use the modifier instead of HCPCS code GAUDX with the once per 12-month limitation, we are further modifying our final policy for use of the modifier with the codes available (please refer to Table 36). If an audiologist furnishes one or more services on the list of available codes without the order of a physician or NPP on a single date of service, the AB modifier must be appended to each of the CPT codes billed for that date of service, and all of the services will be considered payable. However, if a service is billed with the AB modifier on one date of service and the beneficiary returns at a later date for another service (without an order) and that service is within the 12-month period after the prior service is furnished (either for the same or a different service on the list in Table 36), then the subsequent service(s) would not be considered payable under the PFS.

Aligning our final policy to use modifier AB instead of HCPCS code GAUDX necessitates multiple changes to our claims processing systems, which will take some time to operationalize, possibly until mid-year 2023. Until such time, audiologists may use the AB modifier that is available for dates of service on and after January 1, 2023 to provide services/tests to beneficiaries who have directly accessed their services. Audiologists who furnish these services without an order are expected to follow our policy and safeguards built into the AB modifier, as above and in the code descriptor below. As we noted above, we plan to communicate to audiologists via provider education and other guidance, including the Audiology Services web page page at *https://www.cms.gov/audiology-services.*

The long descriptor for Modifier AB is as follows: *Audiology service furnished personally by an audiologist without a physician/npp order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids; service may be performed once every 12 months, per beneficiary.*

L. Medicare Parts A and B Payment for Dental Services

1. Background on Medicare Payment for Dental Services

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made under Medicare Part A for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at 42 CFR 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

However, under our current policy, we make payment under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act or our regulation at § 411.15(i). We make payment when a doctor of dental medicine or dental surgery (hereinafter referred to as a ''dentist'') furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician treating the primary medical illness. In these limited circumstances, Medicare payment can be made for dental services such as, but not limited to, the wiring of teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, and/or an oral or dental examination on an inpatient basis performed as part of a comprehensive workup prior to renal transplant surgery. (See Medicare Benefit Policy Manual (IOM Pub 100–02, Chapter 15, section 150); and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6)). Medicare Administrative Contractors (MACs) make claim-by-claim determinations as to whether a patient's circumstances do or do not fit within the terms of the preclusion and exception specified in section 1862(a)(12) of the Act and § 411.15(i) of our regulations, and in accordance with the CMS manual provisions.

As described in the CY 2023 PFS proposed rule (87 FR 45860, 46033 and 46034), we have received feedback from interested parties suggesting that our interpretation of section 1862(a)(12) of the Act is unnecessarily restrictive, which may contribute to inequitable distribution of dental services for Medicare beneficiaries. Additionally, a recent report from the National Institutes of Health, ''Oral Health in America Advances and Challenges,'' discusses how unequal distribution of dental services and prohibitive costs, particularly for older adults who are at the highest risk for poor oral health, can lead to and further complicate the treatment of other medical conditions (for more information, see *https://directorsblog.nih.gov/2022/06/14/using-science-to-solve-oral-health-inequities/*). The interested parties also suggested that there are instances where dental services are directly related to the clinical success of an otherwise covered medical service under Medicare Parts A and B, and that the regulation at § 411.15(i) should be amended to reflect that Medicare payment is available in these circumstances. Recognizing that there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we stated that we believe that there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. We also stated that we believe that there are circumstances where the dental services are in direct connection with the care,

treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and are not inextricably linked to the clinical success of a covered medical service. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act except when, due to the patient's underlying medical condition and clinical status, or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

To provide greater clarity to our current policies and respond to issues raised by interested parties, in the CY 2023 PFS proposed rule (87 FR 45860, 46033 through 46041) we: (1) proposed to clarify our interpretation of section 1862(a)(12) of the Act and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposed and sought comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; (3) requested comments on other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services; (4) requested comments on the potential establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services; (5) requested comment on other potentially impacted policies; and (6) requested comment on potential future payment models for dental and oral health care services. We sought public comments on these proposals and issues.

2. Clarifying the Interpretation of Section 1862(a)(12) of the Act and Codifying Current Payment Policies for Certain Dental Services

a. Payment for Inpatient Hospital Dental Services

As explained above and in the CY 2023 PFS proposed rule (87 FR 45860, 46033 and 46034), under our interpretation of the statute and our current regulation, and as reflected in our regulation and manuals, items and services furnished in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth generally are not covered, and no payment may be made for them under either Medicare Part A or Part B. Section 1862(a)(12) of the Act and our regulation at § 411.15(i) include an exception to allow Medicare Part A payment to be made for inpatient hospital services in connection with the provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. We stated that we believe that there are instances in which a Medicare beneficiary may require dental services that are in direct connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth such that the application of the Medicare Part A payment exception would apply when hospitalization is required because of: (1) a patient's underlying medical condition and clinical status; or (2) the severity of the dental procedure. Under these circumstances, we would continue to apply the exception under section 1862(a)(12) of the Act, and make payment for inpatient hospital services. We solicited public comments on what professional services, including, but not limited to dental services, may occur during and prior to the patient's hospitalization or procedure requiring hospitalization under this exception. We noted in the proposed rule that we may consider finalizing, based on our review of public comments, additional payment policies in this area.

b. Clarifying the Interpretation of Section 1862(a)(12) of the Act and Codifying Current Payment Policies for Certain Dental Services

As explained above, Medicare payment can be made for inpatient hospital services associated with dental services that fall within the statutory exception under section 1862(a)(12) of the Act. However, under our current policy, if a dental service and other related services (for example, anesthesia or imaging services) are performed as incident to and as an integral part of a covered procedure or service performed by a dentist, the total service performed by the dentist is covered, and payment can be made under Medicare Parts A and B as appropriate. This policy is based on the idea that some dental services that would ordinarily be excluded by statute from payment are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. When that is the case, we stated that then we believe those dental services are not in connection with dental services within the meaning of section 1862(a)(12) of the Act, but are instead inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. As such, we proposed to interpret the statute under section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services and allow payment to be made, regardless of whether the services are furnished in an inpatient or outpatient setting. Under these circumstances, we proposed that the exclusion under section 1862(a)(12) of the Act would not apply, because the service is not in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but instead is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

As described in section II.L.1. of the proposed rule, in a limited number of circumstances, Medicare Part B currently pays for dental services under the PFS when a dentist furnishes a service(s) that is integral to the covered primary procedure or service rendered when treating the primary medical illness. Our current payment policies for dental services are contained in manual provisions (The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100–02, Chapter 15, section 150) and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6)) that reflect the proposed interpretation of section 1862(a)(12) of the Act discussed in the proposed rule.

Our payment policy contained in Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6) [112] (herein ''the NCD Manual'') provides for payment of an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery. In the CY 2023 PFS proposed rule (87 FR 45860, 46035), we stated that we believe Medicare

[112] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.*

payment is permitted under this manual provision for such a dental or oral examination prior to renal transplant surgery, because the examination is inextricably linked to, and substantially related and integral to the clinical success of, the renal transplant procedure. As such, we stated that we believe such services are not subject to the payment preclusion under section 1862(a)(12) of the Act. However, we also stated that we believe that comprehensive workups prior to renal transplant surgery, including related dental examinations, can occur in either the inpatient and outpatient setting. As such, we proposed to provide Medicare payment for oral or dental examinations performed as part of a comprehensive workup prior to renal transplant surgery when these services occur in either the inpatient or outpatient setting, and revise our regulation at § 411.15(i) accordingly.

We noted that the NCD Manual states that, when performing a dental or oral examination, a dentist is not recognized as a physician under section 1861(r) of the Act. We stated that we believe this statement is based on an unnecessarily narrow reading of section 1861(r) of the Act, and is also not consistent with other manual provisions. The statutory definition of physician includes a doctor of dental surgery or dental medicine in section 1861(r)(2) of the Act, and a similar definition of physician is included in our IOM Pub 100–1, Section 70.2[113] when dental or oral examinations, and specific treatments, are within the State scope of practice for the dentist. As such, we proposed to amend § 411.15(i) to clarify that Medicare Part B coverage and payment can be made for such a dental or oral examination prior to renal transplant surgery when performed by a doctor of dental surgery or dental medicine as defined in section 1861(r)(2) of the Act.

The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100–02, Chapter 15, section 150) (herein ''the MBP Manual'') states that if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.[114] The MBP Manual continues by providing several specific examples where CMS would pay for dental services:

- The reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor (other than for dental purposes).
- The wiring of teeth when done in connection with the reduction of a jaw fracture.
- The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.
- The dental splint when performed in conjunction with treatment that is determined to be a covered medical condition.

Specifically, in the MBP Manual, we describe that the reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure and therefore would not generally be eligible for payment. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service. In the case of the procedure of ridge reconstruction occurring in conjunction with the surgical removal of a tumor, we believe that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services, that is, the removal of a tumor; and therefore, Medicare Parts A and B payment could be made. Additionally, the MBP Manual explains that Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture. Once again, we stated that we believe that the dental services of wiring of the teeth are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, which in this case is the reduction of a jaw fracture, and therefore, Medicare Parts A and B payment could be made. Likewise, the MBP Manual states that the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also currently covered. We continue to believe that in this clinical scenario the dental services related to teeth extraction are inextricably linked to, and substantially related and integral to the clinical success of, the radiation treatment of neoplastic disease; and therefore, Medicare Parts A and B payment could be made. The Manual also describes a specific situation in which certain dental services may be considered a covered service, depending on whether the underlying medical condition is deemed to be covered. The Manual explains that dental splints used to treat a dental condition are generally excluded from coverage under section 1862(a)(12) of the Act, but if the treatment is determined to be a covered medical condition (that is, dislocated upper/lower jaw joints), then the splint can be covered. We stated that we believe that dental splint services could be covered and paid, because the dental services could be inextricably linked to, and substantially related and integral to the clinical success of, a covered medical service, such as treatment of a dislocated jaw. Therefore, we proposed to clarify and modify the regulations text at § 411.15(i) to include this scenario of dental splints used in the treatment of a covered medical condition. We sought comments on this aspect of the proposal.

Therefore, we proposed to codify and clarify in the regulation at § 411.15(i) that payment can be made under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, including (1) reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor; (2) the wiring or immobilization of teeth when done in connection with the reduction of a jaw fracture; (3) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (4) a dental splint only when used in conjunction with covered treatment of a medical condition. This provision would clarify existing policy, as we are codifying existing manual provisions in regulation.

The MBP Manual states that payment can be made under Medicare Parts A and B for a covered dental procedure regardless of where the service is performed, noting that the hospitalization or non-hospitalization of a patient has no direct bearing on the coverage, payment, or exclusion of a given dental procedure in specific circumstances. As such, dental services that are not excluded from Medicare payment under section 1862(a)(12) of the Act could be appropriately furnished in inpatient or outpatient settings. We proposed to clarify in the regulation at § 411.15(i) that payment for dental services that do not fall within the scope of section 1862(a)(12) of the Act, and that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, could be made regardless of whether the services are furnished on an inpatient or outpatient basis. We sought comments on whether it is clinically appropriate for these services to be furnished in inpatient or outpatient settings.

[113] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS050111.*

[114] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS012673.*

The MBP Manual further states that the coverage of services such as the administration of anesthesia, diagnostic x-rays, and other related procedures depends upon whether the primary procedure being performed by the dentist is itself covered. The MBP Manual explains that an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered, while a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered. In order to clarify and codify this current policy, we proposed to amend our regulation at § 411.15(i) to provide that payment can be made for dental services provided in conjunction with medical services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, such as X-rays, administration of anesthesia, and use of the operating room.

The MBP Manual also specifies that payment can be made for services and supplies furnished incident to other dental services for which Medicare payment can be made, for example, services furnished incident to the dentist's professional services by a dental technician or registered nurse under the dentist's direct supervision. Medicare payment policy for services furnished incident to the services of the billing practitioner are contained in § 410.26 of our regulations.

Additionally, the MBP Manual provides that when an excluded service is the primary procedure involved, dental services are not covered, regardless of complexity or difficulty. The MBP Manual describes an example of the extraction of an impacted tooth as not covered, and goes on to state that certain procedures, including an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy, are excluded from coverage when either of these procedures is performed in connection with an excluded service, for example, the preparation of the mouth for dentures. Additionally, the MBP Manual states that the removal of a *torus palatinus* (a bony protuberance of the hard palate) may be a covered service, but notes that it is often provided in connection with an excluded service (that is, the preparation of the mouth for dentures), and in that event, Medicare does not pay for this procedure.

We did not propose to modify this policy. No payment is made for dental services when an excluded service is the primary procedure involved. Our interpretation of section 1862(a)(12) of the Act allows for Medicare payment when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. Therefore, no payment is made when dental services are related to medical services that are not covered, even if the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the non-covered services. We stated that the proposed amendment to § 411.15(i) would specify that, in order for Medicare payment to be made, the dental services must be inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

As proposed, the provision to clarify and codify our current payment policy for dental services, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered medical services. When such medically necessary dental services are furnished by a physician or practitioner, including a dentist, Medicare Part A or B payment can be made for the dental services and other services integral or incident to those dental services. Specifically, such services include:

- The wiring of teeth when done in connection with an otherwise covered medical service,
- The reduction of a jaw fracture (such as services described by CPT code sets 21440–21490),
- The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease (such as services described by Current Dental Terminology (CDT) [115] codes D7140 and D7210 for ICD–10 C41.1 Malignant neoplasm of mandible),
- Dental splints only when used in conjunction with covered treatment of a medical condition (such as dislocated upper/lower jaw joints), or
- An oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery (such as services described by ICD–10 Z94.0, and codes D0150, D0180, or D0160).

We proposed that Medicare Parts A and B payment for these dental services can be made, because the services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services. We further sought comment on whether, given current clinical advances, the descriptions of these dental services are clinically accurate and appropriate. For example, we are interested in whether the phrase ''wiring of the teeth'' is still clinically accurate or if other terminology would be more appropriate.

Given that such dental services would not be subject to the preclusion on payment under section 1862(a)(12) of the Act, Medicare would make payment to the furnishing dentist or another physician or practitioner for the professional dental services. As described in the MBP Manual, payment may also be made for services and supplies furnished incident to those dental services furnished by the dentist or other physician or practitioner, and for other ancillary services integral to the dental services. For example, Medicare payment could be made for services furnished incident to the professional dental services by auxiliary personnel, such as a dental hygienist, dental therapist, or registered nurse who is under the direct supervision of the furnishing dentist or other physician or practitioner, if they meet the requirements for ''incident to'' services as described in § 410.26 of our regulations. When such dental services are furnished in a facility setting, such as an inpatient acute care hospital or hospital outpatient department, payment for the facility or ancillary services would be made under the applicable payment system.

In summary, we proposed to amend § 411.15(i) to codify that payment can be made under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, an otherwise covered medical service. We further proposed to amend § 411.15(i) to include examples of services for which payment can be made under Medicare Parts A and B on that basis. Specifically, we proposed to include as examples the following dental services for which payment is permitted under our current policy: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition. We further proposed

[115] *https://www.ada.org/publications/cdt.*

that Medicare payment would be made for these dental services regardless of whether the services are furnished in an inpatient or outpatient setting, and we proposed that payment can also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, use of an operating room, other facility services.

We sought comment on all aspects of this proposal. We stated that, if finalized, we would make conforming changes to the MBP Manual to reflect changes or clarifications, and to remove any text that is no longer applicable. We also noted that we would make conforming changes to other Manual provisions or National Coverage Decision policies as necessary.

As discussed, MACs may determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). The proposed policies outlined in the proposed rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed in the proposed rule and the proposed amendments to § 411.15(i).

c. Update to Current Payment Policies for Dental Services

As discussed in section II.L.2 of the proposed rule, we proposed that payment can be made under Medicare Parts A and B for dental services such as the reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor, the wiring or immobilization of the teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, dental splints only when used in conjunction with covered treatment of a medical condition, and an oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery. We noted in the proposed rule that we believe, after further review of current medical practice, through consultations with interested parties and our medical officers, that there are additional circumstances that are clinically similar to these examples, and where Medicare payment for the service could be made, because the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical service(s).

For example, after further review, we stated that we believe that if a patient requiring an organ transplant has an oral infection, the success of that transplant could be compromised if the infection is not properly diagnosed and treated prior to the transplant surgery. Without an oral or dental examination to identify such an infection, and the necessary treatment, such as restorative dental services, to eradicate it prior to the transplant procedure, the patient's ability to accept the organ transplant could be seriously complicated or compromised. Examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999). If such an infection is not treated prior to transplant, and immunosuppressant therapy is initiated to preserve the transplant, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to sepsis. Similarly, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement [116] or valvuloplasty procedures, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves, seeding surrounding cardiac muscle tissues involved with the surgical site, and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient. Because an oral or dental infection can present substantial risk to the success of these procedures, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present, we noted that we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, these other covered medical services. We noted that, in these circumstances, the necessary treatment to eradicate an infection may not be the totality of recommended dental services for a given patient. For example, if an infected tooth is identified in a patient requiring an organ transplant, cardiac valve replacement, or valvuloplasty procedure, the necessary treatment would be to eradicate the infection, which could result in the tooth being extracted. Additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source prior to surgery. Therefore, we stated that such additional services would not be inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant, cardiac valve replacement, or valvuloplasty services. As such, no Medicare payment would be made for the additional services that are not immediately necessary prior to surgery to eliminate or eradicate the infection.

As discussed, we noted that we believe that there are circumstances where the clinical success of medical or surgical services required for a successful organ transplantation, cardiac valve replacement, and valvuloplasty procedure may require the performance of certain dental services. As such, we proposed to amend our regulation at § 411.15(i)(3) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B for such dental services. We proposed to amend § 411.15(i) to include examples of payable services under Medicare Parts A and B, as: (1) the dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure; and (2) the necessary dental treatments and diagnostics to eliminate the oral or dental infections found during a dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We noted that we believe that clinical practice is such that these services can occur within the inpatient

[116] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834-7819.1991.tb00724.x.*

hospital or outpatient setting, and we further propose that Medicare Parts A and B would make payment for these dental services, as applicable, regardless of whether the services are furnished in an inpatient or outpatient setting. Furthermore, we proposed that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as X-rays, administration of anesthesia, and use of the operating room.

We sought comment on the proposed policy and our proposed amendments to § 411.15(i)(3) to specify that payment under Medicare Parts A and B can be made for an oral or dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We proposed to continue to contractor price the dental services for which payment is made currently, and for the dental services that can be made under the proposed amendments to § 411.15(i)(3) for CY 2023, or until we have further data to establish prospective payment rates. We solicited comment on the proposals, including the expected utilization of these services discussed in our proposals.

i. Other Clinical Scenarios for Dental Services Integral to Other Covered Medical Services

In addition to the examples of dental services for which payment is made under our current policy, and dental services to avoid risk of an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures, we stated that we believe there may be other clinical scenarios where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. These could include certain dental exams and medically necessary diagnostic and treatment services prior to treatments for head and neck cancers, such as radiation therapy with or without chemotherapy, or the initiation of immunosuppressant therapy, such as those used during cancer treatments, where the standard of care is such that it is clinically advisable to eliminate the source of infection prior to proceeding with the necessary medical care, or the standard of care for the primary medical condition would be significantly materially compromised if the dental services are not performed. As with any assessment of patient health prior to initiating immunosuppressant therapy, it may be necessary to eradicate all sites of infection, including oral infections, prior to suppressing the immune system, regardless of the reason for prescribing an immunosuppressant. We also noted that some medications may have an immunosuppressant effect, even though they are not prescribed principally to suppress the immune system. We stated that we believe, in these circumstances, eradicating oral or dental infection prior to beginning a medication that has been found to have a suppressant effect on that part of the immune system required to eradicate infectious agents could be necessary to the clinical success of the medication therapy.

Similarly, in joint replacement surgery (such as total hip and knee arthroplasty surgery) we stated that we believe there may be risks to the outcome of the procedure if an oral infection is not treated. There is evidence that some joint replacement patients have significant dental pathology found before their surgery.[117] Given the incidence of dental pathology in joint replacement patients, there may be some joint replacement patients who would experience a clinically significant benefit from a pre-operative dental exam and medically necessary treatment of oral pathology(ies). As in transplant surgery, patients having joint replacement surgery are at risk for surgical site infection, and there may be an increased risk for those patients with significant dental pathology. The presence of an overlooked oral infection may increase the risk for acute and chronic surgical site infection.[118] [119]

We acknowledged there is other clinical evidence that does not support the need for a dental exam and necessary treatment prior to total joint replacement surgery, specifically total hip and knee arthroplasty.[120] [121] Rather, there is evidence that further study is needed to determine whether pre-operative dental exams and treatments are necessary and clinically beneficial.[122] Therefore, we sought public comment providing systematic clinical evidence as to whether there is an inextricable link between dental service(s) and joint replacement surgery such that the dental services are substantially related and integral to the clinical success of the surgical procedures. We noted that if we receive compelling clinical evidence, we may finalize in this final rule additional clinical scenarios, such as dental services prior to joint replacement surgery (for example, total hip and knee arthroplasty surgery), where payment could be made under Medicare Part A or Part B. We sought comment on whether there is a significant quality-of-care detriment if certain dental services are not provided prior to joint replacement surgery (such as total hip and knee arthroplasty surgery), and if so, we requested a description of that systematic evidence. Specifically, we requested medical evidence that the provision of certain dental services leads to improved healing, improved quality of surgery, and reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the skeletal structure. We stated that evidence needed to be clinically meaningful and represent a material difference that results in some level of persistence in the clinical success of the procedure to support that pre-operative dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore, in connection with, and substantially related and integral to that primary covered medical service. We stated that if commenters were able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to joint replacement procedures such as total hip and knee arthroplasty surgery would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the joint replacement surgery.

We also noted that we believe there may be other clinical scenarios

[117] *https://www.aaos.org/aaosnow/2011/feb/clinical/clinical2/.*

[118] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919067/.*

[119] *https://www.nebh.org/blog/why-its-a-good-idea-to-see-a-dentist-before-your-joint-replacement/.*

[120] Barrere S., Reina N., Peters OA, Rapp L., Vergnes JN, Maret D. Dental assessment prior to orthopedic surgery: A systematic review. Orthop Traumatol Surg Res. 2019 Jun;105(4):761–772. doi: 10.1016/j.otsr.2019.02.024. Epub 2019 May 3. PMID: 31060914.

[121] Young, H., Hirsh, J., Hammerberg, E.M., & Price, C.S. (2014). Dental disease and periprosthetic joint infection. The Journal of bone and joint surgery. American volume, 96(2), 162–168. *https://doi.org/10.2106/JBJS.L.01379.*

[122] *https://www.sciencedirect.com/science/article/pii/S1877056819301318.*

involving dental services that we have not yet considered, where certain dental services may be similarly inextricably linked to, and substantially related and integral to the clinical success of, certain otherwise covered medical service such that the exclusion under section 1862(a)12) of the Act would not apply. For example, we proposed to codify current policy that Medicare payment can be made for the wiring of teeth when done in connection with the reduction of a jaw fracture. We requested comment on whether there are other dental services associated with stabilizing and/or repairing the jaw after accidental injury or trauma and similarly that similarly would not be subject to the exclusion under section 1862(a)(12) of the Act, and for which we should consider providing Medicare payment.

We solicited comment on our current approach to payment for dental services that we have already identified under our current and proposed policies as inextricably linked to, and substantially related and integral to the clinical success of, certain covered services, as well as those services we may yet identify, and other operational topics we should consider further. We acknowledged that there may be other clinical circumstances we have not yet identified where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. There may be other clinical scenarios involving physiologic or anatomic conditions in which dental services could be a medically critical precondition to the clinical success of other services, such as certain surgical procedures or cancer treatments. For these reasons, we solicited comment on whether there are other clinical scenarios for medical or surgical services where the standard of care is such that the performance of certain dental services (for example, an exam, and certain diagnostic and treatment services) is considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment, and therefore, may be similarly inextricably linked to, and substantially related and integral to the clinical success of, a certain covered service, and therefore, not subject to the exclusion under section 1862(a)(12) of the Act. We discussed in the proposed rule that if we were to finalize the proposed policies as discussed under sections II.L.2.a. and II.L.2.b. of the proposed rule, we may consider finalizing, based on our review of public comments, these additional examples of dental services that may not be subject to the payment exclusion under section 1862(a)(12) of the Act because they are similarly inextricably linked to, and substantially related and integral to the clinical success of, covered medical services. We also noted that if we were to finalize such additional examples of dental services, we would list those services as examples under the regulation at § 411.15(i)(3), as discussed in section II.L.2.c. of the proposed rule. Lastly, as discussed above, we stated that we recognize that the dental services we have identified for which Medicare payment could be made under our proposed policies would occur either prior to, or contemporaneously with, the covered medical service. We also solicited comments on whether, on the same basis, there are clinical circumstances under which Medicare payment could be made for dental services furnished after the covered medical procedure or treatment.

ii. Establishment of a Process To Consider Additional Clinical Scenarios for Future Updates

As discussed, we stated that we believe that there may be clinical scenarios where dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. We also stated that we believe there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on this basis. To ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we discussed that we believe it may be appropriate to establish a process whereby interested parties can share recommendations for our consideration, review, and analysis for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3) through future rulemaking. If an interested party believes that there is a clinical scenario in which certain dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we invited interested parties to submit information about the clinical scenario and the medical evidence to support that the standard of care for the medical service is such that one would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially compromised, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. We described that the interested party should explain why the particular dental services should not be subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act, because they are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, and provide the medical evidence to support that conclusion.

To ensure that a thorough review can occur, we encouraged interested parties to include relevant medical literature, clinical guidelines or generally accepted standards of care, and other supporting documentation to support our review and consideration of the clinical scenario involving dental services. To facilitate our consideration of interested parties' recommendations within an annual rulemaking cycle, we requested that interested parties submit this information by February 10th of that year at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Submissions received outside of the public comment period for a PFS proposed rule would be considered for possible inclusion in future notice and comment rulemaking cycles. Recommendations received by February, 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. For example, information received by February 10, 2024, would be reviewed for consideration and potential inclusion within the CY 2025 PFS proposed rule. We encouraged interested parties to engage with us and provide medical evidence to support their recommendations for additional clinical scenarios where dental services may not fall within the scope of the payment preclusion under section 1862(a)(12) of the Act.

As discussed previously, we stated that we may consider finalizing a change, after reviewing public comments, in the CY 2023 PFS final rule to revise the list of examples of dental services for which Medicare payment can be made. Furthermore, we solicited feedback on: (1) whether there are additional clinical circumstances we should consider where dental services are inextricably linked to, and substantially related and integral to the clinical success of, covered medical

services; and (2) the establishment of a process to review additional clinical scenarios identified by the public, which we may consider finalizing, after review of public comments received, in this final rule.

iii. Request for Comment on Dental Services Integral to Covered Medical Services Which Can Result in Improved Patient Outcomes

As described in section II.L.2 of the proposed rule, we stated that we believe there are clinical scenarios where the standard of care is such that there is an immediate need for certain dental services as the necessary clinical prerequisite to an otherwise covered medical service. We stated that we believe there may be other clinical scenarios, however, where the ongoing disease management of the patient receiving the medically necessary procedure may have an improved outcome or see a clinical benefit from the performance of dental services, but that the dental service may not be inextricably linked to, or substantially related and integral to the clinical success of, the otherwise covered medical service.

For example, we believe there may be certain circumstances where the clinical benefit of medical care or treatment of a diabetic patient could be improved if certain dental services are furnished. We solicited public feedback on whether certain dental services (for example, a dental exam, necessary treatment of a dental condition such as the extraction of an infected and mobile tooth) should be considered so integral to the standard of care for an otherwise covered medical service that the preclusion on Medicare payment under section 1862(a)(12) of the Act does not apply.

Additionally, we solicited comments on whether the success of a given surgery is dependent upon eradication of dental or oral infection. As noted in section II.L.2.c. of the proposed rule, we stated that we believe surgeries dealing with organ transplants, cardiac valve replacement, or valvuloplasty procedures may require a dental exam and treatment prior to the surgery because the services to identify and eradicate dental or oral infection are inextricably linked to, and substantially related and integral to the success of, these otherwise covered medical services. However, we solicited feedback on whether there are other types of surgery for which certain dental services would meet this threshold. We invited public comment on whether there are other clinical scenarios involving acute or chronic conditions that would have an improved patient outcome if dental services are furnished, and if so, whether we should consider these services as inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services.

3. Request for Comment on Other Potentially Impacted Policies

As discussed in section II.L.2.a–b of the proposed rule, we proposed to codify and clarify our current payment policies for dental services. We recognized that under these policies there may be instances where multiple health care providers may need to coordinate the performance of certain medical and dental services based on the patients' chronic conditions and/or serious illnesses. We noted that we continue to consider improvements to our payment policies for care management services as health care delivery models evolve. As such, we sought comment on whether our current policies for care management services make clear that time spent by physicians or non-physician practitioners coordinating care with dentists regarding the performance and outcomes of services as proposed under section II.L.2 of the proposed rule, may be counted for purposes of applicable care management codes. We also solicited feedback on whether existing care management codes adequately describe and account for time spent coordinating with dentists and their clinical staff. We sought comments regarding the impact of changes in how health care is delivered, and whether an increased integration and coordination of care among health care providers should also be taken into account in considering dental services that may be inextricably linked to, and substantially related and integral to the clinical success of, a primary medical service. Additionally, we sought comment as to whether, and to what extent, the proposed policies as described in section II.L.2 of the proposed rule would address any inequitable distribution of dental services for Medicare beneficiaries.

Finally, we recognized that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan or other plan offering. We noted that if we were to finalize in the CY 2023 PFS final rule our proposed policies as described further in section II.L.2 of the proposed rule, we sought comment on how current coordination of dental benefits operates, and where improvements could be provided. Additionally, we sought comment on what aspects of coordinating benefits among supplemental dental providers we should consider if we were to finalize the proposed policies as specified under section II.L.2 of the proposed rule.

4. Request for Comment on Potential Future Payment Models for Dental and Oral Health Care Services

Our authority under section 1115A(d)(1) of the Act provides broad authority for the Secretary to waive such requirements of title XVIII of the Act, which pertain to Medicare, as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

In 2014, the Health Care Innovation Awards (HCIA) Round 2, a limited time grant initiative, included awards with the goal to improve the health of populations through activities focused on engaging beneficiaries, prevention, wellness, and comprehensive care that extended beyond the clinical service delivery setting. Several participants used their HCIA Round 2 funds to test models of clinical care that included payment for dental and oral care services. For further information regarding the success of these awards as applied to dental and oral care services please review the HCIA Round 2 Final Awardee Evaluation Report (2014–2018).[123]

We sought comment on additional ways to integrate the payment for dental and oral health care services within existing and future payment models using the Innovation Center's waiver authority in existing or future service delivery models, including models focused on equity, care coordination, total cost of care and specific disease condition.

Summary of Finalized Policies

As described further in the following sections, we are finalizing effective for CY 2023 (1) a clarification our interpretation of section 1862(a)(12) of the Act and codification of certain of our current Medicare FFS payment policies for medically necessary dental services; (2) Medicare Parts A and B payment for dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures effective CY 2023; (3) For CY 2024, we are finalizing Medicare Parts A and B payment for dental services, such as dental

[123] *https://innovation.cms.gov/data-and-reports/2020/hcia2-fg-finalevalrpt.*

examinations, including necessary treatments, performed as part of a comprehensive workup prior to the treatment for head and neck cancers, which we indicated we may consider finalizing based on comments received on the proposed rule; and (4) Effective CY 2023, the establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services, which we indicated we may consider finalizing in this final rule.

We are also finalizing amendments to our regulation at § 411.15(i) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service(s) are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B, under the applicable payment system, for such dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. We are also finalizing, with modifications, an amendment to § 411.15(i) to include examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B.

The policies we are finalizing take into account commenters' feedback and information provided in clinical literature, such as peer reviewed publications or clinical guidelines supported by clinical evidence, supporting the inextricable link between dental services and certain covered medical services. First, commenters supported our interpretation of section 1862(a)(12) of the Act that there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services. Second, many commenters provided recommendations that CMS collaborate with interested parties to allow for more time to explore the link between medical and dental services, refine the policy, and respond to many of the operational and implementation questions raised. We believe that the process we are finalizing, as described in section II.L.2.c.ii, to engage with interested parties and review their recommendations regarding the inextricable link between dental services and certain covered medical services will serve the need expressed by commenters for continued engagement on these issues. We are also finalizing for CY 2024, Medicare payment under Parts A and B for dental services prior to treatment for head and neck cancers, as an additional example of dental services that are inextricably linked to certain covered medical services than was presented in the proposed rule. This will allow us to continue to further consider definitional issues over the coming year. Additionally, we intend to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for certain dental services that do not fall within the preclusion or exclusion under section 1862(a)(12) of the Act and related topics. Furthermore, we remain open to adjusting our finalized policy through future rulemaking and/or additional guidance as necessary. We appreciate the thoughtful questions raised by commenters and are committed to continued engagement.

We are not finalizing, at this time, payment for dental services prior to the initiation of immunosuppressant therapy, joint replacement surgeries, or other surgical procedures, which we had indicated in the CY 2023 PFS proposed rule that we may finalize in this final rule. As further described below, we agree with the feedback received from many commenters that additional time is necessary to consider the inextricable link between dental services and these covered medical services, and with commenters' requests to develop definitions to guide decision making. We are committed to continuing to explore the potential inextricable relationship between dental services and these covered medical services through the process we proposed, as described under section II.L.2.c.ii of this final rule, and are finalizing beginning for CY 2023.

Comments and Responses to the Policies Discussed in the Proposed Rule

In this section, we summarize and respond to public comments on the policies that we either proposed within the CY 2023 PFS proposed rule (87 FR 45860, 46033 through 46040) or indicated that we may consider finalizing within the CY 2023 PFS final rule. Commenters included individuals, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, and health insurance companies, among others. We note that some commenters requested that we consider Medicare coverage policies that were outside the scope of the policies discussed in the CY 2023 PFS proposed rule. We thank the commenters and note that we will take these comments into consideration for the future.

We note that many commenters responded to our request for information under section II.L.2.c.iii. of this rule to express the view that payment of dental services could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. Many commenters encouraged CMS to apply its authority to pay for dental services associated with certain covered medical services to as broad of a range of clinical scenarios as possible, including, but not limited to, payment for routine dental care for patients with (or at risk of developing) medical conditions such as diabetes, cardiovascular disease, some lung diseases, or physical and cognitive impairments that impact individuals' ability to perform activities of daily living (including tooth brushing). Commenters also encouraged us to consider the provision of dental care in relation to treatments such as bisphosphonate therapy, substance use disorder treatment, prescription of certain psychiatric medications, or any surgery that may result in hospitalization. We thank commenters for both the personal and clinical information submitted regarding the importance between dental and oral health, and various medical conditions and certain medical services. We are still reviewing the wide array of suggestions, clinical information to elucidate the connection between dental health and clinical outcomes of many of the medical services, and other information provided in response to this request for information. Given these factors, we want to continue to engage with interested parties and consider this material through the public process as finalized under section II.L.2.c.ii. of this final rule or potentially in future rulemaking. Additionally, we encourage additional public discussions and engagement on a wide range of issues relating to Medicare payment for certain dental services that do not fall within the exclusion under section 1862(a)(12) of the Act.

Finally, we thank commenters for their thoughtful feedback on the requests for information on other potentially impacted policies (section II.L.3. of this final rule) and potential future payment models for dental and oral health care services (section II.L.4. of this final rule). We did not indicate in the CY 2023 PFS proposed rule that

we may finalize policies in these areas in the CY 2023 PFS final rule. We continue to review this feedback and will consider these comments on other potentially impacted payment policies within the public process we are finalizing, as described under section II.L.2.c.ii. of this final rule, and in potential future rulemaking or guidance, as necessary. We also look forward to ongoing discussions with the public on issues relating to the provisions described in this rule as well as dental services that do not fall within the exclusion under section 1862(a)(12) of the Act.

Payment for Inpatient Hospital Dental Services and Request for Comment

Comment: Commenters generally expressed support for our interpretation of the statute and our current regulation to allow Medicare payment for inpatient hospital services in connection with the provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Some commenters recommended that CMS undertake a Medicare demonstration for beneficiaries with underlying medical conditions who require integral dental services as a condition of their covered primary Medicare Part A service to determine the financial and operational efficiencies.

Other commenters requested that CMS provide further clarity around the type of dental services, medical conditions and services, and patient clinical statuses that would allow for Medicare payment in this manner. Commenters also requested that CMS further define whether the types of underlying medical conditions include hospitalizations for mental health or substance use disorders.

Response: We appreciate the commenters' support for our proposal to clarify and codify our current policy to allow Medicare payment to be made for inpatient hospital services in connection with the provision of dental services, if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. We appreciate the requests made by commenters for additional guidance to promote consistent application of the policy. We also believe that the codification and clarification of our current policy will assist in fostering consistent national application of this policy. We intend to provide additional guidance to CMS Medicare Administrative Contractors (MACs) and the public as needed to facilitate further consistent application of this policy.

Clarifying the Interpretation of Section 1862(a)(12) of the Act and Codifying Current Payment Policies for Certain Dental Services

Comment: Many commenters supported our proposal to interpret section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services, where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. These commenters supported our proposal to allow payment to be made because they agreed that the service is not in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but instead is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. The majority of commenters also supported our proposal to clarify in regulation that payment for dental services that do not fall within the scope of section 1862(a)(12) of the Act because they are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, could be made regardless of whether the services are furnished on an inpatient or outpatient basis. These commenters encouraged CMS to apply this policy in all clinical circumstances where appropriate. Some commenters suggested that such outpatient dental services might be provided through mobile clinics, via teledentistry, and in congregate care settings such as nursing facilities, assisted living facilities, etc.

One commenter questioned whether current hospital billing requirements would influence whether patients needing dental services will be admitted on an inpatient basis or treated as on an outpatient basis, and whether that would affect how much beneficiaries pay for these services.

Other commenters suggested that our proposal was focused too narrowly, and suggested broader interpretations of 1862(a)(12). One commenter suggested that oral care services (such as examinations; biopsies; radiological studies; other tests; and treatments of growths and lesions, benign or malignant, of the cheeks, lips, and tongue) are distinct from, and therefore not excluded from Medicare payment as dental services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Similarly, another commenter suggested that the Medicare statute excludes coverage and payment only for those dental services performed primarily for the purpose of treatment of the teeth or structures directly supporting the teeth, and therefore all other dental services performed to support another Medicare-covered procedure would be eligible for payment.

Response: We appreciate commenters' support for our proposal to permit Medicare payment under Parts A and B for dental services, where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; and to allow payment to be made regardless of whether the services are furnished in an inpatient or outpatient setting. As such, we are finalizing our proposal to codify and clarify in the regulation at § 411.15(i) that payment can be made under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; and that payment will be allowed for services furnished in inpatient and outpatient settings (where clinically appropriate) with payment being made for covered services under the applicable payment system. We appreciate the concerns raised by commenters regarding our interpretation of section 1862(a)(12) of the Act. However, we believe that section 1862(a)(12) allows for payment in this manner because such dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Instead, we believe they are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are substantially related and integral to that primary medical service. We appreciate commenters' request for guidance on this policy and will work to provide additional guidance, as needed, to promote consistent application of this policy. We expect such guidance may also reinforce and clarify that medical care involving the mouth, not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, is not subject to exclusion under section 1862(a)(12) of the Act, that CMS MACs may make claim-by-claim determinations, as necessary.

Comment: Some commenters recommended that we limit the scope of Medicare payments for oral examinations prior to certain covered medical services. These commenters stated that Medicare should continue to make payment for oral examinations under Medicare Part A if performed by a dentist on a hospital's staff; however, Medicare Part B should only make payment for oral examinations performed by a physician, excluding dentists. These commenters requested that CMS not clarify in regulation that the statutory definition of physician under section 1861(r)(2) of the Act applies in these circumstances, and instead requested that CMS maintain, as stated in the NCD Manual (IOM Pub 100–03, Chapter 1, Part 4, section 260.6), that when performing a dental or oral examination, a dentist is not recognized as a physician under section 1861(r) of the Act. These commenters stated that physicians should be the leaders of the patient care team and that diagnosis of the medical issue, and subsequent care plan, should be determined only by the medical professional, not the dentist. Other commenters asked whether medical professionals could perform the dental exams in accordance with current policy. These commenters further requested clarification as to whether we would apply equivalent physician administrative (such as electronic health record reporting and merit-based incentive payments), enrollment, and compliance requirements to dentists as are applied to other physician professionals under Medicare Part B.

Response: We appreciate commenters' questions regarding our proposal to provide Medicare payment for oral or dental examinations performed as part of a comprehensive workup prior to certain covered medical services, and acknowledge their request to narrow the scope of the proposal. However, we continue to believe that the current language in the NCD manual is based on an unnecessarily narrow reading of section 1861(r) of the Act, and is not consistent with other manual provisions. We believe the statutory definition of physician under section 1861(r) of the Act is clear in its inclusion of a doctor of dental surgery or of dental medicine, and a similar definition of physician is included in our Medicare General Information, Eligibility, and Entitlement Manual (IOM Pub 100–1, Chapter 5, section 70.2) when dental or oral examinations, and specific treatments, are within the State scope of practice for the dentist.

We thank commenters for their request for clarification of the medical professionals' (physician or non-physician practitioner) role within the performance of dental services that are inextricably linked to the clinical success of certain covered medical services. We agree that involvement and integration between medical and dental professionals is an important component of the delivery of these medical services, and is fundamental to our policy permitting payment for certain dental services under Medicare Parts A and B. Further, we appreciate the commenters' point, and also believe that physician and non-physician practitioner engagement in the patient's care team is important. As such, Medicare Parts A and B payment for dental services not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act can occur only when dental and medical services are integrated and when the dental services are inextricably linked to certain covered medical services. Without both integration between the medical and dental professional, and the inextricable link between the dental and covered medical services such that the dental services are integral to the clinical success of the medical services, Medicare payment for the services would be precluded under Medicare Part B and therefore section 1862(a)(12) of the Act. We note that dental services that are precluded from payment under Part B under the statutory payment exclusion in section 1862(a)(12) of the Act may be eligible to be covered and paid by supplemental dental plans.

We believe integration between medical and dental professionals can occur when these professionals coordinate care. This level of coordination can occur in various forms such as, but not limited, to a referral or exchange of information between the medical professional (physician or non-physician practitioner) and the dentist. This coordination should occur between a dentist and another medical professional (physician or other non-physician practitioner) regardless of whether both individuals are affiliated with or employed by the same entity. We note that to be eligible to bill and receive direct payment for professional services under Medicare Part B, the medical professional and dentist would need to be enrolled in Medicare and meet all other requirements for billing under the PFS. (Alternatively, a dentist not enrolled in Medicare could perform services incident-to the professional services of a Medicare enrolled physician. In that case, the services would need to meet the requirements for incident-to services under § 410.26, including the appropriate level of supervision. Payment would be made to the enrolled physician who would bill for the services.) Furthermore, the state scope of practice for the medical and dental professional must support the professional performing the specific dental service(s). If there is no exchange of information between the medical professional (physician or other non-physician practitioner) and the dental professional, then we do not believe there can be an inextricable link between the dental and covered medical service for purposes of Medicare payment for the dental services within the meaning of section 1862(a)(12) of the Act. This is because the medical and dental professionals would not have the necessary information to decide that the dental service is inextricably linked to a covered medical service, and therefore, not subject to a statutory payment exclusion under section 1862(a)(12) of the Act.

In regard to commenters' request for clarification as to whether equivalent administrative, enrollment, and compliance requirements would apply to dentists as are applied to other physicians, practitioners, and healthcare professionals under Medicare Part B, we note that dentists are included in the statutory definition of physician at section 1861(r)(2) of the Act, and would generally be considered and treated as a physician for purposes of enrollment, compliance, and other administrative programs including the Merit-Based Incentive Payment Systems (MIPS) (for more information about MIPS eligibility please see: *https://qpp.cms.gov/mips/how-eligibility-is-determined*), which includes requirements related to electronic health record (EHR) usage for physicians, and is applicable to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Because ''a physician'' is specified as an eligible professional under this definition, and a doctor of dental surgery or dental medicine is included in the definition of physician in section 1861(r) of the Act, the MIPS reporting requirements would apply to dentists who are determined to MIPS eligible clinicians.

We appreciate the concerns raised by commenters and will work to provide additional guidance to answer enrollment, billing, compliance, and other administrative questions for dentists as needed.

Comment: Commenters generally supported our proposal to codify examples of dental services for which payment is permitted under our current

policy: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition. One commenter suggested that the term ''wiring of the teeth'' be instead identified as ''stabilization of teeth'' to align with current medical terminology. Another commenter noted that ''wiring'' and ''splinting'' are commonly used and accepted terms, and that they are sometimes used interchangeably, along with ''stabilization.'' The same commenter requested clarification as to the rationale for including, ''dental splints only when used in conjunction with covered treatment of a medical condition such as dislocated jaw joints'' in proposed § 411.15(i)(3)(i)(E) as well as ''wiring or immobilization of teeth in connection with the reduction of a jaw fracture'' in proposed § 411.15(i)(3)(i)(C) and suggested that the two related paragraphs be combined.

Response: We appreciate commenters' support for our proposal to codify examples of dental services for which payment is permitted under our current policy. We thank commenters for suggesting updates in medical terminology. We agree that the dental services examples provided under current policy: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition, are examples of dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore, continue to believe that Medicare Parts A and B payment could be made for them.

As such, we are finalizing our proposal to amend § 411.15(i) to clarify that: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery (and as discussed in detail below, we are expanding this to include all organ transplant surgeries); (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; and (3) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, are examples of dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore, and continue to believe that Medicare Parts A and B payment could be made for them.

We were persuaded by the information provided by commenters regarding the medical terminology we use at § 411.15(i)(3)(C), the suggestion to replace ''wiring or immobilization of the teeth'' with ''stabilization,'' and also the suggestion to combine two related paragraphs, §§ 411.15(i)(3)(C) and 411.415(i)(3)(E). In response to comments, we are finalizing a revision to § 411.15(i) to merge the two related paragraphs into one paragraph at § 411.15(i)(3)(C). The revised paragraph will refer to, ''The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture and dental splints only when used in conjunction with covered treatment of a covered medical condition, such as dislocated jaw joints.''

Comment: Several commenters expressed support for our proposal to provide that payment can be made for ancillary services and supplies furnished incident to covered dental services, including but not limited to x-rays, administration of anesthesia, and use of the operating room. Several commenters recommended removal of any requirements for direct supervision of auxiliary personnel, such as for services performed by dental hygienists, for ancillary services and supplies furnished incident to covered dental services, because they stated the physical presence of the dentist could limit access to services. These commenters stated that requiring direct supervision of dental hygienists would also be in conflict with some state's scope of practice for these auxiliary personnel. Other commenters requested that certified registered nurse anesthetists (CRNAs) continue to be recognized as anesthesia professionals able to administer anesthesia in these circumstances and receive Medicare payment.

Response: We appreciate commenters' support for our proposal to provide that Medicare payment can be made for ancillary services and other supplies furnished incident to covered dental services, such ancillary services including but not limited to x-rays, administration of anesthesia, and use of the operating room. We note that we did not propose to modify our current policies with respect to the scope of professional services, or the administration of anesthesia services, by CRNAs.

In order for physicians and other practitioners, including dentists, to receive Medicare Part B payment for services that are performed by auxiliary personnel incident to their professional services, the services generally must be performed under the direct supervision of the physician or practitioner. This is one of the requirements specified in our regulation at § 410.26 for ''incident to'' services, such as services performed by dental hygienists and billed by the dentist incident to their professional services. We note that the definition of direct supervision does not require the physician or dentist to be physically present within the room during the performance of the dental services. We did not propose to modify our regulatory requirements under § 410.26 for services furnished incident to physicians' services. Therefore, those regulatory requirements continue to apply. We will consider the commenters' recommendations for adjusting the supervision requirements of auxiliary personnel, including dental hygienists, performing covered dental services incident to dental services of a physician for potential future rulemaking.

Update to Current Payment Policies for Dental Services

Comment: Many commenters supported the proposed updates to include payment for medically necessary dental services related to additional conditions (prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures), stating that dental services in these circumstances are inextricably linked to the proposed medical services, are medically necessary, and providing payment for them will foster and improve patient outcomes related to these medical conditions.

Response: We appreciate the commenters' support and agree that the payment policy updates we proposed represent examples of dental services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services. As discussed, these examples include payment for dental services prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures. As such, we are finalizing

our proposal that Medicare Part A and Part B payment can be made for dental or oral examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are inextricably linked to, and substantially related and integral to the clinical success of, these covered medical services.

Comment: Many commenters expressed support for the proposed update for payment for medically necessary dental services related and integral to the clinical success of organ transplants, cardiac valve replacement or valvuloplasty procedures, as the commenters believe that these revisions would serve to promote health equity and increase access to medically necessary services for vulnerable members of the Medicare population. The commenters asserted that underserved populations generally do not have access to the necessary oral health services required for successful outcomes related to organ transplantation and cardiac valve replacement or valvuloplasty procedures.

Response: We appreciate the commenters' support regarding the potential health equity impact of the proposed updates to the current policy for payment under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services to now include organ transplant, cardiac valve replacement, or valvuloplasty procedures. We further appreciate the feedback that Medicare payment for dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures could help advance health equity for people who are medically underserved.

Comment: Many commenters expressed support for the proposal to include Medicare Parts A and B payment for dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to an organ transplant. Commenters indicated that it is standard practice for candidates for organ transplants to require a dental assessment and/or screening for, and treatment of, decay and infections including periodontal disease before transplant surgery, as these conditions potentially compromise the outcomes of surgery including organ rejection. Commenters noted a wide variation of terms and clinical scenarios where certain dental services may be necessary for certain patients surrounding a transplantation procedure, and requested CMS further delineate specific circumstances where payment may be made under Medicare Parts A and B.

Commenters stressed the importance of remedial oral or dental care in advance of transplantation to reduce dental and oral infection and stated that the resolution or stabilization of dental problems prior to transplant procedures lowers the risk for infection and sepsis post-transplant. Several of these commenters provided citations from opinion pieces to support their perspectives. Some commenters noted that, according to the National Institute of Dental and Craniofacial Research, ''Whenever possible, all active dental disease should be aggressively treated before transplantation, since post-operative immunosuppression decreases a patient's ability to resist systemic infection.'' We note that the authors further stated that, ''there was an association between dental focus and hospital readmission/stay. However, our methods do not provide conclusive proof of causality. Hospitalization due to acute dental infection was rare.'' [124]

Commenters also asserted that inflammation combined with required immune suppression for transplant procedures can yield poor outcomes post-transplantation and that high rates of poor oral health, including periodontal disease and xerostomia, are risk factors for compromising successful transplant outcomes. Moreover, a few commenters noted that patients are generally required to demonstrate good oral hygiene to even be considered active on the organ transplant waiting list.

Commenters also stated that they believe dental services that are substantially related and integral to the clinical success of transplants need to be provided to candidates before any such procedure, regardless of whether transplantation ultimately occurs. Commenters noted that the elimination of oral or dental infection is necessary prior to surgery, even if the procedure does not take place. Commenters also noted that medically necessary services may be required during the transplantation procedure, as some oral issues may not be identified until the procedure is underway.

Moreover, commenters expressed concerns that some patients who may be awaiting transplantation services could receive dental services and then undergo the transplantation procedure only to experience organ rejection, other non-ideal outcomes, or ultimately not receive transplantation procedure due to extenuating circumstances. The commenters were concerned that while the dental services are substantially related and integral to the clinical success of the planned or furnished covered transplantation services, in the event the transplant procedure is ultimately not successful due to rejection or the procedure does not occur for various medical reasons, Medicare could deny payment for the dental care that is substantially related and integral to the organ transplant because the transplant surgery was not completed or unsuccessful.

Commenters explained that life-threatening infections related to the weakened immune systems of older adults (immunosenescence) and transplant-related immunosuppression can be serious complications of transplantation after the transplantation occurs. These commenters also stated that transplant patients typically take multiple medications involving long-term use of immunosuppressive drugs, as well as multiple medications for co-morbidities like diabetes and cardiovascular disease, and that dental services may be required in addressing these post-transplantation conditions.

Several commenters requested that CMS provide payment under Medicare Parts A and Part B for medically necessary diagnostic and treatment services after an organ transplant, rather than only before or during the transplant procedure because they stated that dental services both before and after the transplantation procedure itself influence the outcome of the transplant. A commenter stated that screening for and treatment of oral inflammation and infections must begin pre-transplantation and continue as appropriate post-transplantation, for a duration of approximately 3 to 6 months, in order to prevent sepsis and organ rejection until immunosuppression is resolved. Other commenters supported Medicare payment for dental services that occur post-transplant by asserting the importance of post-transplant oral care to clinical outcomes. Lastly, these commenters requested that CMS reconsider the statement asserting that no payment would be made for services that are not immediately necessary prior to surgery to eliminate or eradicate infection.

[124] National Institute of Dental and Craniofacial Research. April 2011. Dental Management of the Organ Transplant Patient. *https://www.in.gov/health/files/OrganTransplantProf.pdf.*

Response: We appreciate the commenters' thoughtful and evidence-based feedback regarding the link between oral or dental examinations, medically necessary diagnostic and treatment services to eliminate an oral or dental infection, and organ transplants.

We agree with commenters that there is clinical evidence to support that the medically necessary dental care may advance the clinical success of organ transplants. We appreciate the clinical studies referenced to support the link between dental services prior to organ transplantation and improved health outcomes for certain patients. Therefore, we believe that payment can be made under Medicare Parts A and B for dental services such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery and medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate the infection or its source that are provided before transplantation because such services are inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant procedure.

We also agree that medically necessary dental diagnostic and treatment services may be immediately necessary to eliminate or eradicate an infection or its source contemporaneously with the organ transplant. We understand that it may not be feasible to provide certain dental or oral services in advance of the transplant procedure and that the services may instead occur during the surgery itself.

Examples of dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as filling procedures—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999).

Additionally, we note that when dental services, such as dental examinations, including necessary treatment, are performed as part of a comprehensive workup prior to organ transplant surgery, and medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate the infection or its source, prior to, or contemporaneously with, the organ transplant occur, and, ultimately, the transplantation procedure does not yield ideal clinical outcomes including organ rejection etc., payment may still be made under Medicare Part A and Part B for the dental services provided. The dental services are inextricably linked to, and substantially related and integral to the clinical success of the transplantation procedure, and achievement of ideal clinical outcomes (for example, no occurrence of organ rejection) is not a requirement for the payment of these medically necessary services.

Furthermore, we appreciate the commenters' feedback regarding those individuals who are awaiting organ transplantation and the commenters' request that Medicare provide payment for medically necessary dental services prior to transplantation, with the understanding that the transplantation procedure may not ultimately occur, and that payment should still be made under Medicare Part A and Part B for those medically necessary dental services.

In a case where an individual is awaiting organ transplantation, we believe that it is appropriate for Medicare to provide payment for, including but not limited to, an oral or dental examination, and medically necessary diagnostic and treatment for only those services that are considered immediately necessary to eliminate or eradicate the infection or its source prior to the organ transplant. As previously discussed in this final rule, when a service is in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but not inextricably linked to, and substantially related and integral to the clinical success of, the covered medical services, then payment may be made but only in specific circumstances as discussed in section II.L.2.a of this rule. We do not currently believe that our interpretation of section 1862(a)(12) of the Act would allow payment for dental services not inextricably linked to, and substantially related and integral to the clinical success of anticipated covered medical services. Therefore, payment would not be made in those circumstances.

We appreciate the commenters' feedback regarding Medicare payment for medically necessary dental services after the transplantation procedure occurs. We thank commenters for the evidence they provided to connect the importance of dental care received after the organ transplant on the success of that transplant procedure. We received significant input from commenters in this area and want to thoroughly review the evidence provided. We plan to continue to review this evidence and engage with interested parties to issue additional guidance or future rulemaking, as determined necessary.

With regard to commenters' questions on the types of clinical scenarios where dental services may be necessary prior to transplantation procedures, we reiterate that MACs have the flexibility to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). We will provide additional guidance to the MACs in order to make these determinations and further note that the finalized policies outlined in this section of this final rule would not prevent a MAC from making the type of determination that payment can be made for dental services in other circumstances not specifically addressed within this final rule and the finalized amendments to § 411.15(i).

In light of commenters' feedback, effective for CY 2023, we are finalizing that payment can be made under Medicare Part A and Part B for dental services for, including but not limited to, an oral or dental examination, and medically necessary diagnostic and treatment services that are considered immediately necessary to eliminate or eradicate the infection or its source prior to, or contemporaneously with, the organ transplant and when those dental services are determined to be inextricably linked to, and integral to the clinical success of, the transplant procedure. We plan to continue reviewing evidence submitted by commenters and may refine or explain this policy further in future guidance or rulemaking.

We encourage the public to use the nomination process as finalized in section II.L.2.c.ii. of this final rule to identify additional clinical scenarios under which Medicare payment could be made for certain dental services that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. We invite interested parties to submit information about clinical scenarios and related medical evidence to support that the standard of care for the medical service is such that one would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially

compromised, such that clinical outcomes of the medical service could be compromised absent the provision of the inextricably-linked dental services.

Comment: Several commenters noted that while they acknowledge the connection between dental services and potential improved health outcomes in the cases of the proposed organ transplant, cardiac valve replacement, and/or valvuloplasty procedure scenarios, they urged CMS to delay any updates and use a methodical approach to adding further services as examples of clinical scenarios where Medicare payment could be made for certain dental services. Several commenters requested that CMS postpone finalizing the addition of dental exams and necessary treatments prior to organ transplants, heart valve replacements and valvuloplasty procedures until the establishment of a formal review process that could more thoroughly assess the clinical inextricable link between dental services and certain covered medical services before finalizing any additional examples of payable services.

One commenter asserted that CMS had provided insufficient scientific justification for the addition of the organ transplant, cardiac valve replacement, or valvuloplasty procedure scenarios for the purposes of Medicare Parts A and B payment for dental services and therefore did not support the finalization of these additional scenarios. Additionally, a few commenters asserted that MACs already have the ability to make case-by-case determinations for dental services inextricably tied to Medicare Part A procedures, and therefore, the addition of the proposed categories were not necessary. Other commenters stated that CMS lacked the statutory authority to finalize payment for these types of dental services.

Response: We appreciate the commenters' request that we conduct a thorough review of the clinical evidence related to the proposals. As discussed, we believe that the clinical evidence is clear that in cases of organ transplant, cardiac valve replacement, and valvuloplasty procedures, certain dental services are substantially related and integral to the clinical success of these scenarios because the success of the procedure would be compromised without eradicating the dental or oral infection prior to the initiation of such medical service. Therefore, we are amending § 411.15(i) to include these clinical scenarios as examples under which Medicare payment under Part A and Part B would not be excluded.

Additionally, as described further below, we are finalizing for CY 2024 the inclusion of dental services prior to the treatment for head and neck cancers as a clinical scenario under which Medicare payment under Part A and Part B would not be excluded. We are finalizing this policy for CY 2024 to allow us additional time with the clinical data and to conduct additional analysis to consider whether greater specificity may be needed when implementing this policy and the applicability of certain terms with the medical services involved in this type of treatment. We reiterate that MACs have the flexibility to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). We further note that the finalized policies outlined in this section of this final rule would not prevent a MAC from making the type of determination that payment can be made for dental services in other circumstances not specifically addressed within this final rule and the finalized amendments to § 411.15(i).

We appreciate the request that we continue to review whether there is an inextricable link between dental and medical services in general and we will continue to evaluate and review the clinical considerations submitted by commenters. We may refine or explain this policy further through future guidance or rulemaking. We also note that we are finalizing a process to review public recommendations for clinical scenarios where there may be an inextricable link between certain dental services and covered medical services, and encourage commenters to engage with us through the process we are finalizing in this final rule.

With regard to the commenter who stated we did not have statutory authority to finalize a policy in this area, we continue to recognize that there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services. Furthermore, we believe that there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, we continue to believe, based on the review of comments, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service.

Comment: Several commenters requested clarification regarding the definition of organ transplant as it applies to Medicare payment for dental services that are substantially related and integral to the clinical success of certain covered medical services. Specifically, they requested that the definition include not only organ transplants, but also hematopoietic stem cell and other transplants.

Commenters stated that dental examination and stabilization, specifically resolution of concerns related to oral health, are considered a standard of care in hematopoietic stem cell transplants (HSCT) since any patients who are on immunosuppressant therapies while receiving chemotherapy and radiation receive a clinical benefit from dental or oral stabilization care pre-transplant and continued care post-transplant,[125] which the commenters assert represents the majority of the HSCT patient population.

Some of these commenters also noted that bone marrow transplantation may also require dental services that are inextricably linked to, and substantially related and integral to the clinical success of these covered medical services, as commenters asserted that dental and oral services serve to improve clinical outcomes for these types of transplants. Additionally, commenters stated that dental services prior to CAR–T cell therapies may also benefit the patient receive the medical service.

Response: We appreciate the commenters' feedback regarding the scope of organ transplant as it applies to Medicare Parts A and B payment for dental services that are inextricably linked to, and substantially related and integral to the clinical success of certain covered medical services. We agree with the evidence commenters provided regarding the inextricable link between dental services and hematopoietic stem cell and bone marrow transplantation as consistent with the other organ transplants, particularly with regard to the risk of infection for patients requiring all of these organ transplants.

[125] 2 Elad, S., Raber-Durlacher, J.E., Brennan, M.T. et al., Basic oral care for hematology–oncology patients and hematopoietic stem cell transplantation recipients: a position paper from the joint task force of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and the European Society for Blood and Marrow Transplantation (EBMT). Support Care Cancer 23, 223–236 (2015). doi.org/10.1007/s00520–014–2378–x.

In response to comments, we are clarifying that Medicare payment may be made under Parts A and B for dental or oral services prior to organ transplants, which for the purposes of this policy includes scenarios where the patient receives an organ transplant, including a bone marrow or hematopoietic stem cell transplant. We also recognize that term ''organ transplant'' may not be considered to include bone marrow or hematopoietic stem cell transplants in all contexts, and note that Medicare payment policies for organ procurement organizations or other payment policies may be applied differently for the purposes of paying for bone marrow and stem cell transplantations.

Comment: Many commenters supported our proposal to provide Medicare payment for a dental or oral examination as part of a comprehensive workup and the necessary dental treatments and diagnostics to eliminate oral or dental infections prior to cardiac valve replacement or valvuloplasty procedures. Commenters indicated that poor dental health has proven to be highly associated with chronic disease and higher cardiovascular risks and that oral infections can undermine recovery from cardiac valve replacement or valvuloplasty procedures. Commenters also stated that dental infections and poor oral health increase the risk of infection in a newly implanted heart valve, and that patients may have primary bacterial endocarditis or secondary prosthetic valve endocarditis to neglected dental health and chronic dental abscesses. The commenters further stated that these life-threatening situations could be prevented with the provision of medically necessary oral or dental services prior to and, as necessary, during a cardiac valve replacement or valvuloplasty procedure.

Response: We appreciate commenters' support regarding these proposed updates to the existing policy for payment under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of certain covered medical services, and provided prior to and/or contemporaneously with, those covered medical services, such as cardiac valve replacement and valvuloplasty procedures. We agree that the evidence supports that dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to and/or contemporaneously with cardiac valve replacement or valvuloplasty procedures, are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. Specifically, we note that after a valve replacement, the valve is at risk of being a seeding source for future endocarditis. Endocarditis can carry high risk for mortality for these patients, so eliminating an infection prior to or contemporaneously with the procedure would be important for preventing future endocarditis seeding at the new valve.

For these reasons, we are finalizing our proposal that Medicare Part A and Part B payment can be made for certain dental services, such as dental or oral examinations, including necessary treatment, performed as part of a comprehensive workup prior to, and/or contemporaneously with, cardiac valve replacement or valvuloplasty procedures, that are inextricably linked to, and substantially related and integral to the clinical success of, the procedures.

Comment: Several commenters suggested that CMS provide additional guidance that would aid in processing claims for dental services that are inextricably linked to the Medicare-covered medical service. Commenters suggested we provide additional guidance about what types of specific dental treatments would be billable if provided under our finalized policy prior to, or contemporaneously with, Medicare-covered organ transplant, heart valve replacement, and valvuloplasty procedures. Some commenters requested CMS issue specific procedure and diagnosis codes associated with this policy. Other commenters recommended specific professional services codes, procedure codes and diagnosis codes for CMS to reference. Many commenters requested this information to allow a consistent application of the policy and for clinical decision-making purposes. A few commenters requested that CMS require the use of a modifier to identify dental services and claims that are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. Others requested that CMS implement prior authorization policies so that healthcare professionals have prior approval of the inextricable linkage between the dental and medical services. However, some commenters argued that the use of modifiers or prior authorization could be overly burdensome to providers.

Response: We appreciate the commenters' request for additional guidance regarding how to identify what services may be payable, such as the use of modifiers or the prior authorization process, and how to ensure that the claims themselves can be successfully processed.

Additionally, we note that if clinically necessary, Medicare could make payment for dental services occurring over multiple visits. We recognize that it may not be clinically appropriate to receive the totality of dental services, which are necessary to immediately eradicate an infection, that are inextricably linked to the covered medical services, within one visit. As such, Medicare could make payment, for example, for the required dental services immediately necessary to eradicate the infection if such services require multiple dental services and it is clinically advisable for those services to occur over multiple visits prior medical services such as an organ transplant, cardiac valve replacement, or valvuloplasty procedures.

We will continue to consider commenters' request for additional specific considerations and scenarios, and may issue additional guidance or further address our policies in this area in future rulemaking. Furthermore, we will provide guidance to the MACs to assist them in determining this inextricable link between dental and medical services so that they can continue to make determinations on a claim-by-claim basis for patient and clinical circumstances do or do not fall within the examples of services listed under § 411.15(i), or within the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i).

Additionally, we are continuing to explore commenters' suggestions that we use claim modifiers or prior authorization policies.

Comment: Multiple commenters supported the proposal that certain dental services that are substantially related and integral to the clinical success of organ transplant, cardiac valve replacement, or valvuloplasty procedure can occur within the inpatient hospital or outpatient settings and agreed that Medicare Parts A and B payment should be made for associated dental services, regardless of whether the services are furnished in an inpatient or outpatient setting.

Response: We appreciate the commenters' support regarding the settings in which payment can be made for dental services. We agree that payment can be made for dental services that are inextricably linked, and substantially related and integral to the clinical success of, certain covered medical services can be furnished in multiple settings. As such, we are finalizing that Medicare Parts A and B payment can be made for such covered

dental services, as applicable, regardless of whether the services are furnished in an inpatient or outpatient setting, as clinically appropriate; and that payment under the applicable payment system. We will also make updates to appropriate Medicare payment data files to ensure that appropriate payments can be made under the applicable payment system. We note that this policy is consistent with the payment policy as specified within our existing manual guidance (See Medicare Benefit Policy Manual (IOM Pub 100–02, Chapter 15, section 150).)

Comment: Several commenters supported our proposal that payment under the applicable payment system could also be made for services that are ancillary to dental services for which Medicare payment can be made, such as x-rays, administration of anesthesia, and use of the operating room.

Response: We appreciate the commenters' support and agree that payment can be made for ancillary services or supplies associated with the provision of covered, medically necessary dental services. As such, we are finalizing our proposal that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

Comment: Several commenters requested additional information regarding the operational aspects of both the proposal to codify and clarify existing policy and the proposal to update dental services that are inextricably linked to, and substantially related and integral to the clinical success of, the covered medical services. Specifically, commenters raised concerns about issues, including: (1) what claims form dentists would use to submit claims for dental services; (2) what procedure code set and what diagnostic codes would be reflected on the claims; (3) if National Coverage Determinations (NCDs) will be issued to ensure consistent claim payment across the country; (4) clarification on any frequency limits, documentation requirements, and authorization processes; and (5) Medicare enrollment processes for dentists and any efforts CMS may make to ensure network adequacy.

Other commenters suggested that CMS establish a demonstration to initially test the operational feasibility of a Medicare payment policy of this magnitude. These commenters suggested, that by using a demonstration format for payment in this manner, we could continue to refine the policy and operational aspects of the policy with input from interested parties prior to implementing nationally.

Response: We appreciate the commenters' thoughtful feedback and questions. We note first that under our current policy (which is being codified in this final rule), dental services with an inextricable linked to certain Medicare-covered medical services can, and have been, paid under Medicare Parts A and B. At this time, dentists, as appropriate, should continue to enroll in Medicare according to the current process. Dentists and other qualified practitioners who furnish dental services that are eligible for payment under Parts A and B (because they are inextricably linked to another Medicare-covered medical service) should continue to submit claims using current processes, and can consult with their MACs for specific claims submission questions.

However, we also recognize that with the codification and clarification of our policies regarding dental services that are inextricably linked to Medicare-covered medical services (including prior to organ transplant, cardiac valve replacement, and valvuloplasty), the volume of dental service claims being submitted may increase. We appreciate the commenters' thoughtful feedback and questions regarding the operational aspects of this proposal, and we agree that these are necessary areas to address. We acknowledge the need to address and clarify certain operational issues, and we are working to address these issues, including claims processing questions raised by the commenters. We anticipate resolving many of the additional operational issues raised by commenters potentially as soon as CY 2024, including efforts to adopt the dental claim form. We will also make updates to appropriate Medicare payment data files to ensure that covered dental services can be billed and paid (in a manner described below) based on the applicable payment system for services furnished. We will continue to work with our MACs and encourage continued feedback from interested parties to help identify concerns or questions regarding submission and processing of dental claims. We also plan to provide guidance and engage in further rulemaking, as necessary, as operational strategies and plans are refined and implemented. We will also monitor service utilization to identify any concerns about consistency of claims processing and adequacy of access across the country. We appreciate the questions raised by commenters and plan to take them into consideration as we continue to refine operational issues relating to this policy, and make any necessary refinements.

Comment: Several commenters supported our proposal to continue to contractor price dental services that are substantially related and integral to the clinical success of certain covered medical services for CY 2023, or until such time that CMS has data to establish prospective payment rates. Conversely, several commenters objected to MAC-specified payment, as the commenters expressed concern regarding potential for incongruent payment amounts based on MAC region and also expressed apprehension regarding potential health equity impacts if payments were not aligned across geographies. Commenters made recommendations regarding the creation of a framework that ensures applicable payment policies across MAC regions and also requested annual updates for these payments. Other commenters requested that CMS encourage the use of specific public data sources in setting payment rates for dental services, and in order to account for geographic variations in the costs of providing dental and oral services.

Response: We appreciate the commenters' feedback regarding our proposal to contractor price dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, including organ transplant, cardiac valve replacement, or valvuloplasty procedures. We continue to believe that MACs are appropriately situated to establish contractor prices for these services given that the MACs currently establish contractor pricing for the dental services for which payment is currently made. As it is for dental services currently payable under Medicare Parts A and B, we believe that it is appropriate to continue contractor pricing for dental services for which payment is made in the additional clinical scenario examples we are finalizing in this final rule, until we have additional pricing data that could enable national pricing. As such, we are finalizing our proposal to continue to contractor price these services based on the applicable payment system for services furnished. However, we agree with the suggestions made by commenters that there may be publicly available data sources that could aid MACs in determining these payment rates. We plan to issue operational guidance to the MACs for these final policies and will note the potential usefulness of these data sources when establishing payment rates for these applicable dental services.

Comment: A few commenters expressed concerns regarding the financial impact of possible payment under Medicare Parts A and B for dental services substantially related and integral to the clinical success of certain covered medical services, including organ transplant, cardiac valve replacement, or valvuloplasty procedures. The commenters stated that these services are high-volume procedures and expressed concerns that paying for these dental services through the PFS would negatively impact the budget neutrality adjustments to the conversion factor, and would negatively impact payments for other physicians' services. These commenters urged CMS to consider the implications on the PFS payment system prior to finalizing any expanded policy in this area, or until financial impact was better understood and available for interested parties' review and comment.

Response: We appreciate the commenters' feedback regarding possible financial impacts for payments made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. Also, we proposed to clarify our interpretation of section 1862(a)(12) of the Act and codify certain aspects of our current Medicare PFS payment policies for dental services. We also proposed and sought comment on payment for other dental services, such as dental exams and potential necessary treatments prior to organ transplants, cardiac valve replacements and valvuloplasty. Because we proposed to codify and update existing policy, these proposals would not impact budget neutrality under the PFS, or require adjustments to the PFS conversion factor. Additionally, while we recognize that the impact of access to these services to individual beneficiaries may be very significant, we still do not anticipate significant impact in the context of overall spending and utilization under the Physician Fee Schedule. We intend to closely study the trends in utilization and payment for these services and make refinements to the payment policy as needed in future rulemaking.

Other Clinical Scenarios for Dental Services Integral to Other Covered Medical Services

Comment: Many commenters supported our suggestions that dental care may be inextricably linked to the clinical success of, treatments for head and neck cancer, immunosuppressive therapy, or joint replacement. Commenters also noted general support for coverage of dental care in both inpatient and outpatient settings, and coverage of ancillary services such as x-rays and anesthesia, needed to perform any covered dental care. Many commenters supplied data and studies that spoke to the prevalence of chronic conditions or health disparities among different populations, as well as information supporting the benefits of good dental health. However, only a few commenters provided clinical evidence with their comments to explicitly support the link between dental services and the clinical success of these specific medical services.

Many commenters noted that without clear definitions or narrowly tailored guidance, identifying dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service may prove challenging. Several commenters noted that this standard could be interpreted overly broadly since, as many commenters noted, there is a great deal of evidence suggesting that dental health is generally an important component of overall health. Alternatively, a few commenters were concerned that this standard could be interpreted too narrowly, such as by assuming that a dental service must always be performed contemporaneously with another covered procedure to be considered ''integral'' to that procedure. These commenters collectively worried that beneficiaries, practitioners, and MACs may be confused about what dental services can be covered, which would lead to inconsistent payment of claims and potential unanticipated financial burdens on beneficiaries or practitioners.

Response: We thank the commenters for these insights and agree that these are critical issues to consider as we review recommendations and clinical evidence relating to Medicare payment for dental services. However, we note that while many commenters expressed support for the inextricable link between dental services and medical services such as immunosuppressive therapy, or joint replacement, we do not currently believe we have sufficient clinical evidence to fully evaluate whether certain dental services are inextricably linked to, and substantially related to the clinical success of, medical services such as the initiation of immunosuppressant therapy, or joint replacement surgeries, and need more time to review. We will continue to review the information submitted by commenters during the rulemaking cycle, and we encourage the public to provide additional information, including through the finalized process under section II.L.2.c.ii. of this rule.

Comment: Many commenters agreed with our analysis that dental services prior to head and neck cancer treatments are integral to the clinical success of those treatments. One commenter recommended that we specify that by ''head and neck cancer,'' we are referring to treatment for patients with cancer related to the ''mid-neck through skull.'' Many commenters provided links to resources that they believed provided clinical evidence to support the link between dental care and the clinical success of, or standard of care for patients receiving treatment for head and neck cancer. Commenters also provided numerous examples of the consequences that can occur if cancer treatment is undertaken in a patient with poor dental health, and shared personal experiences to note the interrelationship between dental health and cancer treatment, including the physical and financial impacts of the extensive damage that can be caused by poor dental health during and after cancer treatments.

Commenters also submitted specific information showing that radiation therapy used to treat head and neck cancer can cause a number of oral conditions, including radiation caries, problems with the salivary glands, mucositis, candidiasis, dysgeusia, xerostomia (dry mouth), and osteoradionecrosis (bone cell death) of the jaw. Several commenters noted that osteoradionecrosis, if not prevented, is difficult to treat and can necessitate surgery that may disfigure and functionally impair the patient's face and jaw. Several commenters also provided data illustrating that conditions such as mucositis or osteonecrosis may require multiple hospitalizations and other costly treatment.

Commenters suggested that if dental infections are not addressed prior to radiation treatment, the treatment may be less effective, or the patient may be prone to other infections. One commenter stated that treating dental infections prior to the start of radiation can reduce some of the tissue damage in the mouth that can result from the radiation. Several commenters shared studies to support the assertion that dental care prior to radiation treatment is integral to the clinical success of head and neck cancer treatment and survivorship (although one commenter noted that the reasons why dental care prior to radiation therapy improves survival rates is not entirely clear). Several commenters observed that

Medicare already covers extractions of teeth prior to radiation treatment for neoplastic disease, and regarded dental exams as a close analog to this preparatory care.

Commenters also provided information showing that chemotherapy drugs used for treatment of head and neck cancers can have many side effects, including sores and lesions in the mouth and throat tissues, difficulty swallowing, bleeding in the mouth, and tooth decay. Additionally, commenters stated that because chemotherapy reduces the body's ability to fight opportunistic infections, patients who begin chemotherapy with untreated infections (including infections in the oral cavity) are at risk of developing a number of complications, ranging from fungal or viral infections of the mouth and throat to systemic infections or fatal sepsis. Commenters observed that complications arising from untreated infections could cause treatment interruptions which could compromise the success of the treatment and the patient's outcomes. One commenter observed that the need for removing oral infection prior to starting chemotherapy is analogous to the rationale for providing oral care prior to renal transplant, and thus (like dental exam prior to renal transplant) should be considered substantially related and inextricably linked to the clinical success of the treatment. Commenters recommended that patients receiving chemotherapy for head or neck cancer receive a dental exam and stabilization, if applicable. Several commenters noted that providing an oral exam prior to starting chemotherapy is the standard of care in many cancer centers.

Response: We thank the commenters for the information. We appreciate the individual examples and the clinical information commenters shared illustrating connections between head and neck cancer treatments and dental care. We will continue to refer to the relevant conditions by the common term ''head and neck cancer,'' but appreciate the suggested clarification offered by one of the commenters and will consider further refining what is meant by ''head and neck cancers,'' beyond the treatment such as radiation therapy with or without chemotherapy, as part of our ongoing operationalization work.

As discussed in sections II.L.1. and II.L2. of this rule, we are finalizing the codification of existing Medicare payment policy provide that payment can be made under Medicare Parts A and B for extractions of teeth to prepare the jaw for radiation treatment of neoplastic disease. We agree with commenters that providing dental exams and necessary treatments to eradicate infection and/or otherwise prepare the oral cavity for the treatment of head and neck cancer presents an analogous clinical circumstance for which we currently provide payment. We note that the presentation of an analogous clinical circumstance is not the sole basis on which we plan to add head and neck cancer treatments to our list of examples in § 411.15(i) of dental services that are inextricably linked to Medicare-covered medical services. However, we find that the analogous clinical circumstance between head and neck cancer treatment and radiation treatment in the jaw, in addition to clinical evidence showing an inextricable link between dental services and the success of head and neck cancer treatment (discussed below) is compelling.

We find clinical evidence supplied by commenters linking dental care and the clinical outcomes of cancer treatments for head and neck cancers persuasive. We looked particularly to a systematic review and meta-analysis cited by commenters that was supportive of the inextricable link between dental care and successful treatment of head and neck cancer, showing a significantly higher survival rate in those who receive recommended dental care prior to and during treatment of their cancer.[126] We also received references from several commenters to a literature review that concluded that good oral hygiene (including topical fluoride treatments) is critical for patients being treated with radiation for head and neck cancer, due to the lowered biological potential for healing of the periodontium (alveolar bone, periodontal ligament, cementum) after radiotherapy.[127] We believe that this information is sufficient to support the basic assertion that removing infections in the oral cavity (in addition to potentially removing teeth) is necessary to prepare patients for treatment and is inextricably linked to, and substantially related and integral to the clinical success of radiation treatment (with or without chemotherapy) for cancers of the head and neck. As such, we are finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting (as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection), prior to or contemporaneously with Medicare-covered treatments for head and neck cancer.

We believe there are several aspects of this policy that may require additional refinement or clarification. As noted in an earlier response, we are cognizant of concerns that, absent clear guidelines and definitions, beneficiaries, practitioners, and MACs may need additional information prior to providing payment under Medicare Parts A and B, and without it could lead to inconsistent application of the policy. In particular, we believe it is important to determine whether any additional guidance is necessary to identify conditions considered ''head and neck cancer'' and qualifying covered medical services considered within the treatments for these cancers beyond just radiation (with or without chemotherapy). ''Head and neck cancer'' is a commonly-used term that describes a number of specific conditions; the treatments for these cancers are delivered through multiple modalities. We would also like to review and consider specifically if ''head and neck cancers'' implies any neoplasm, whether primary or metastatic, located in the head and neck, regardless of where the cancer originated. We would like to review and consider whether further definitions and guidance are necessary. Additionally, given that some patients might undergo medical services under multiple rounds of treatment, we plan to review how this is applied when payment may be made for dental services provided prior to or contemporaneously with covered medical services.

We believe finalizing this policy for CY 2024 will acknowledge our agreement with commenters that the clinical scenario of dental services associated with head and neck cancers is one where Medicare Part A and Part B payment could be made in accordance with our interpretation of section 1862(a)(12), and also allow us to continue to engage with interested parties to further develop and refine the policy as necessary in the interim. We reiterate that we are open to additional refinements or clarifications to our definitions of head and neck cancer treatment, which we would develop and

[126] Refer to Haynes, D., Vanison, C., Gillespie, M., Laryngoscope 2022 Jan;132(1):45–52. doi: 10.1002/lary.29494. Epub 2021 Feb 26. The Impact of Dental Care in Head and Neck Cancer Outcomes: A Systematic Review and Meta-Analysis.

[127] Refer to Acharya, A. Geist, S.-M.R.Y., Powell, V. & Torres-Urquidy, M.H. (2019). Chapter 3: An environmental scan of the various oral-systemic contact points. In Acharya, A. Powell, V., Torres-Urquidy, M.H., Posteraro, R.H., & Thyvalikakath, T.P. (Eds.), *Integration of medical and dental care and patient data* (2nd ed., pp.35–46), citing to Vissink A, Burlage FR, Spijkervet FK, et al. Prevention and treatment of the consequences of head and neck radiotherapy. Crit Rev Oral Biol Med. 2003;14(3):213–25.

discuss through future rulemaking or through additional guidance as needed or necessary. We also note that the finalized policies outlined in this section of this final rule (including the policy we are finalizing here for CY 2024) would not prevent a MAC from making determinations on a claim-by-claim basis for dental services furnished in other circumstances not specifically addressed within this final rule and the finalized amendments to § 411.15(i).

We also encourage interested parties to submit additional information through the process that we are finalizing under section II.L.2.c.ii. of this rule that could inform further refinements or clarifications to this policy.

Comment: Several commenters recommended that we pay for additional types of dental services, such as preventive, diagnostic (including imaging), periodontal, caries removal, and extractions in both hospital inpatient and outpatient settings. Commenters recommended dental services including exam, extraction, scaling, and root planing as needed prior to and in some cases during cancer treatment. Additionally, several commenters recommended fluoride treatment for patients receiving radiation therapy for head and neck cancer to help strengthen the teeth. Several commenters provided lists of specific dental codes that should be payable.

Response: We thank the commenters for the specific suggestions. As noted above, we are finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting (as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection), prior to Medicare-covered treatments for head and neck cancer. We will make conforming edits to § 411.15(i)(3) for CY 2024 to add to our list of examples of dental services that may be paid under Medicare Parts A and B dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting (as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection), prior to Medicare-covered treatments for head and neck cancer. We will continue to make refinements to the policy as necessary, which we would discuss through future rulemaking or through additional guidance as needed.

We note again that the finalized policies outlined in this section of this final rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed within this final rule and the finalized amendments to § 411.15(i). Under the PFS, we will continue to contractor price the dental services for which payment can be made in accordance with our regulation at § 411.15(i)(3) as inextricably linked to, and integral to the clinical success of, covered medical services. This includes dental services for which payment may be made under our current payment policy, which we are codifying and clarifying, those for which payment can be made under the finalized amendments to § 411.15(i)(3), and other dental services for which MACs may determine payment can be made. We note that we will continue to contractor price covered dental services prior to head and neck cancer treatments, consistent with our current policy, until we have further data to establish prospective payment rates. We will also update associated payment files so that these services can be billed appropriately under the applicable payment system for services furnished in either the inpatient or outpatient setting.

Comment: Some commenters recommended that patients treated for head and neck cancer receive follow-up or ongoing dental care after treatment, noting that patients continue to be at risk for many or all of the conditions discussed above (including dental caries, osteonecrosis, and so forth) even after treatment is concluded. Some commenters noted that there is a period after treatment when patients remain immunosuppressed, and recommended that follow-up care be provided until the immunosuppression ends and, as applicable, when all dental infections are resolved. Several other commenters also described scenarios in which teeth may become impacted or brittle after radiation treatment and require eventual extraction after the radiation therapy has concluded. Other commenters noted that it is not always possible to perform restorative surgeries at the same time as the cancer treatment and requested that we pay for restorative dental services performed on a later date.

Response: As discussed, we are finalizing for CY 2024 that payment can be made under Medicare Parts A and B for dental services furnished prior to or contemporaneously with head and neck cancer treatment in order to prepare the patient's oral cavity for treatment; we will continue to review feedback provide by commenters regarding potential follow-up dental services necessary for patients receiving head or neck cancer treatments to consider whether dental services provided after the medical service are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services for head and neck cancer.

Comment: Some commenters also suggested that we clarify whether Medicare payment would extend to surgical procedures to fix physical damage caused by cancer treatments; commenters observed that surgical reconstructions can be essential to restoring capacity to eat, drink, and swallow to maintain nutrition and overall health. Commenters noted that we already pay for procedures like ridge repair when they are performed simultaneously with tumor removal. One commenter provided a list of recommended services for which Medicare Parts A and B should payment for patients who have had portions of bone removed as a result of cancer treatment. Another commenter also suggested we define specific dental services allowed for patients who had gum removal due to mouth cancer.

Response: We thank the commenters for their suggestions. The commenters provided a number of scenarios, with varying level of detail, and we cannot, at this time, make categorical statements about whether the scenarios presented by commenters would be payable under Medicare Parts A and B. Some scenarios that commenters provided may be contemplating might fall within our statutory exclusion of dental services at section 1862(a)(12) of the Act, which prohibits Medicare payment for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. However, others depending on the specific circumstances may fall within our policy for dental services performed prior to or contemporaneously with Medicare-covered treatment for head and neck cancer. We note that the policies finalized in this section do not prevent a MAC from making appropriate determinations, on a claim-by-claim basis, as to whether a patient's clinical scenario fits within the terms of the exceptions specified in section 1862(a)(12) of the Act and § 411.15(i).

Comment: Commenters also noted that patients with other types of cancer would benefit from coverage of dental examinations prior to or after cancer treatment. Many commenters recommended that we expand payment of dental care to all cancer patients. Commenters noted that the increased risk of infections and sepsis among cancer patients can constitute major health setbacks that are costly to treat

and can compromise the success of the cancer treatment.

Response: We thank the commenters for the additional information. We will continue to review and evaluate information that supports the relationship between dental care and covered treatments (including treatments related to conditions not localized in the head, neck, or oral cavity). Please refer to the discussion in L.2.c.ii. relating to our finalized policy to create a process to review recommendations for other scenarios in which dental care may be inextricably linked, and substantially related and integral to the clinical success of, covered medical services.

Comment: We received many comments in response to our request for information about the relationship between dental care and immunosuppressant treatments. Commenters shared personal experiences of dental challenges arising from immunosuppression. Commenters also noted that some individuals without dental coverage often cannot afford dental treatment and may be left with an impaired ability to eat, speak, or swallow. Many of these commenters discussed how general dental health, or routine dental care, impacts a patient's overall health.

Commenters recommended Medicare pay for dental care for patients taking immunosuppressants for a variety of auto-immune conditions. We also received many comments recommending that we pay for dental services for patients on immune checkpoint inhibitors, patients on immunosuppressants as part of a cancer treatment, or who have experienced immunosuppression as a result of cancer treatments, and patients taking immunosuppressants following a transplant surgery. Several commenters stated that evidence suggests that screening for and treatment of oral inflammation and infections, including decay (extractions, fillings), gingivitis, and periodontitis (scaling and root planing), should begin pre-transplantation and continue as appropriate post-transplantation, after 3–6 months, to prevent sepsis and organ rejection until immunosuppression is resolved.

These commenters noted that immunocompromised patients are at increased risk of serious infection that can lead to severe conditions. Some commenters noted that individuals with blood cancers, such as leukemia and lymphoma, or other types of cancers may be prone to infections. Other commenters noted that older adults naturally have lowered immune systems, which can compound the effects of a weakened immune system and that patients on immunosuppressive therapies with secondary health conditions can also be especially susceptible to dental infections. Some commenters provided clinical evidence that they indicated supported the need for Medicare payment, while others did not include references. Additionally, several commenters stated that additional time was needed for interested parties to consider the inextricable link between dental services and medical services for immunocompromised patients. Others ask clarifying questions and how immunocompromised could be defined and which types of therapies could meet the definition. Others asked how CMS planned to define an immunocompromised patient, while additional commenters asked whether certain clinical scenarios or therapies with immunosuppressive side effects would meet the definition of ''immunocompromised'' for the purposes of this policy. Lastly, some commenters provided clinical scenarios where they stated cause a patient to be susceptible to infection, and therefore, are immunocompromised.

Response: We thank the commenters for both the personal and clinical information regarding the interrelationship between various immunocompromised and immunosuppressed conditions and dental health. Some commenters provided clinical evidence related to dental services for people who are immunocompromised or who are receiving therapies that cause immunosuppression, others provided opinion pieces, no supporting clinical literature, or literature to support that general dental health benefits a patient's overall health.

We appreciate the many thoughtful questions and comments raised by commenters surrounding how to define immunosuppression or an immunocompromised patient. As discussed, we continue to consider these questions and the clinical literature provided by commenters to determine whether other clinical scenarios, such as the initiation of immunosuppressive therapies, where Medicare payment should not be excluded for dental services under section 1862(a)(12) of the Act because the services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. We agree with commenters that people who are immunocompromised may be prone to serious infection. We also believe that information provided by commenters further supports the idea that, broadly, dental health is an important component of good overall health. However, we reiterate that dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth are statutorily excluded from payment under Medicare Parts A and B unless a specific exception applies.

We agree with commenters that beneficiaries undergoing treatment for bone cancers could be immunocompromised and also prone to infection. We note that treatment protocols for some of these patients could include bone marrow transplants, and, as described previously, we are finalizing that Medicare Parts A and B payment can be made for dental services prior to and contemporaneously with organ transplants, including bone marrow transplants.

Some commenters requested that CMS take additional time to review the clinical literature and to engage with CMS to a payment policy in this area further. Given the clarifying questions raised by commenters and the need to future review the clinical literature to determine whether there is an inextricable link between dental services and the medical services treating conditions for immunocompromised patients, we agree with commenters and believe we need additional time to consider definitions surrounding immunosuppressant therapy (such as distinctions between therapies prescribed specifically for their immunosuppressive effect and therapies that are prescribed to treat a different condition but have a side effect of immunosuppression). We look forward to reviewing clinical evidence that will help us to identify among these clinical scenarios where dental services are inextricably linked with specific clinical outcomes of a medical services of people with immunosuppression. Such review may allow us to propose relevant policies in next year's notice and comment rulemaking.

As discussed, we are open to continued engagement with interested parties through the process that we will be creating under our final policy as described in section II.L.2.c.ii. of this rule, and to considering future refinements to our policy through potential guidance or future rulemaking as needed. These specific questions are ones that we will explore and contemplate further in CY 2024 rulemaking and through the finalized process to review recommendations for future rulemaking. We encourage parties

interested in this specific policy to engage with us through the process as described in section II.L.2.c.ii. of this rule. Specifically, we would encourage interested parties to submit medical evidence to support the inextricable link between dental services and the medical services involved in treating immunosuppressed patients (for example, empiric evidence to support a strong association between dental services prior to the initiation immunosuppressive therapies and reduced infection) by providing any of the following: (1) relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care; (2) evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario (we would prefer the clinical guidelines to have undergone clinical rigor in their development); (3) other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services; and/or (4) suggestions for definitions, and supporting rationales for those definitions, surrounding this policy for further consideration.

Comment: Some commenters supported the idea that dental care prior to joint replacement surgery or joint arthroplasty could be beneficial. One commenter observed that as hip and knee replacements are among the most common joint replacement surgeries, providing dental care to patients prior to hip and knee surgeries would benefit a large number of joint replacement recipients. Commenters offered some research studies showing that dental care prior to a joint replacement was associated with a reduction of infection at the surgical site. Some commenters also noted that dental care prior to any type of surgery may have a positive impact with only some commenters providing supporting evidence. Other commenters noted that additional time was necessary to review whether there was an inextricable linkage between dental services and joint replacement surgeries. Others also commented that clinical evidence is lacking to support the causation between dental services and the success of joint replacement surgeries. Some commenters providing clinical evidence to support that the clinical evidence for antibiotic use prior to joint replacement surgery was inconclusive.

Response: We thank the commenters for the information regarding the possible relationship between joint replacement surgery and dental health. Several commenters discussed the benefits that good dental health has on general outcomes for joint replacement surgeries rather than the inextricable linkage between dental services and the arthroplasty procedure. Although some commenters were supportive, we are unable to determine from the studies and other evidence we received whether there is an inextricable link to the clinical success of joint replacement surgery and dental care. It is important for us to delineate between evidence suggesting that dental services are integral to the clinical success of the covered medical services and evidence suggesting a possible improvement in outcomes for a medical condition. We also encourage interested parties to submit additional information through the process that we are finalizing under section II.L.2.c.ii. of this rule that could inform further refinements or clarifications. Specifically, we would encourage interested parties to submit medical evidence to support the inextricable link between dental services and the medical services involved in joint replacement surgeries (for example, empiric evidence to support a causal inference of dental services being necessary before joint replacement surgeries to prevent infection) by providing any of the following: (1) relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care; (2) evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario (we would prefer the clinical guidelines to have undergone clinical rigor in their development); (3) other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services; and/or (4) suggestions for definitions, and supporting rationales for those definitions, surrounding this policy for further consideration.

Comment: We received general support for permitting payment for dental care that might be associated with traumatic injury of the jaw. One commenter also provided a list of congenital maxillofacial conditions that require surgical repair.

Response: We thank commenters for their support. We note that we are finalizing our proposal to codify and clarify current payment policies related to services such as, but not limited to, the stabilization of teeth when done in connection with a reduction of a jaw fracture and certain dental services associated with a dislocated jaw unit regardless of whether the services are associated with accidental injury. We note that these services would not be subject to the exclusion under section 1862(a)(12) of the Act, and would be eligible for Medicare payment. We are uncertain if the recommendations we received from commenters are referring to services that are already covered by the exception under section 1862(a)(12) of the Act or if the commenters were describing services the commenters believed to be currently excluded from payment under Medicare Parts A and B. We encourage these commenters to discuss with us further whether they were referring to dental services prior to maxillofacial surgeries or just the maxillofacial surgeries themselves. We also encourage interested parties to submit additional information through the process that we are finalizing under section II.L.2.c.ii. of this rule that could inform further refinements or clarifications.

Establishment of a Process To Consider Additional Clinical Scenarios for Future Updates

Comment: The majority of commenters supported the creation of a process for considering whether there are additional examples clinical scenarios where dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services. These commenters stated that such a process would allow for further clinical evaluation and analysis of the inextricable link between certain medical and dental services. These commenters also stated that clear definitions of the link between medical and dental services would be beneficial, as such a process would also allow for a thorough exploration of the threshold of this connection, and further definition of immediately necessary, integral dental treatments. Commenters stated that the evaluation of the efficacy other medically necessary dental treatments for covered medical services should rely on comprehensive clinical reports to confirm the intrinsic relationship of the dental services to a certain medical outcome. These commenters urged CMS to engage with interested parties through the creation of an advisory panel or formal process.

Response: We appreciate the commenters' support regarding the establishment of a process for the consideration of additional examples of clinical scenarios that we should consider for future updates to our regulation at § 411.15(i)(3) to identify dental services that may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services. We believe such a process will allow for review,

evaluation, and modification to the list of those dental services for which payment is not excluded under the statute at section 1862(a)(12) of the Act and can be made under Medicare Parts A and B. We agree with commenters that the establishment of a process would also allow for a thorough review of clinical evidence, allow CMS to modernize policies with evolving medical advances, and engage with interested parties.

Comment: Several commenters provided recommendations regarding possible features for a potential process for consideration of additional clinical scenarios. Commenters asserted that the annual notice and comment rulemaking process for the PFS serves as an appropriate mechanism for CMS to consistently revisit the process for and identification of covered medical conditions and associated dental services that are substantially related and integral to the clinical success of the proposed covered medical services.

Several commenters stated that the clinical examination of proposed additional scenarios should be transparent and open to the public, with the agency providing notification regarding any dental, medical, or other groups that submit such suggested procedures.

A few commenters requested that CMS institute a process to allow medical and dental experts to serve on an advisory panel that would hear and evaluate relevant evidence and research on which covered medical services require dental services that are substantially related and integral to the clinical success of the covered medical services. The commenters contended that thorough clinical consideration should occur for each proposal before any additional scenarios are considered payable.

A few commenters also requested that CMS require the presentation and review of research, as well as clinical evidence to justify the link between a proposed, covered Medicare Parts A or B medical service and dental services that are inextricably linked to, substantially related and integral to the clinical success of certain covered medical services. Commenters suggested that the requirements for submission should include clinical evidence that demonstrates that dental services are effective in addressing the proposed medical scenario, treatment timelines for each medical diagnosis and correlated dental care for the stage(s) of the disease, and other considerations for communication or coordination amongst the care team.

Several commenters requested that CMS expressly solicit proposals regarding the ancillary services (such as anesthesia or x-rays) associated with the proposed Medicare Part A or Part B procedures and that those proposals also be shared publicly for public comment and possible inclusion.

Response: We appreciate commenters' suggestions regarding the review process for the addition of possible clinical scenarios. We agree with the commenters that the process should be consistent and that supporting materials for proposed clinical scenarios should be evidence-based, all of which should be partnered with the opportunity for interested party feedback regarding possible future updates to the policies for Medicare Parts A and B payment for dental services. We seek to engage with interested parties and collaborate with respect to identifying those medical services that include dental services that are inextricably linked to, and substantially related and integral to the clinical success of the covered medical service. Additionally, we agree that ancillary or related services should be considered when evaluating a medical scenario for inclusion in this policy.

We appreciate the commenters' recommendation that CMS establish and then leverage an expert advisory panel for the review of clinical scenarios for future updates. We also agree with commenters that thoughtful engagement with interested parties is important to further clarifying the link between dental services and certain covered medical services. We therefore believe that it is important to create a process that can be implemented in a time-sensitive fashion, which would facilitate and expedite the identification of medical services that are potentially inextricably linked to corresponding dental services because such dental services are substantially related and integral to the clinical success of that covered medical service.

We agree with commenters that public feedback is important, especially when considering Medicare payment for critical treatments that may benefit the clinical outcomes for certain covered medical services for Medicare beneficiaries. We believe that discussing the recommendations we are considering further in the course of our annual rulemaking will allow the public to comment and submit further medical evidence to assist us in evaluating whether the standard of care for that medical service is such that one would not proceed with the medical procedure or service without performing the dental service(s), because the covered medical services would or could be significantly and materially compromised, such that clinical outcomes could be compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. This would also allow the public to comment on whether the particular dental services should or should not be subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act, because they are or are not inextricably linked to, and substantially related and integral to the clinical success of, covered medical services; and provide the medical evidence to support their position. We have an existing process within the framework of annual PFS rulemaking, which we believe we should continue to leverage to allow for this level of public engagement. We believe that this would be an efficient approach and would provide an immediately achievable avenue for submissions from the public, and review and analysis by CMS and the public.

Therefore, we are finalizing an annual process for the review of public nominations. We will use the PFS annual rulemaking process to determine whether certain dental services should be considered not subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services. This process serves to facilitate the codification and clarification of our existing policy as described in section II.L. of this final rule, as a nomination process that will allow us to evaluate additional examples under which payment could be made under Medicare Part A and Part B for dental services.

The establishment of an advisory panel would require significant time and procedural effort per statute and regulation.[128] [129] At this time, we will not be implementing an advisory panel, but appreciate this recommendation.

The public is encouraged to engage with us regularly to submit clinical scenarios for consideration. In order for public recommendations to be potentially considered within the annual PFS rulemaking cycle, interested parties should submit evidence and nominations for consideration by

[128] *https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/statutes-and-related-legislation.*

[129] *https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/faca-final-rule-2001.*

February 10th of each calendar year. This date is consistent with the date used for submission of other information to CMS for consideration in the upcoming rulemaking process, such as nominations for misvalued codes, additions to the telehealth services list, and submission of invoices for pricing direct PE supply and equipment items. We will evaluate the supporting documentation and decide whether the medical services should be further considered as not subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act during that calendar year's rule-making cycle. For example, information received by February 10, 2023, would be reviewed for consideration and potential inclusion within the CY 2024 PFS proposed rule. Submissions received after February 10th will still be reviewed, but may be considered in subsequent rulemaking instead of that calendar year's rulemaking cycle.

We note that we may identify additional clinical scenarios for review based on our review of public submissions or identified through our own internal research and if so, would make those clinical scenarios available for public review through the annual PFS rulemaking cycle.

We agree with commenters that clinical evidence should be thoughtfully considered and evaluated by interested parties. As such, we encourage stakeholders who believe they have identified dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services to nominate these scenarios, supported by documentation, through the public process. Commenters are also welcome to submit additional information regarding some of the clinical scenarios presented, but not included in a finalized policy, in this final rule, including immunosuppressant therapies, joint replacement surgeries, and management of chronic conditions such as diabetes, and other surgical procedures. We also encourage interested parties to submit to us suggestions for further clarification of current policy, such as but not limited to, recommendations on implementation, payment, and provider enrollment.

We agree with commenters that we should thoroughly consider the clinical evidence to review whether there is an inextricable link between certain dental and medical services. As such, accompanying documentation should be provided to support or refute the link between certain medical and dental services. Specifically, this medical evidence should support that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the skeletal structure. We expect evidence to be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore not subject to the statutory payment preclusion in section 1862(a)(12) of the Act. The clinical evidence should be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient.

This evidence should include at least one of the following: (1) relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care; (2) evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario; (3) other ancillary services that may be integral to the covered medical services; and/or (4) other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

Interested parties are encouraged to submit their recommendations by February 10th of a calendar year via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov* for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. Interested parties should include the words 'dental recommendations for CY 2XXX review' in the subject line of their submission email to facilitate processing (CY 2XXX should refer to the rulemaking cycle for the year). We note that we may also consider proposals submitted as public comments during the comment period following the publication of the PFS proposed rule.

Final Action: After consideration of the comments received, and for the reasons previously discussed, we are finalizing our proposals, effective CY 2023, to: (1) clarify our interpretation of section 1862(a)(12) of the Act and codify certain of current Medicare FFS payment policies for medically necessary dental services; and (2) our proposal that payment may be made for other dental services, such as dental or oral examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplantations (including hematopoietic stem cell and bone marrow transplantations), or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. We are also finalizing for CY 2024 that Medicare Parts A and B payment may be made for dental services, such as dental or oral examinations, including necessary treatment, performed as part of a comprehensive workup prior to treatment for head and neck cancers, for which we stated we may consider finalizing in this final rule, because those services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. We are not finalizing, at this time, that payment may be made under Medicare Parts A and B for dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures or other surgical procedures, for which we stated we may consider finalizing in this final rule. We remain committed to exploring the inextricable link between dental and medical services associated with immunosuppressant therapy, joint replacement surgeries and other surgical procedures, and we will continue to review the clinical evidence to determine whether the services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services and would welcome continued engagement from the public. We will address additional clinical scenarios involving dental services, such as services inextricably linked and integral to particular kinds of treatments for immunocompromised patients, in 2024 rulemaking.

Effective CY 2023, we are finalizing the establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services. We note that we stated in this proposed rule that we may consider finalizing such process in this final rule after a review of the commenters received. Specifically, we

are finalizing an annual process for the review of public nominations of dental services that the public is recommending not be considered subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act. Interested parties should submit evidence and nominations via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, and should include the words dental recommendations for CY 2XXX review' in the subject line of their submission email to facilitate processing (CY 2XXX should refer to the rulemaking cycle for the year), by February 10th of each calendar year in order for these recommendations to be potentially considered within the annual PFS rulemaking cycle. Recommendations may also make suggestions for clarifications for this policy generally, such as but not limited to, recommendations on implementation, payment, and provider enrollment.

We expect accompanying documentation to be provided. The medical evidence should support or refute whether the provision of certain dental services is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. This evidence should include any of the following: (1) relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care; (2) evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario; (3) other ancillary services that may be integral to the covered medical services; and/or (4) other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

We are finalizing our proposed amendments to the regulations at § 411.15(i). First, we are finalizing our proposed amendments, without modifications, to our existing regulations at § 411.15(i)(1) and (2) that dental services are not covered in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, with the exception for dental services for inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

- The individual's underlying medical condition and clinical status; or
- The severity of the dental procedures.

Second, we are finalizing, with modifications, to the regulations at § 411.15(i), to include examples of services for which payment can be made under Medicare Parts A and B on that basis. Specifically, we are amending § 411.15(i)(3)(i), to allow for payment under Medicare Part A and Part B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, including, but not limited to: (1) the dental or oral examination as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedure; (2) the necessary dental treatments and diagnostics to eliminate the oral or dental infections found during a dental or oral examination as part of a comprehensive workup prior to, and contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure; (3) reconstruction of a ridge when it is performed as a result of, and at the same time as, the surgical removal of a tumor; (4) the stabilization or immobilization of teeth in connection with the reduction of a jaw fracture and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints; and (5) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and We will make conforming changes to the MBP Manual to reflect these changes or clarifications, and to remove any text that is no longer applicable.

We will make amendments to § 411.15(i)(3)(i)(A) for CY 2024 to specify that payment under Medicare Parts A and B can be made for an oral or dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to, or contemporaneously with, treatment for head and neck cancers. These amendments to § 411.15(i)(3)(i)(A) would conform with the policy finalized in this rule for CY 2024, as clarified by any further rulemaking, and add to the regulation as an example of dental services for which payment can be made under Medicare Parts A and B dental services furnished prior to and contemporaneously with the treatment for head and neck cancers.

We are also finalizing our proposal, without modification, to amend our regulation at § 411.15(i)(3)(i) to provide that payment can be made for dental services provided in conjunction with medical services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, such as X-rays, administration of anesthesia, and use of the operating room. Additionally, we are finalizing with modification the removal the word ''other'' from the description of ''ancillary services and other supplies furnished incident to covered dental services'' to improve clarity and to avoid suggesting that ''services'' are ''supplies.'' This modification does not modify the proposed or final policy.

Medicare will make payment under Parts A and B for these dental services that are determined to be inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service, prior to or contemporaneously with certain covered medical services. No payment is made for dental services when an excluded service is the primary procedure involved. We continue to contractor price the dental services for which payment is made currently, and for the dental services that can be made under the amendments to § 411.15(i)(3) for CY 2023 and CY 2024, and until we have further data. We will update the applicable payment files so that services may be furnished and paid under the applicable payment system.

We will make payment when a doctor of dental medicine or dental surgery (referred to as a dentist) furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician, or non-physician practitioner, treating the primary medical illness. If there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) in regard to the primary medical service and the dentist in regard to the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3). As such, the services would be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Without both integration between the Medicare enrolled medical and dental professional, and the inextricable link between the dental and covered medical services, dental services fall outside of the Medicare Part B benefit as they would be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the

Act; though they may be covered by types of supplemental health or dental coverage.

Payment may also be made for services and supplies furnished incident to those dental services furnished by the dentist or other physician or practitioner, and for other ancillary services integral to the dental services. Medicare payment could be made for services furnished incident to the professional medical or dental services by auxiliary personnel, such as a dental hygienist, dental therapist, or registered nurse who is under the direct supervision of the furnishing dentist or other physician or practitioner, if they meet the requirements for ''incident to'' services as described in § 410.26 of our regulations.

The finalized policies outlined in this section of this final rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed as examples within this final rule and the finalized amendments to § 411.15(i). MACs may continue to determine on a claim-by-claim basis whether a patient's clinical circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i).

Lastly, we may provide additional guidance or future rulemaking regarding these policies as determined appropriate or necessary. We encourage continued engagement through the process as finalized under section II.L.2.c.ii. of this final rule so that we may consider revisions to this policy potentially in the future.

M. Rebasing and Revising the Medicare Economic Index (MEI)

1. Background

The Medicare Economic Index (MEI) is authorized under section 1842(b)(3) of the Act, which relates to the reasonable charge-based payment methodology that was in place for physicians' services prior to the PFS implementation. That section states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. CMS began calculating the MEI for this purpose on July 1, 1975 and continues to do so today for several statutory and other purposes. The MEI reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services.

The MEI is a fixed-weight input price index comprised of two broad categories: (1) Physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, private nonfarm business total factor productivity (previously referred to as multifactor productivity).[130] The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.

The current form of the MEI was described in the November 25, 1992 **Federal Register** (57 FR 55896) and was based in part on the recommendations of a Congressionally-mandated meeting of experts held in March 1987. Since that time, the MEI has been updated or revised on five instances. First, the MEI was rebased in 1998 (63 FR 58845), which moved the cost structure of the index from 1992 data to 1996 data. Second, the methodology for the productivity adjustment was revised in the CY 2003 PFS final rule with comment period (67 FR 80019) to reflect the percentage change in the 10-year moving average of economy-wide private nonfarm business total factor (multifactor) productivity. Third, the MEI was rebased in the CY 2004 PFS final rule with comment period (68 FR 63239), which moved the cost structure of the index from 1996 data to 2000 data. Fourth, the MEI was rebased in 2011 (75 FR 73262), which moved the cost structure of the index from 2000 data to 2006 data. Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74264), the MEI cost share weights were revised based on recommendations from the MEI technical advisory panel (MEI–TAP). From May 2012 through September 2012, the MEI Technical Advisory Panel conducted a technical review of the MEI, including analyses of the inputs, input weights, price-measurement proxies, and productivity adjustment. Details regarding the Panel's work and documents such as transcripts, meeting summaries, presentations, and the final report with recommendations to the Secretary of Health and Human Services are available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP* and in the CY 2014 PFS proposed rule (78 FR 43311) which provides details related to how the MEI TAP panel recommendations were implemented into the revised 2006-based MEI. The current 2006-based MEI relies on data collected from the American Medical Association (AMA) for self-employed physicians from the Physician Practice Information Survey (PPIS). The AMA has not fielded another survey since that 2006 data collection effort and so the MEI has continued to be based on 2006-based costs. In its August 28, 2012 report, the MEI–TAP expressed concern regarding the representativeness and availability of data to support the MEI and provided two recommendations regarding the data sources to update the MEI in the future. Recommendation 2.1 stated that CMS should research whether using self-employed physician data for the MEI cost weights continues to be the most appropriate approach given the trend toward larger, physician-owned practices, as well as the movement from physician-owned practices toward hospital-owned practices. Recommendation 2.2 stated that CMS should scan for and research additional data sources that may allow for more frequent updates to the MEI's cost categories and their respective weights.[131]

Updates to the PFS conversion factor (CF) were previously calculated based on a prescribed statutory formula that used a combination of the MEI and a ''sustainable growth rate''; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 115–05, April 16, 2015) repealed the previous statutory update formula and specified the update adjustment factors for calendar years 2015 and beyond. Therefore, effective beginning with CY 2015, the MEI was no longer used in calculating the annual update to the PFS CF. The annual growth in the MEI continues to be used to update the following: the Medicare telehealth originating site facility fee under section 1834(m)(2)(B)(i) of the Act, the KX

[130] *https://www.bls.gov/news.release/prod5.nr0.htm.*

[131] The MEI–TAP's final report, including all findings and recommendations, are available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.*

Modifier Thresholds (formerly the therapy caps) under section 1833(g)(2) of the Act, targeted medical review (MR) threshold amounts (beginning in 2029) under section 1833(g)(7)(B)(ii) of the Act, Rural Health Clinic Payment Limits under section 1833(f)(2) of the Act, and the annual update to the non-drug portion of the Opioid Treatment Program payment as finalized in the CY 2020 PFS final rule (84 FR 62668 and 62669).

While the MEI annual percentage change increase is not directly used in determining the update to the PFS CF, the MEI cost weights have historically been used to update the GPCI cost share weights to weigh the four components of the practice expense GPCI (employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses), as discussed in detail in section II.G. of the final rule, and to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs, as discussed in section II.B. and VI. of the final rule. The most recent recalibration was done for the CY 2014 RVUs when the MEI was last updated. As described in the CY 2014 PFS final rule (78 FR 74236 through 74237, and 74241), in steps 3 and 10, we adjusted the aggregate pool of PE costs in proportion to the change in the PE share in the revised MEI cost share weights. These adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275). Therefore, as discussed in the CY 2023 PFS proposed rule (87 FR 460462), we believe that the MEI cost weights need to be updated to reflect more current market conditions faced by physicians in furnishing physicians' services, but note that we are finalizing to delay the implementation of the rebased and revised MEI cost weights for both CY 2023 PFS ratesetting and the finalized CY 2023 GPCIs. We explained that we believe that doing so will allow interested parties the opportunity to review and comment on the proposed rebased and revised MEI cost share weights discussed in section II.M. of the proposed rule and their potential impacts before we use such rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and updating the GPCIs. We refer readers to our discussion about using the proposed rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and to update the GPCIs for CY 2023 in sections II.B. and VI. of this final rule. In those sections, we discuss our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have on PFS payments. We solicited comments on the proposed delay and potential use of the proposed updated MEI cost weights in future years to recalibrate the RVU shares and to update the GPCI cost share weights, which were last realigned to the revised MEI weights in the CY 2014 PFS final rule (78 FR 74380 through 74391).

This section of the final rule provides an overview of the methodology for updating the MEI cost share weights and the results of the rebasing and revising of the MEI for purposes of estimating annual input price inflation for physician services, used for purposes of updating payments outside of the PFS ratesetting. We note that specific comments relating to the delayed implementation of the MEI in PFS ratesetting and CY 2023 GPCIs are discussed in sections II.B. and VI. of this final rule.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of an input price index while revising relates to other types of changes such as using different data sources, cost categories, or price proxies in the input price index. Effective with this CY 2023 PFS rulemaking cycle, we proposed to rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership; that is, not limited to only self-employed physicians. We detailed the proposals regarding the derivation of the cost categories and associated cost share weights, selection of the price proxies in the MEI, and the results of the proposed 2017-based MEI as compared to the current 2006-based MEI in the proposed rule as well as below.

2. Developing the Cost Weights for Use in the MEI

The 2006-based MEI was last rebased in the CY 2011 PFS final rule with comment period (75 FR 73262 through 73275) and subsequently revised in the CY 2014 PFS final rule with comment period (78 FR 74264 through 74278). The proposed 2017-based MEI cost weights are derived predominantly from the annual expense data from the U.S. Census Bureau's Services Annual Survey (SAS, *https://www.census.gov/programs-surveys/sas.html*). Other data sources that were considered and analyzed as potential sources of expense data for Physician Offices included the BEA Benchmark Input-Output data, the Internal Revenue Services (IRS) Statistics of Income data for sole proprietors, and the Medical Group Management Association (MGMA) cost and revenue data. While each of these data sources provided information on physician input price expenses, we found the SAS data to be the most technically appropriate data source available based on various factors including public availability, level of detail of expense categories, and sample representativeness of the universe. The SAS data are publicly available data that provide annual receipts estimates for the service industries. Collected data include sources of revenue and expenses by type for selected industries and selected industry-specific items. Specifically, we proposed to use the 2017 SAS data from Table 5, Estimated Selected Expenses for Employer Firms for NAICS 6211 (Office of Physicians). The survey data collection in 2018 and 2019 were scaled back and therefore, data by expense category was limited for those years in comparison to the 2017 data. For example, the SAS expense data for lease and rental payments, professional and technical services, repair and maintenance services, and detailed utility costs were unavailable in 2018 and 2019. The 2020 data included a return to the more comprehensive collection of expense data; however, the presence of the PHE for COVID–19 raised questions regarding the representativeness and stability of the data given impacts on the utilization of physicians' services and associated expenses. Therefore, we proposed to use the 2017 SAS data for the proposed 2017-based MEI because it was the most recently available and complete data available at the time of rulemaking.

We proposed to supplement the 2017 SAS expense data by using several data sources for further disaggregation of compensation costs and all other residual costs, including the 2017 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), the 2012 Bureau of Economic Analysis (BEA) Benchmark Input-Output data (I/O), the 2006 AMA PPIS, and the 2020 AMA Physician

Practice Benchmark Survey. Table 37 lists the set of mutually exclusive and exhaustive cost categories and weights for the proposed 2017-based MEI compared to the 2006-based MEI.

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TABLE 37: Proposed 2017-based MEI and 2006-based MEI Cost Categories and Weights

Cost Category	Proposed 2017-based	Current 2006-based
MEI Total	**100.000%**	**100.000%**
Physician Compensation	**47.261%**	**50.866%**
Wages and Salaries	39.226%	43.641%
Benefits	8.034%	7.225%
Practice Expense	**52.739%**	**49.134%**
Non-physician Compensation	**24.716%**	**16.553%**
Non-physician Wages	**20.514%**	**11.885%**
Non-health, non-physician Wages	12.306%	7.249%
Professional and Related	1.381%	0.800%
Management	2.171%	1.529%
Clerical	7.947%	4.720%
Services	0.807%	0.200%
Health-related, non-physician Wages	8.208%	4.636%
Non-physician Benefits	**4.202%**	**4.668%**
Other Practice Expense	**28.024%**	**32.582%**
Utilities	0.366%	1.266%
All Other Products	2.055%	2.478%
Telephone	0.471%	1.501%
Postage	-	0.898%
All Other Professional Services	**13.914%**	**8.095%**
Professional, Scientific, and Tech. Services	6.350%	2.592%
Administrative & Waste Services	2.341%	3.052%
All Other Services	5.223%	2.451%
Capital	**7.748%**	**10.310%**
Fixed Capital	5.527%	8.957%
Moveable Capital (including medical)	2.221%	1.353%
Professional Liability Insurance	**1.398%**	**4.295%**
Medical Equipment	-	1.978%
Medical Supplies	2.071%	1.760%

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Total costs equal the sum of the costs for Physician Compensation and Practice Expenses. The development of the cost weights for each cost category in the proposed 2017-based MEI is described, in detail, as follows.

a. Physician's Compensation

The component of the MEI that reflects physician work is represented by the estimated portion of compensation expenses attributable to physicians. The proposed 2017 cost weight associated with the physician's work (otherwise referred to as the Physician Compensation cost weight) is based on the estimated share of 2017 SAS expenses for total compensation associated with physician compensation. Since the compensation expense in the SAS data is only reported as an aggregate for all employees, we proposed to split the compensation expenses between physicians (including non-physician practitioners that can bill independently such as nurse practitioners (NPs), physician assistants (PAs), and other clinical personnel) and all other workers using the following process.

Step 1: Total compensation costs are calculated by summing the reported expenses in the SAS for gross annual payroll, employer costs for fringe benefits (including health insurance, defined benefit, and defined contribution plans, payroll taxes, employer-paid insurance premiums, and all other benefits), and temporary staff and leased employees as reported in the 2017 SAS data for NAICS 6211 (Office of Physicians).

Step 2: Determine the ratio of physician (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) wage costs to total wage costs. This ratio is calculated using data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) May 2017 National Industry-Specific Occupational Employment and Wage Estimates for Offices of Physicians (NAICS 6211). This data reports the number of employees by occupational category based on the Standard Occupational Classification System (SOC) and the mean hourly wage for each occupation. For each occupation, we multiplied the

number of employees by the mean hourly wage to estimate the total mean hourly wage expense. The sum of expenses for each occupation category represents total mean hourly wage expenses for all occupations in NAICS 6211. Then to derive the total mean hourly wage expenses for physicians (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) we proposed to sum the expenses for the following occupations: Physicians and Surgeons (29–1060); Chiropractor (29–1011); Optometrist (29–1041); Podiatrist (29–1081); Physical Therapist (29–1123); Dieticians & Nutritionists (29–1031); Physician Assistants (29–1071); Nurse Practitioners (29–1171); and All Other Diagnosing & Treating Occupations (29–11XX)), which includes compensation costs for Registered Nurses (29–1141). The ratio of physician total mean hourly wage costs to total mean hourly wage costs is 63.2 percent.

Step 3: We proposed to multiply the total compensation expenses from Step 1 by the ratio determined in Step 2 to derive estimated Employed Physician Compensation Expenses, which in 2017 were estimated to account for 42.4 percent of total costs.

Next, since the expenses estimated above reflect only employed physician compensation, we proposed to add an estimate of compensation costs to account for physician practice owners that are not classified as employees but instead would be included in the net income of the practice. The net income physician compensation costs are estimated by the following methodology. This amount is determined in three steps:

Step 1: We proposed to subtract total expenses from total revenue as reported in the 2017 SAS data for NAICS 6211.

Step 2: We estimated the share of owners versus employees of physician practices for 2017 based on the average share of ''owners'' for 2016 and 2018 as reported in Exhibit 1 of the 2020 AMA Physician Practice Benchmark Survey. This estimated share for 2017 is 46.5 percent.

Step 3: We multiplied the share determined in step 2 by the amount determined in step 1, which represents the estimated expenses for net income for owners of physician practices and is 4.845 percent of total costs in 2017.

The proposed aggregate 2017-based Physician Compensation cost weight is the sum of the Employed Physician Compensation cost weight (42.416 percent) and Estimated Net Income for Physician Practice Owners cost weight (4.845 percent), or 47.261 percent. By comparison, the 2006-based Physician Compensation cost weight was 50.866 percent and reflects the net income for self-employed physicians and the expenses for non-physician clinical staff that can bill Medicare independently. The proposed 2017-based MEI cost weight for Physician Compensation is 3.6 percentage points lower than the 2006-based MEI cost weight. This difference is due to two key factors: (1) any changes that occurred in the cost to provide physician services between 2006 and 2017, and (2) the SAS data reflects relative costs for all physician ownership practices while the 2006 AMA PPIS data reflected relative costs only for self-employed physician practices.

We proposed to split the Physician Compensation cost weight into two cost categories: Physician Wages and Salaries, and Physician Benefits. The proposed Physician Wages and Salaries cost weight is calculated by multiplying the total Physician Compensation weight by the ratio of the gross payroll to the sum of gross payroll and employer's cost for fringe benefits in the 2017 SAS data, which is 83 percent. The proposed Physician Benefits cost weight is calculated by multiplying the total physician compensation weight by the ratio of the employee benefits to the sum of gross payroll and employer's cost for fringe benefits in the 2017 SAS data, which is 17 percent. As a result, the proposed Physician Wages and Salaries cost weight is 39.226 percent and the proposed Physician Benefits cost weight is 8.034 percent in the 2017-based MEI.

b. Practice Expenses

The Practice Expenses cost weight reflects all remaining operating costs other than physician compensation. We proposed to determine the remaining Practice Expense cost weights in the 2017-based MEI using the 2017 SAS Expense data for NAICS 6211 expressed as a percentage of total costs. The explanations for the derivation of the individual cost weights under Practice Expenses are detailed below.

(1) Non-Physician Compensation

We proposed to estimate the cost weight for Non-physician Compensation using the 2017 SAS data for these expenses. As mentioned previously, since the compensation expenses in the SAS data are only reported as an aggregate for all employees, we proposed to multiply the 2017 SAS total compensation expenses for NAICS 6211 by 36.8 percent, which is the residual of the 63.2-percent share determined for physicians (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel).

Then, we proposed to multiply the total compensation expenses by the ratio of non-physician compensation expenses to total compensation expenses. This results in the proposed Non-physician Compensation cost weight of 24.716 percent in the proposed 2017-based MEI.

Next, we proposed to split the Non-physician Compensation cost weight into two cost categories: Non-physician Wages and Salaries, and Non-physician Benefits. The Non-physician Wages and Salaries cost weight is calculated by multiplying the total Non-physician Compensation cost weight by the ratio of the gross payroll to the sum of gross payroll and employer's expense for fringe benefits in the 2017 SAS data, which is 83 percent. The Non-physician Benefits cost weight is calculated by multiplying the total Non-physician Compensation weight by the ratio of the employee benefits to the sum of gross payroll and employer's expenses for fringe benefits in the 2017 SAS data, which is 17 percent. As a result, the proposed Non-physician Wages and Salaries cost weight is 20.514 percent in the proposed 2017-based MEI and the proposed Non-physician Benefits cost weight is 4.202 percent. For comparison purposes, the 2006-based MEI cost weights are 11.885 percent and 4.668 percent, respectively. We also proposed to disaggregate the Non-physician Wages and Salaries cost weight into two categories: (1) Health-related, non-physician; and (2) Non-health, non-physician Wages and Salaries.

Of the 36.8 percent of total SAS compensation costs associated with non-physicians, 14.7 percentage points are determined to be associated with Health-related, non-physician Wages and Salaries. This percentage reflects the ratio of mean hourly wages to total mean hourly wages from the 2017 OEWS data for the following occupations: Health Technologists and Technicians (29–2000); Other Healthcare Practitioners and Technical (29–9000); and Healthcare Support (31–0000). Applying this share (about 40 percent) to the non-physician wages cost weight results in a proposed weight of 8.208 percent for the health-related, non-physician Wages and Salaries cost weight for the proposed 2017-based MEI.

The remaining share of non-physician compensation costs are associated with Non-health, non-physician Wages and Salaries (22.1 percentage points of the 36.8 percent). This percentage reflects the ratio of mean hourly wages to total

mean hourly wages from the 2017 OEWS data for the following occupations: Management (11–0000); Business and Financial Operations (13–0000); Computer and Mathematical (15–0000); Architecture and Engineering (17–0000); Life, Physical, and Social Science (19–0000); Community and Social Service (21–0000); Legal (23–0000); Education, Training, and Library (25–0000); Arts, Design, Entertainment, Sports, and Media (27–0000); Protective Service (33–0000); Food Preparation and Serving Related (35–0000); Building and Grounds Cleaning and Maintenance (37–0000); Personal Care and Service (39–0000); Sales and Related (41–0000); Office and Administrative Support (43–0000); Construction and Extraction (47–0000); Installation, Maintenance, and Repair (49–0000); Production (51–0000); and Transportation and Material Moving (53–0000). Applying this share (about 60 percent) to the non-physician wages cost weight results in a proposed weight of 12.306 percent for the non-health, non-physician Wages and Salaries cost weight for the proposed 2017-based MEI.

Next, since the non-health, non-physician wages represent various types of occupations that may experience different wage inflation pressures, we proposed to disaggregate the non-health, non-physician Wages and Salaries cost weight of 12.306 percent into four occupational subcategories. To arrive at a distribution for these separate occupational categories (Professional & Related (P&R) workers, Managers, Clerical workers, and Service workers), we determined an estimate of annual earnings for each using the Standard Occupational Classification (SOC) system. The professional and related wages & salaries consist of the following occupational categories: Business and Financial Operations (13–0000); Computer and Mathematical (15–0000); Architecture and Engineering (17–0000); and Life, Physical, and Social Science (19–0000). The Clerical wages & salaries consist of the occupational category Office & Administrative Support (43–0000). The Services wages & salaries consist of the following occupational categories: Community and Social Service (21–0000); Arts, Design, Entertainment, Sports, and Media (25–0000); Protective Service (33–0000); Food Preparation and Serving Related (35–0000); Building and Grounds Cleaning and Maintenance (37–0000); Personal Care and Service (39–0000); Sales and Related (41–0000); Construction and Extraction (47–0000); Installation, Maintenance, and Repair (49–0000); Production (51–0000); and Transportation and Material Moving (53–0000).

The non-health, non-physician Wages and Salaries cost weight of 12.306 percent is multiplied by the relative share of each category to arrive at the detailed distribution. The occupational distribution in the proposed 2017-based MEI, as well as the distribution for the 2006-based MEI, is presented in Table 38.

TABLE 38: Percent Distribution of Non-physician Wages and Salaries Cost Weights by Occupational Group: Proposed 2017-based MEI and 2006-based MEI

Cost Category	Proposed 2017_weight	2006_weight
Non-physician wages & salaries	**20.514%**	**11.885%**
Non-health, non-physician wages & salaries	12.306%	7.249%
Professional and Related wages & salaries	1.381%	0.800%
Management wages & salaries	2.171%	1.529%
Clerical wages & salaries	7.947%	4.720%
Services wages & salaries	0.807%	0.200%
Health-related, non-physician wages & salaries	8.208%	4.636%

(2) Other Practice Expenses

We proposed that the remaining aggregate Other Practice Expenses would be derived using the 2017 NAICS 6211 SAS expense data and calculated as the sum of the expenses for the detailed categories expressed as a percentage of total expenses. The aggregate Other Practice Expenses include all SAS expenses other than gross annual payroll, fringe benefits, and temporary staff and leased employee expenses. Additionally, we proposed to remove the estimated expenses for drugs and separately billable supplies (which are paid outside of the PFS system) from total expenses in order to be consistent with the PFS. The Other Practice Expenses share of total costs in the proposed 2017-based MEI is 28.023 percent compared to a cost weight of 32.582 percent in the 2006-based MEI.

We further proposed to use the 2017 SAS data for NAICS 6211 to disaggregate the Other Practice Expenses into the following ten cost categories: Utilities; All Other Products; Telephone; Administrative Support & Waste Services; All Other Services; Professional, Scientific, and Technical; Fixed Capital; Moveable Capital; Professional Liability Insurance; and Medical Supplies. Table 39 shows the 10 detailed cost weights for the Other Practice Expenses for the 2017-based MEI, which is 6 fewer categories than the 2006-based MEI. The major differences are: (1) we proposed to have one cost category for All Other Products in the proposed 2017-based MEI instead of having separate cost categories for Chemicals, Paper, Rubber and Plastics, and Other Miscellaneous Products as done for the 2006-based MEI, (2) we proposed to eliminate the separate cost category for Postage as the cost weight was small (less than 0.2 percentage point) and include the expenses for postage in the proposed All Other Products cost weight, and (3) we proposed to eliminate the cost category for Medical Equipment as the cost weight for the Moveable Capital in the proposed 2017-based MEI includes the expenses for all types of machinery and equipment, including medical equipment; we do not have a data source available to split the expenses between Medical Equipment and All Other Equipment in the SAS or I–O data.

TABLE 39: 2006-Based and Proposed 2017-Based Cost Categories and Weights for Other Practice Expenses

Cost Category	Proposed 2017	2006
Other Practice Expense	**28.023%**	**32.582%**
Utilities	0.366%	1.266%
All Other Products	2.055%	2.478%
Telephone	0.471%	1.501%
Postage*	-	0.898%
All Other Professional Services	**13.914%**	**8.095%**
Professional, Scientific, and Technical Services	6.350%	2.592%
Administrative Support & Waste Services	2.341%	3.052%
All Other Services	5.223%	2.451%
Capital	**7.748%**	**10.310%**
Fixed Capital	5.527%	8.957%
Moveable Capital*	2.221%	1.353%
Professional Liability Insurance	**1.398%**	**4.295%**
Medical Equipment	-	1.978%
Medical Supplies	2.071%	1.760%

*For the 2017-based MEI, the postage expenses are included in the All Other Products cost weight, and the expenses for medical equipment are included in the Moveable Capital cost weight.

As previously mentioned, we proposed to make one adjustment to the medical supplies expenses as reported on the SAS data to exclude estimated expenses associated with drugs and separately billable supplies. We proposed to make this adjustment in order to exclude the expenses that are paid outside of the PFS and to be consistent with the expenses that were also excluded in the 2006-based MEI. Finally, we proposed to use the BEA 2012—Benchmark I/O data aged to 2017 to determine the split between All Other Products and All Other Services that are captured in the residual ''all other expenses'' line in the 2017 SAS data. The BEA 2012—Benchmark I/O data can be accessed at *https://www.bea.gov/industry/input-output-accounts-data#supplemental-estimate-tables.* We noted that this method of splitting residual expenses is similar to the methodology used in the 2006-based MEI where the 2002 Benchmark I/O data was aged to 2006 to further disaggregate the residual expense from the AMA PPIS.

The following is a description of the types of expenses included in each of the detailed categories under Other Practice Expenses:

(a) Utilities

The proposed weight for Utilities was calculated using the 2017 SAS expense data expressed as a percentage of total expenses. Utilities expenses are calculated as the sum of the expenses from SAS for: (1) purchased electricity, (2) purchased fuels (except motor fuels), and (3) water, sewer, refuse removal, and other utility payments. The SAS survey questionnaire defines the purchased electricity expenses as costs paid for electricity. The SAS survey questionnaire defines the purchased fuels (except motor fuels) as the costs for fuel for heating, power, or generating electricity (for example, natural gas, propane, oil, coal). The SAS survey questionnaire defines the water, sewer, refuse removal, and other utility payments as the costs for hazardous waste removal. If the utility payments for any of these expenses are included with lease and rental payments then they are captured in the SAS question for lease and rental payments for land, building, structures, storage spaces, or offices. The proposed cost weight for Utilities in the 2017-based MEI is 0.366 percent.

(b) Telephone Services

The Telephone cost weight in the proposed 2017-based MEI includes 2017 SAS expenses reported for purchased communication services. The SAS survey questionnaire defines purchased communication services as telephone, cellular, and fax services; computer-related communications (for example, internet, connectivity, online), and other wired and wireless communication services. The proposed cost weight for Telephone Services is 0.471 percent.

(c) All Other Products

The proposed cost weight for All Other Products for the proposed 2017-based MEI was calculated in two steps. First, all other operating expenses are calculated as a percentage of total expenses from the 2017 SAS, which was 9.158 percent. The SAS survey questionnaire defines the All Other operating expenses as operating expenses not reported or captured by any other survey expense question or specifically excluded in the general instructions. These expenses specifically excluded in the general instructions are: transfers made within the company, capitalized expenses, interest, bad debt, impairment, and income tax.

Second, All Other Products expenses are calculated as the estimated percentage of expenses from SAS for all other operating expenses using Benchmark I/O data. In order to split the aggregate all other operating expenses, which reflects both products and services, we proposed to rely on the 2012 Benchmark I/O data for NAICS 6211, Offices of Physicians aged to 2017 for the NAICS categories that align with expenses in the SAS all other operating expenses. The process for doing this is explained step by step as follows:

Step 1: We crosswalked the NAICS categories in the 2012 Benchmark I/O data to the expense questions in the 2017 SAS data. This process allowed for all Benchmark I/O costs to be grouped into similar buckets as the SAS Expenses as closely as possible.

Step 2: We aged the 2012 Benchmark I/O costs to 2017 for each of the following major buckets of expenses: Physician Compensation, Non-Physician Compensation, Capital-related expenses (fixed and moveable), PLI, Professional Services, Other Products, Other Services, Utilities, and Medical Supplies using the growth of the various price proxies used for these cost categories in the 2006-based MEI.

Step 3: The share of each of the aged 2012 I/O expenses were calculated as a percentage of the total aged 2012 I/O expenses. The aged 2012 I/O categories of other products and other services were estimated to account for about 9.6 percent of total costs. This share is similar to the SAS residual cost share weight of 9.158 percent.

The following Table 40 shows the Benchmark I/O NAICS categories that were crosswalked to the SAS all other operating expenses for all other product expenses.

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TABLE 40: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting All Other Products

ALL OTHER PRODUCTS	
111400	Greenhouse, nursery, and floriculture production
321100	Sawmills and wood preservation
321200	Veneer, plywood, and engineered wood product manufacturing
321910	Millwork
3219A0	All other wood product manufacturing
327100	Clay product and refractory manufacturing
327200	Glass and glass product manufacturing
327310	Cement manufacturing
327320	Ready-mix concrete manufacturing
327330	Concrete pipe, brick, and block manufacturing
327390	Other concrete product manufacturing
327910	Abrasive product manufacturing
331110	Iron and steel mills and ferroalloy manufacturing
331200	Steel product manufacturing from purchased steel
332310	Plate work and fabricated structural product manufacturing
332710	Machine shops
332720	Turned product and screw, nut, and bolt manufacturing
339920	Sporting and athletic goods manufacturing
311513	Cheese manufacturing
31161A	Animal (except poultry) slaughtering, rendering, and processing
311810	Bread and bakery product manufacturing
311910	Snack food manufacturing
311920	Coffee and tea manufacturing
312110	Soft drink and ice manufacturing
313200	Fabric mills
314900	Other textile product mills
315000	Apparel manufacturing
316000	Leather and allied product manufacturing
322120	Paper mills
322130	Paperboard mills
322299	All other converted paper product manufacturing
324121	Asphalt paving mixture and block manufacturing
324122	Asphalt shingle and coating materials manufacturing
325120	Industrial gas manufacturing
325130	Synthetic dye and pigment manufacturing
325180	Other Basic Inorganic Chemical Manufacturing
325190	Other basic organic chemical manufacturing
325510	Paint and coating manufacturing
325520	Adhesive manufacturing
325610	Soap and cleaning compound manufacturing
3259A0	All other chemical product and preparation manufacturing
326110	Plastics packaging materials and unlaminated film and sheet manufacturing
326120	Plastics pipe, pipe fitting, and unlaminated profile shape manufacturing
326140	Polystyrene foam product manufacturing
326150	Urethane and other foam product (except polystyrene) manufacturing
326160	Plastics bottle manufacturing
326190	Other plastics product manufacturing
326210	Tire manufacturing
425000	Wholesale electronic markets and agents and brokers
491000	Postal service

Step 4: The share of expenses for the aged 2012 Benchmark I/O all other products to the aged total all other operating expenses in the Benchmark I/O were calculated. This resulted in products accounting for 22.4 percent

and services accounting for 77.6 percent of the I/O expenses classified as all other costs. We then multiplied the SAS all other operating expenses (9.158 percent) by 22.4 percent to estimate expenses for the all other products.

Step 5: Lastly, we divided the estimated all other products SAS expenses by the total SAS expenses and the resulting proposed 2017-based MEI cost weight for All Other Products is 2.055 percent.

(d) Administrative Support and Waste Services

The proposed weight for Administrative Support and Waste for the proposed 2017-based MEI is based on a portion of the 2017 SAS all other operating expenses (Residual). Similar to the methodology to calculate the All Other Products cost weight we follow a similar process for the Administrative Support & Waste Services cost weight and the All Other Services cost weight discussed in the next section. First, we estimated the total SAS residual expenses associated with other services by multiplying the SAS all other operating expenses by 77.6 percent, or a cost weight of 7.103 percent accounting for the SAS residual expenses associated with services rather than products.

Next, we carved out a portion of these all other services expenses that we identified as Administrative Support and Waste Services from the I/O categories as shown in Table 41. These categories accounted for about 26 percent of All other operating expenses. Finally, we divided the estimated Administrative Support and Waste Services expenses by the Total SAS Expenses and the resulting proposed 2017-based MEI cost weight for Administrative Support and Waste Services is 2.341 percent.

TABLE 41: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting Administrative Support & Waste Services

ADMINISTRATIVE SUPPORT & WASTE	
492000	Couriers and messengers
533000	Lessors of nonfinancial intangible assets
561700	Services to buildings and dwellings
561100	Office administrative services
561200	Facilities support services
561400	Business support services
561500	Travel arrangement and reservation services
561600	Investigation and security services
561900	Other support services
813B00	Civic, social, professional, and similar organizations

(e) All Other Services

The proposed weight for All Other Services for the proposed 2017-based MEI was determined in two steps. First, as was done for other products, we identified I/O categories (as shown in Table 42) associated with other services that would crosswalk to the 2017 SAS data for all other operating expenses. Next, we carved out a portion of these all other services expenses that were not assigned to Administrative Support and Waste Services from the I/O categories, the categories assigned to all other services are shown in Table 35. Using this information, we determined that All Other Services accounted for 52 percent of the SAS expenses for other operating expenses, or a weight of 4.762 percent.

TABLE 42: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting All Other Services

ALL OTHER SERVICES	
481000	Air transportation
484000	Truck transportation
485000	Transit and ground passenger transportation
486000	Pipeline transportation
48A000	Scenic and sightseeing transportation and support activities for transportation
493000	Warehousing and storage
511110	Newspaper publishers
511120	Periodical Publishers
511130	Book publishers
5111A0	Directory, mailing list, and other publishers
512100	Motion picture and video industries
5191A0	News syndicates, libraries, archives and all other information services
522A00	Nondepository credit intermediation and related activities
52A000	Monetary authorities and depository credit intermediation
523900	Other financial investment activities
523A00	Securities and commodity contracts intermediation and brokerage
524113	Direct life insurance carriers
711100	Performing arts companies
711200	Spectator sports
711500	Independent artists, writers, and performers
711A00	Promoters of performing arts and sports and agents for public figures
713900	Other amusement and recreation industries
722110	Full-service restaurants
722211	Limited-service restaurants
722A00	All other food and drinking places
812300	Dry-cleaning and laundry services
812900	Other personal services

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Second, we also proposed to include the expenses directly reported on the SAS survey for purchased repairs and maintenance to machinery and equipment in the other services category. The SAS survey questionnaire defines these expenses to include expensed repair and maintenance services to machinery, vehicles, equipment, and computer hardware. These expenses accounted for 0.461 percent of total expenses, and when added to the 4.762 percent calculated above, results in a proposed 2017-based MEI cost weight for All Other Services of 5.223 percent.

(f) Professional, Scientific, and Technical Services

The Professional, Scientific and Technical Services cost weight includes the sum of the 2017 SAS expenses for three categories: (1) data processing and other purchased computer services, (2) purchased advertising and promotional services, and (3) purchased professional and technical services. The SAS survey questionnaire defines data processing and other purchased computer services to include expenses for web hosting, computer facilities management services, computer input preparation, data storage, computer time rental, optical scanning services, and other computer-related advice and services (including training). The SAS survey questionnaire defines purchased advertising and promotional services to include marketing and public relations services. The SAS survey questionnaire defines purchased professional and technical services to include management consulting, accounting, auditing, bookkeeping, legal, actuarial, payroll processing, architectural, engineering, and other professional services. The cost weight for Professional, Scientific, and Technical Services is 6.350 percent in the proposed 2017-based MEI.

(g) Fixed Capital

The Fixed Capital cost weight includes the sum of the 2017 SAS expenses for four categories: (1) purchased repairs and maintenance to buildings, structures, and offices, (2) lease and rental payments for land, buildings, structures, store spaces, and offices, (3) an estimated portion of depreciation and amortization charges, and (4) governmental taxes and license fees. The SAS survey questionnaire defines purchased repairs and maintenance to buildings, structures, and offices as repair and maintenance to integral parts of buildings (for example, elevators, heating systems). The SAS survey questionnaire defines lease and rental payments for land, buildings, structures, store spaces, and offices to include the rental or lease expenses paid for these items including any penalties incurred for broken leases. The SAS survey questionnaire defines depreciation and amortization charges to include depreciation charges taken against tangible assets owned and used by this firm, tangible assets owned and used by this firm within leaseholds, tangible assets obtained through capital lease agreements, and amortization charges against intangible assets (patents, copyrights). We proposed to include the share of the depreciation expenses applicable to only the

structures by multiplying the total depreciation expenses by the share of total lease and rental payments that were associated with land, buildings, structures, store spaces, and offices as reported on the SAS, which is 89 percent. The SAS survey question defines governmental taxes and license fees as payments to government agencies for taxes and licenses including business and property taxes. The proposed cost weight for Fixed Capital for the proposed 2017-based MEI is 5.527 percent.

(h) Moveable Capital

The Moveable Capital cost weight includes the sum of the 2017 SAS expenses for five categories: (1) expensed equipment, (2) expensed purchases of other materials, parts, and supplies, (3) expensed purchases of software, (4) an estimated portion of depreciation and amortization charges, and (5) lease and rental payments for machinery, equipment, and other tangible items. The SAS survey questionnaire defines expensed equipment as expensed computer hardware and other equipment (for example, copiers, fax machines, phones, shop and lab equipment, CPUs, monitors). The SAS survey questionnaire defines depreciation and amortization charges to include depreciation charges taken against tangible assets owned and used by this firm, tangible assets owned and used by this firm within leaseholds, tangible assets obtained through capital lease agreements, and amortization charges against intangible assets (patents, copyrights). We proposed to include the share of the depreciation expenses applicable to only the machinery and equipment by multiplying the total depreciation expenses by the share of total lease and rental payments associated with machinery and equipment as reported on the SAS, which is 11 percent. The SAS survey question defines lease and rental payments for machinery, equipment, and other tangible items as lease and rental of transportation equipment without operators including penalties incurred for broken lease agreements. The proposed cost weight for Moveable Capital for the proposed 2017-based MEI is 2.221 percent.

(i) Professional Liability Insurance (PLI)

The Professional Liability Insurance (PLI) cost weight includes 2017 SAS expenses reported for professional liability insurance. The SAS survey questionnaire defines professional liability insurance as the premiums paid for professional liability insurance and the amounts set aside for self-insurance. The proposed cost weight for PLI is 1.398 percent in the proposed 2017-based MEI.

(j) Medical Supplies

The Medical Supplies cost weight includes 2017 SAS expenses reported for Medical supplies with an adjustment to remove the estimated expenses for drugs and separately billable medical supplies. The SAS survey questionnaire defines medical supplies as the materials and supplies used to provide medical services to others (except for medical equipment). Since the reported expenses in the SAS would include the expenses for drugs and biologicals, as well as the expenses for supplies that generally are paid separately under Medicare we proposed to remove the expenses for these two items from the SAS expenses reported using the following methodology:

Step 1: To remove the separately billable drug expenses, we rely on the reported expenses for separately billable drugs from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for separately billable drugs to 2017 using the growth in Medicare Part B physician-administered drug spending. Using this method, we inflated the 2006 AMA PPIS expenses for separately billable drugs to 2017 by an increase factor of 1.784 (or 78.4 percent).

Step 2: To remove the non-separately billable drug expenses, we rely on a similar method where we start with the reported expenses for non-separately billable drugs from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for non-separately billable drugs to 2017 using the growth in the PPI for prescription drugs. Using this method, we inflate the 2006 AMA PPIS expenses for non-separately billable drugs to 2017 by an increase factor of 2.122 (or 112.2 percent).

Step 3: To remove the non-separately billable supply expenses, we start with the reported expenses for non-separately billable supplies from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for non-separately billable supplies to 2017 using the growth in the Medical supplies price proxy in the 2006-based MEI (a 50/50 blend of the PPI—Commodity—Medical and surgical appliances and supplies and the CPI—Medical equipment and supplies). Using this method, we inflate the 2006 AMA PPIS expenses for non-separately billable supplies to 2017 by an increase factor of 1.048 (or 4.8 percent).

Step 4: We then calculate the share of estimated 2017 expenses for all drugs and separately billable supplies from steps 1–3 as a percentage of total drugs and medical supplies expenses from the 2017 SAS for NAICS 6211. This share is 80 percent.

Step 5: We multiply the SAS 2017 total medical supplies expenses by a factor of 0.2 (or 1–0.8) in order to estimate the 2017 SAS expenses for non-separately billable medical supplies only.

Taking the 2017 estimated expenses for non-separately billable medical supplies as a ratio of total expenses as reported on the 2017 SAS for NAICS 6211 results in a proposed Medical Supplies cost weight of 2.071 percent in the proposed 2017-based MEI.

The following is a summary of the public comments received on the proposed 2017-based MEI and our responses:

Comment: Many commenters agreed that the data currently used for the MEI is outdated and endorsed the principle of having a methodology that allows for regular and frequent updates to the MEI in the future to help ensure that payment rates reflect the current underlying realities of work, practice expenses, and malpractice insurance. A few commenters supported the proposal to update the MEI using publicly available data sources to estimate base year expenses that reflect current market conditions, thus they supported moving forward using the proposed 2017-based MEI methodology. However, a majority of the commenters urged CMS to delay any change in the MEI until the AMA's practice cost data collection work is completed in order to compare the weights based on the AMA and SAS data. The commenters noted that this will allow interested parties a better ability to provide comments on the potential impact to the PFS of refinements to physician practice expense distributions. Some commenters stated they believe it is important to retain consistency with the MEI measurement that has been based on data collected from the AMA Physician Practice Information (PPI) Survey that has been used by CMS since 1975. Some commenters stated that if the MEI revisions are adopted, they urge that they be phased in over a period of at least four years. Commenters noted that a transition approach would be consistent with other significant payment changes in the PFS including how CMS updated prices of supply and equipment inputs and its current transition of clinical labor updates for use in its PE methodology.

Response: As detailed in the proposed rule (87 FR 46419 through 46425), we are continuing to use the current 2006-

based MEI cost share weights for CY 2023 PFS ratesetting and GPCIs, effectively delaying the implementation of the rebased and revised MEI cost share weights for purposes of PFS ratesetting and CY 2023 GPCIs. However, we believe that it is important to rebase and revise the MEI to a more recent period. We look forward to reviewing future data when that information is available to compare to the results to our proposed methodology.

Comment: MedPAC commented that they support CMS' proposal to rebase the MEI using data from 2017 because the MEI is currently based on data on physicians' expenses from 2006, which raises questions about its accuracy. However, they stated that CMS' proposed methodology for rebasing the MEI is not transparent and relies on several disparate data sources because no single data source contains information at the level of detail necessary to rebase the MEI. The commenter also stated that in the long term, CMS should strive to identify or develop a single data source that has more comprehensive information about physicians' input costs, such as physician compensation and compensation for other workers. However, the commenter supported CMS using its proposed rebased MEI in the interim, as well as waiting until 2024 to use the new MEI cost weights to update the practice expense GPCI cost share weights and to recalibrate the total pools of physician work, PE, and PLI RVUs.

Response: We agree that the current 2006-based MEI is outdated and this raises questions about its accuracy for measuring input price inflation for providing physician services. We provided detailed explanations of which data sources were used and while we agree that the methodology is complex as it relies on several disparate data sources, we believe that we have proposed a methodology that relies on the best available data for this purpose. For this final rule we have included additional language in order to more clearly explain how we have combined data sources to disaggregate cost data. We also would highlight that we believe that the proposed methodology for the 2017-based MEI relies on data that are updated on a regular basis, publicly available, and reflective of the changing practice patterns of the overall industry.

We appreciate the commenter's suggestion that CMS identify or develop a single data source that has more comprehensive information about physicians' input costs. While we share these aspirations, we are not currently aware of any such data source. We will continue to explore our options for a more comprehensive data source in the future, and any changes to the MEI thereof would be proposed in future rulemaking and subject to public comments.

Comment: One commenter stated concern that the proposed MEI methodology would include expenses for all types of physician practice ownership, not just self-employed physicians. They state that they believe that using all types of physician practice ownership is another adjustment for which specialized care will shoulder the burden.

Response: We believe that the MEI should reflect the current market for physician practices. There have been significant changes to physician practice ownership patterns since the MEI was originally implemented in the 1970s, and even more recently since the MEI was last rebased to reflect 2006 experience. Therefore, we believe that it is technically appropriate for the MEI to reflect the current physician practice ownership shares rather than only reflecting expenses for self-employed physicians. We note that the share of self-employed physicians has declined steadily over time, based on data from the AMA Physician Practice Benchmark Survey.

Comment: Many commenters stated that the 2017 Service Annual Survey (SAS) data for the ''Offices of Physicians'' industry was not designed with the purpose of updating the MEI and that seven percent of the revenue for ''Offices of Physicians'' on the 2017 SAS was from non-patient care sources (for example, grants, investment income) and any expenses associated with these sources cannot be excluded.

Response: While we agree that there are non-patient care sources of revenue mixed in with the SAS revenue data, we note that the SAS revenue data for ''Offices of Physicians'' is used only to estimate the cost weight for owners of physician practices (or net income). Since the MEI is comprised of relative costs, the composition of the SAS revenue data would have a minimal impact on the proposed 2017-based MEI cost weights. We believe this methodology for estimating the proposed MEI cost share weights using the 2017 SAS data is a technical improvement over the 2006-based MEI.

Comment: Many commenters expressed concerns with the proposed method for splitting the aggregate payroll and benefits expenses from the SAS data between physician and non-physician compensation. The commenters stated that the proposed method relies on a series of assumptions to determine the relative distribution of salaries between physician and non-physician compensation and results in skewed weights that underrepresent the portion of physician compensation relative to non-physician compensation. Commenters had several specific concerns with the proposed method.

First, commenters stated that both the Census Bureau's SAS and BLS OEWS datasets only include costs for employed physicians within NAICS 6211 and excludes 36 percent of physicians who are employed in other health care settings, such as hospitals. The commenters claim that hospital-based physicians have a higher proportion of physician earnings and PLI cost relative to other practice costs, as many of these other costs are the responsibility of the hospital or other facility.

Secondly, commenters stated that the proposed methodology for estimating compensation for practice owners (that is, net income) to be unreasonable. The commenters stated that the estimated share of net income represents just 10 percent of total compensation for all physicians and QHPs, which they claim is an unreasonable estimate since nearly half of physicians in the United States are owners.

The third methodological concern raised was the estimated share of employee compensation attributed to physicians and QHPs from the 2017 of 63.2 percent is incorrect because it incorrectly classified registered nurses (RNs) in the estimated share of physician expenses rather than classified to non-physician compensation.

Finally, MedPAC suggested that the occupational splits derived from the OEWS data as proposed do not account for differences in the number of hours worked by different occupational categories. The commenter suggested that including differentials in the average hours worked by occupation is technically appropriate and should be considered.

Response: As mentioned by commenters, the SAS expense data does not explicitly report compensation separately for physicians/QHPs and non-physicians, and therefore, we proposed a methodology relying on other data sources in order to split the costs between the two categories of workers. Though we agree with the first comment that both the SAS and OEWS for NAICS 6211, Offices of Physicians, do not include expenses or revenues for physicians who are employed in other healthcare settings directly, such as hospitals, we do not believe that

including costs for physicians that do not incur any operating expenses associated with running a practice would be technically appropriate. We note that the establishments selected for NAICS 6211, Offices of Physicians are defined as establishments of health practitioners having the degree of M.D. (Doctor of Medicine) or D.O. (Doctor of Osteopathy) primarily engaged in the independent practice of general or specialized medicine (for example, anesthesiology, oncology, ophthalmology, psychiatry) or surgery. These practitioners operate private or group practices in their own offices (for example, centers or clinics) or in the facilities of others, such as hospitals or HMO medical centers. Therefore, while the SAS data would not necessarily reflect physicians directly employed by a hospital they would reflect establishments that operate physician offices in other settings such as hospitals or HMO medical centers. Additionally, the current cost share weights based on the 2006 AMA Physician Practice Information Survey (PPIS) data also appropriately do not reflect the expenses of physicians employed directly by other industries such as hospitals or skilled nursing facilities. Therefore, we believe that the SAS and BLS OEWS data for Offices of Physicians are technically appropriate data sources to use to derive the cost share weights for the index that measures relative input price pressures of providing physician services.

In response to commenters' second concern, the proposed methodology for estimating the net income for practice owners from the 2017 SAS data was developed to capture the proportion of net income from a physician practice that would reflect physician compensation but is not reported as payroll. The 2017 SAS data includes gross payroll expenses for employees, which would exclude the proportion of expenses that are compensation to proprietors or partners for unincorporated businesses. A sole proprietorship or partnership is often an unincorporated business owned and run by one or more individuals, with no distinction between the business and its owner. The owners of these unincorporated businesses are entitled to all profits and are also solely responsible for all the business's debts, losses and liabilities. Based on this definition, income to sole proprietors and partnerships from profits is not captured in the SAS gross payroll data; however, employed physicians who are not sole proprietors or unincorporated business would be eligible for inclusion in the sample and their compensation would be reported in the gross payroll costs. Therefore, we proposed to include a proportion of net income for owners of physician offices that are sole proprietors, partnerships, or unincorporated businesses to physician compensation expenses estimated from the SAS.

As discussed in the proposed rule, in order to adjust the 2017 SAS expense levels, we first calculated the total net income for the industry. Within the SAS survey data for Offices of Physicians, the difference between total revenues and expenses would reflect compensation to the physician (net income) as well as funds that are likely reinvested in the business or used for other purposes, such as expansion or savings. Therefore, we proposed to allocate only a portion of the 2017 difference between revenues and expenses to physician compensation to account for the net income of owners of unincorporated businesses, and we believed using the proportion of physicians that are self-employed to be a reasonable assumption in determining this adjustment. We note that the estimated share of net income from the SAS data declined from 11.3 percent in 2006 to 9.2 percent in 2017. At the same time the percentage of physicians reported as owners of a practice rather than employees declined from 61 percent in 2006 to 46.5 percent in 2017, according to the AMA Physician Practice Benchmark Survey data.

Given that the commenters felt that the proposed method to estimate net income wasn't reflecting the proportion of the revenue and expense difference that was allocated to physician compensation, we conducted further research and considered an alternative method. The IRS Statistics of Income (SOI) data for Offices of Physicians, by type of ownership, provides the level of revenue/receipts and net income separately for corporations, partnerships, and sole proprietors. The 2017 SOI data shows that net income as a share of total receipts varies across ownership type. For example, the share of net income as a percentage of revenue is 49.6 percent for sole proprietors, 19.5 percent for partnerships, and 6.9 percent for corporations. Since the SAS gross revenue less expenses amount would reflect a combination of ownership types, we believe that revising our method to account for the differences in shares of net income, by ownership type, would be an improvement over using the share of self-employed physicians of overall physicians. Our revised method is based on the following steps:

Step 1: We estimated the share of total revenue for the three ownership types as reported on the 2017 IRS SOI data. For NAICS 6211, Offices of Physicians, corporations account for 74 percent of total industry revenue, partnerships account for 17 percent of total industry revenue, and sole proprietors account for 8 percent of total industry revenue. We applied these percentages to the total revenue amount reported in the 2017 SAS data to estimate the level of revenue for the three ownership types.

Step 2: Using the 2017 IRS SOI data, we calculated the share of net income as a percentage of revenue/receipts for the three ownership types. The share of net income as a percent of revenue for corporations is 6.9 percent, for partnerships is 19.5 percent, and for sole proprietors in 49.6 percent.

Step 3: We multiply the share of net income as a percentage of revenue for corporations, partnerships, and sole proprietors (calculated in step 2) to the revenue amounts for corporations, partnerships, and sole proprietors (calculated in step 1) to determine the net income by ownership type for each of the three practice types.

Step 4: We add the estimated net income for partnerships and sole proprietors (calculated in step 3) together to determine the amount of net income from the 2017 SAS data that should be allocated to physician compensation.

We believe this methodology addresses the commenters' concerns that the proposed method did not consider the variation in the percentage of costs assumed to be allocated to net income for sole proprietors and partnerships. We do not allocate any of the net income or profit for corporations to physician compensation as we believe that corporations would use the annual profit to reinvest in the business or for other business purposes. This revised method for estimating the net income for physician compensation relies upon IRS data for sole proprietors and partnerships in order to estimate net income that is not directly captured by the SAS survey question. We are unaware of any other publicly available data source available that would provide this information.

This revised methodology results in an increase in the cost weight for net income from the proposed 4.8 percent of total expenses to 8.2 percent of total expenses. Additionally, the revised method increases the share of physician net income as a share of total physician compensation from 10.3 percent to 16.7 percent of physician compensation costs. We believe this is a better estimate for deriving net income since it

takes into account the differences in the relative share of net income by ownership type, which the proposed method did not consider. Therefore, we are finalizing the revised method for estimating the net income add-on expense amount based on the revised method described above for the final 2017-based MEI.

In response to commenters' third concern regarding the error in classification of RN compensation expenses, we agree that registered nurses (RNs) were inadvertently classified in the estimated share of physician expenses but would be more appropriately classified in non-physician compensation. Within the BLS OEWS data, RNs are reported in the SOC 29–1141. Based on commenters' concerns we reallocated the associated expenses for RN compensation from Physician Compensation expenses to Clinical, non-physician Compensation expenses. The revised distribution results in a smaller share of SAS reported compensation costs allocated to physician compensation and an increase to the share of Clinical, non-physician compensation.

In response to the final comment related to including variation in hours worked by occupation into the methodology for deriving the physician and non-physician split, we agree with the suggestion that the estimated shares for Office of Physicians occupational mix could be refined to account for differences in the number of hours worked by occupation. We obtained average weekly hours worked by occupation for NAICS 6211 from the Census Bureau's Current Population Survey (CPS). We have revised the proposed methodology for estimating the occupational mix of total compensation shares by multiplying the mean hourly earnings by occupation from the BLS OEWS survey by the average weekly hours by occupation from the CPS data. This product of mean hourly wage * average weekly hours by occupation is then multiplied by the number of employees by occupation as reported by the BLS OEWS data. This revised method for estimating the occupational mix shares to account for variation in the number of hours worked by occupation relies upon data captured by the CPS. We are unaware of any other publicly available data source that would provide this information.

The revised distribution of the compensation weights accounting for both a reclassification of RNs to clinical non-physician compensation and accounting for average hours worked, by occupation, is shown in Table 43. Accounting for the differences in the average weekly hours by occupation increases the weight for physician compensation and decreases the weight for clinical, non-physician compensation, and non-health related compensation compared to the proposed 2017-based MEI.

TABLE 43: 2017 Occupational Mix of Total Compensation Shares Accounting for Average Weekly Hours by Occupation, NAICS 6211, Offices of Physicians

	Revised Weights reclassifying RNs and Average Weekly Hours	Revised Weights reclassifying RNs only	Proposed Weights
All Employees	100.0%	100.0%	100.0%
Physician Compensation	60.7%	55.7%	63.2%
Clinical, non-physician compensation	19.1%	21.7%	14.7%
Non-health related compensation	20.2%	22.6%	22.1%

For the reasons detailed above, we believe that the three methodological revisions to the proposed method based on public comment feedback produces an improvement to the decomposition of SAS compensation expenses between physician compensation and non-physician compensation for purposes of the MEI.

Comment: Several commenters noted they did not agree with the proposed method to exclude expenses for separately billable supplies and drugs. Commenters stated that the use of growth in Medicare Part B drug spending to age expenses forward is not entirely appropriate and that the use of an index that is inclusive of all drugs, such as the CPI or PPI to account for inflation would be better. Commenters also expressed concern that the total expenses that were being compared were estimated from different surveys and the expenses to include in each survey could be entirely different.

Response: We disagree with commenters' concerns with the proposed approach for estimating the portion of separately billable supply and drug expenses. We believe that the question on the AMA PPIS survey for drugs and medical supplies align similarly with the types of expenses collected on the SAS survey questionnaire. The SAS survey questions for medical supply expenses asks respondents to report the costs for materials and supplies used in providing medical services to others (and States not to include costs for medical equipment in this amount). This medical supply expense would include drug costs as well as other medical supply costs. The AMA PPIS survey collects the expenses for drugs and medical supplies using two separate questions. The AMA question for medical supply expenses asks respondents to report ''total expenses for medical supplies such as sterile gloves, needles, bandages, specimen containers, and catheters.'' The AMA question also instructs respondents to not include expenses for medical equipment costs with medical supplies. The question for drug expenses asks respondents to report ''total expenses for all drugs administered in the office (for example, local anesthetics, infusions, antibiotics, vaccines) and instructs respondents to report the cost of the drugs, after considering any discounts and rebates.'' Additionally, the two questions on the AMA PPIS survey for medical supplies and drugs asks for the dollar amount of medical supplies and drugs that were separately billable; this information is not collected on the SAS questionnaire. Given the data available, we believe that the proposed method for removing all

drug expenses and separately billable supply expenses for the 2017-based MEI is appropriate and is consistent with how these costs were excluded in the 2006-based MEI. The estimated price growth in Part B drugs and the estimated growth in the PPI for prescription drugs are relatively similar. The proposed method excludes approximately 80 percent of medical supply expenses from the SAS data. If the separately billable drug expenses were inflated by the PPI for prescription drugs instead of the growth in Part B drug spending, then 81.8 percent of expenses would be excluded rather than 80 percent. We believe that the difference between the two methods is insignificant and believe the proposed approach is the better one.

Comment: Many commenters stated that the decrease in the weight for PLI costs was unrealistic. One commenter noted that a weight of 1.4 percent applied to Medicare spending on its share of these premiums and self-insured actuarial costs would equate to an unreasonably low premium amount that would contradict CMS's volume weighted national PLI premium costs of $21,700. The commenters, using this logic, stated that they believe a 4–5 percent PLI weight is more appropriate than the proposed 1.4 percent weight.

Response: The proposed cost share weight for the 2017-based MEI, reflecting all types of physician ownership practices is substantially lower than the current 2006-based MEI PLI weight, which reflected the relative cost of PLI for self-employed physicians only. The drop in the PLI weight is the result of using both a more recent year of physician cost data as well as also using a sample of physicians that is inclusive of various ownership types.

Based on analysis of several data sources, the 2017 cost weight for PLI shows that it is lower than the weight in the 2006-based MEI. For example, the IRS Statistics of Income data for Sole Proprietors shows a 2006 PLI cost share weight of about 3.9 percent, which is relatively close to the 2006-based MEI PLI weight of 4.3 percent based on AMA PPIS data. Using the same data source the SOI data shows a 2017 PLI weight of 2.1 percent. This information indicates that trends between 2006 and 2017 for self-employed, sole proprietors would by itself result in a drop of approximately 2 percentage points.

However, as mentioned earlier, the data for the proposed 2017-based MEI also includes corporations and physician group practices that are not self-employed, including those that are hospital owned. These practices tend to be larger and have higher overall expenses than sole proprietor physician offices; additionally, group practice data indicates the relative share of PLI expenses is even lower (for instance, one private data source indicates a PLI weight below 1 percent in recent years).

For these reasons, we believe the proposed 2017-based cost weight is appropriate, given the data sources available reporting these costs. As we noted, the PLI weight in the MEI reflects the total expenses associated with paid PLI premiums for the industry relative to the total costs for other business expenses such as compensation, and equipment costs. Thus, it is not comparable to a measure of an average national premium such as the CMS national PLI premium cost of $21,700 referenced in the rule.

After consideration of the public comments, we are finalizing the proposed 2017-based MEI cost share weights as proposed for all cost categories in the MEI except for the compensation cost category weights where we are revising the methodology based on public comments received and summarized above. Specifically, we are: (1) revising the methodology for estimating the 2017 expenses for physician net income; (2) correcting the allocation of registered nurse (RN) compensation costs from physician compensation to clinical, non-physician compensation; and (3) adjusting the shares for allocating SAS compensation costs between physician and non-physicians by factoring in differences in average weekly hours by occupation. The following section highlights the specific changes we are finalizing to the proposed methodology and the resulting revised 2017-based MEI weights relative to both the 2006-based and the proposed 2017-based MEI weights.

The development of the revised cost weights based on public comments is described, in detail, as follows.

a. Physician's Compensation

The component of the MEI that reflects physician work is represented by the estimated portion of compensation expenses attributable to physicians. The revised 2017 cost weight associated with the physician's work (otherwise referred to as the Physician Compensation cost weight) is based on the estimated share of 2017 SAS expenses for total compensation associated with physician compensation. Since the compensation expense in the SAS data is only reported as an aggregate for all employees, we split the compensation expenses between physicians (including non-physician practitioners that can bill independently such as nurse practitioners (NPs), physician assistants (PAs), and other clinical personnel) and all other workers using the following process.

Step 1: Total compensation costs are calculated by summing the reported expenses in the SAS for gross annual payroll, employer costs for fringe benefits (including health insurance, defined benefit and defined contribution plans, payroll taxes, employer paid insurance premiums, and all other benefits), and temporary staff and leased employees as reported in the 2017 SAS data for NAICS 6211 (Office of Physicians).

Step 2: Determine the ratio of physician (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) wage costs to total wage costs. This ratio is calculated using data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) May 2017 National Industry-Specific Occupational Employment and Wage Estimates for Offices of Physicians (NAICS 6211). This data reports the number of employees by occupational category based on the Standard Occupational Classification System (SOC) and the mean hourly wage for each occupation. We proposed to revise the calculation of expenses for each occupation to also account for the variation in the average weekly hours worked, which were obtained for NAICS 6211 from the Census Bureau's Current Population Survey (CPS). Therefore, for each occupation, we multiply the number of employees by the mean hourly wage times the average weekly hours to estimate the total mean weekly wage expense. The sum of weekly expenses for each occupation category represents total mean weekly wage expenses for all occupations in NAICS 6211. Then to derive the total mean weekly wage expenses for physicians (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) we sum the expenses for the following occupations: Physicians and Surgeons (29–1060); Chiropractor (29–1011); Optometrist (29–1041); Podiatrist (29–1081); Physical Therapist (29–1123); Dieticians & Nutritionists (29–1031); Physician Assistants (29–1071); Nurse Practitioners (29–1171); and All Other Diagnosing & Treating Occupations (29–11XX). We note that the proposed methodology included the allocation of compensation costs for Registered Nurses (29–1141) within the All Other Diagnosing & Treating Occupations category (29–11XX). As commenters highlighted, the compensation expenses

for RNs were inadvertently allocated to physician compensation. Therefore, we are correcting this error and correctly allocating these costs to the clinical, non-physician compensation cost category. As a result of these revisions, the ratio of physician mean weekly wage costs to total mean weekly wage costs falls to 60.7 percent compared to the proposed 63.2 percent. This change is the combination of two offsetting effects, correcting for the classification of RN expenses to clinical, non-physician compensation lowers the physician compensation share from 63.2 percent to 55.7 percent; then accounting for differences in weekly hours by occupation subsequently increases the physician compensation share from 55.7 percent to 60.7 percent.

Step 3: We multiply the total compensation expenses from Step 1 by the revised ratio of 60.7 percent determined in Step 2 to derive the revised Employed Physician Compensation Expenses, or 39.3 percent of total costs.

Next, since the expenses estimated above reflect only employed physician compensation, we proposed to add an estimate of compensation costs to account for physician practice owners that are not classified as employees but instead would be included in the net income of the practice. Based on comments received we re-evaluated the proposed methodology used to estimate the net income expenses.

The IRS Statistics of Income (SOI) data for Offices of Physicians, by type of ownership provides the level of revenue/receipts and net income separately for corporations, partnerships, and sole proprietors. The 2017 SOI data shows that net income as a share of total receipts varies across ownership type. For example, the share of net income as a percentage of revenue is 49.6 percent for sole proprietors, 19.5 percent for partnerships, and 6.9 percent for corporations. Since the SAS revenue less expense amount would reflect a combination of ownership types we revised our method to account for the differences in shares of net income, by ownership type using the following steps:

Step 1: We estimated the share of total revenue for the three ownership types as reported on the 2017 IRS SOI data. For NAICS 6211, Offices of Physicians, corporations account for 74 percent of total industry revenue, partnerships account for 17 percent of total industry revenue, and sole proprietors account for 8 percent of total industry revenue. We applied these percentages to the total revenue amount reported in the 2017 SAS data to estimate the level of revenue for the three ownership types.

Step 2: Using the 2017 IRS SOI data, we calculated the share of net income as a percentage of revenue/receipts for the three ownership types. The share of net income as a percent of revenue for corporations is 6.9 percent, for partnerships is 19.5 percent, and for sole proprietors in 49.6 percent.

Step 3: We multiply the share of net income as a percentage of revenue for corporations, partnerships, and sole proprietors (calculated in step 2) to the revenue amounts for corporations, partnerships, and sole proprietors (calculated in step 1) to determine the net income by ownership type for each of the three practice types.

Step 4: We add the estimated net income for partnerships and sole proprietors (calculated in step 3) together to determine the amount of net income from the 2017 SAS data that should be allocated to physician compensation. We do not allocate any of the net income or profit for corporations to physician compensation as we believe that corporations would use the annual profit to reinvest in the business or for other business purposes.

This revised methodology results in an increase in the cost weight for net income from the proposed 4.8 percent of total expenses to 8.2 percent of total expenses. The revised method increases the share of physician net income as a share of total physician compensation from 10.3 percent to 16.7 percent of physician compensation costs.

The revised aggregate 2017-based Physician Compensation cost weight is the sum of the Employed Physician Compensation cost weight (39.297 percent) and estimated Net Income for Physician Practice Owners cost weight (8.226 percent), or 47.522 percent. By comparison, the 2006-based Physician Compensation cost weight was 50.866 percent. The revised 2017-based MEI cost weight for Physician Compensation is 0.3 percentage point higher than the proposed 2017-based MEI cost weight and is 3.3 percentage points lower than the 2006-based MEI cost weight.

We proposed to split the Physician Compensation cost weight into two cost categories: Physician Wages and Salaries and Physician Benefits. We did not make any revisions to the proposed methodology for splitting physician compensation into Physician Wages and Salaries and Physician Benefits, therefore we split the physician compensation weight between wages and benefits using an 83/17 split. As a result, the Physician Wages and Salaries cost weight is 39.443 percent and the Physician Benefits cost weight is 8.079 percent in the revised 2017-based MEI.

b. Practice Expenses

The Practice Expenses cost weight reflects all remaining operating costs other than physician compensation. Based on public comments received on the proposed method, we are revising the cost weights for the non-physician compensation categories. We are finalizing the cost category weights for all practice expense cost categories other than non-physician compensation cost categories as proposed. We explain the revisions to the cost weights for the non-physician compensation practice expense cost weights.

(1) Non-Physician Compensation

We proposed to estimate the cost weight for Non-physician Compensation using the 2017 SAS data for these expenses. As mentioned previously, since the compensation expenses in the SAS data are only reported as an aggregate for all employees, we proposed to multiply the 2017 SAS total compensation expenses for NAICS 6211 by the residual of the share determined for physicians (including non-physician practitioners that can bill independently such as NPs, PAs, and other clinical personnel). The revised share for non-physician compensation is 39.307 percent. Multiplying the total compensation expenses by this ratio results in the final Non-physician Compensation cost weight of 25.451 percent, slightly higher than the proposed 24.716 percent.

Finally, we revised the weights for disaggregating the non-physician wages and salaries into two categories: (1) Health-related, non-physician and (2) Non-health, non-physician Wages and Salaries.

Of the 39.3 percent of total SAS compensation costs associated with non-physicians, 19.1 percentage points are determined to be associated with Health-related, non-physician Wages and Salaries. This percentage reflects the ratio of mean weekly wages to total mean weekly wages from the 2017 OEWS data for the following occupations: Registered Nurses (RNs) (29–1141); Health Technologists and Technicians (29–2000); Other Healthcare Practitioners and Technical (29–9000); and Healthcare Support (31–0000). Applying this share (about 49 percent) to the non-physician wages cost weight results in a weight of 10.858 percent for the health-related, non-physician Wages and Salaries cost weight for the final 2017-based MEI.

The remaining share of non-physician compensation costs are associated with

non-health, non-physician Wages and Salaries (20.2 percentage points of the 39.3 percent). This percentage reflects the ratio of mean weekly wages to total mean weekly wages from the 2017 OEWS data for the following occupations: Management (11–0000); Business and Financial Operations (13–0000); Computer and Mathematical (15–0000); Architecture and Engineering (17–0000); Life, Physical, and Social Science (19–0000); Community and Social Service (21–0000); Legal (23–0000); Education, Training, and Library (25–0000); Arts, Design, Entertainment, Sports, and Media (27–0000); Protective Service (33–0000); Food Preparation and Serving Related (35–0000); Building and Grounds Cleaning and Maintenance (37–0000); Personal Care and Service (39–0000); Sales and Related (41–0000); Office and Administrative Support (43–0000); Construction and Extraction (47–0000); Installation, Maintenance, and Repair (49–0000); Production (51–0000); and Transportation and Material Moving (53–0000). Applying this share (about 51 percent) to the non-physician wages cost weight results in a weight of 10.266 percent for the non-health, non-physician Wages and Salaries cost weight for the final 2017-based MEI.

Next, since the non-health, non-physician wages represent various types of occupations that may experience different wage inflation pressures, we proposed to disaggregate the non-health, non-physician Wages and Salaries cost weight into four occupational subcategories. To arrive at a distribution for these separate occupational categories (Professional & Related (P&R) workers, Managers, Clerical workers, and Service workers), we determined an estimate of annual earnings for each using the Standard Occupational Classification (SOC) system. While we did not make any changes to the occupations included in each of the categories from what was proposed, the final cost weights are revised due to the revised non-physician wages and salary weight and the inclusion of average weekly hours by occupation.

The non-health, non-physician Wages and Salaries cost weight of 10.858 percent is multiplied by the relative share of each category to arrive at the detailed distribution. The occupational distribution in the final 2017-based MEI, the proposed 2017-based MEI, and the 2006-based MEI is presented in Table 44.

TABLE 44: Percent Distribution of Non-physician Wages and Salaries Cost Weights by Occupational Group: Final 2017-based MEI, Proposed 2017-based MEI and 2006-based MEI

Cost Category	Final 2017_weight	Proposed 2017_weight	2006_weight
Non-physician wages & salaries	**21.124%**	**20.514%**	**11.885%**
Non-health, non-physician wages & salaries	10.858%	12.306%	7.249%
Professional and Related wages & salaries	1.312%	1.381%	0.800%
Management wages & salaries	2.101%	2.171%	1.529%
Clerical wages & salaries	6.750%	7.947%	4.720%
Services wages & salaries	0.695%	0.807%	0.200%
Health related, non-physician wages & salaries	10.266%	8.208%	4.636%

Table 45 lists the set of mutually exclusive and exhaustive cost categories and weights for the final 2017-based MEI, proposed 2017-based MEI, and the 2006-based MEI. While the methodology for deriving all other practice expenses did not change from the proposed method, their cost share weights are slightly lower due to the increases in total expenses that reflect the revised method for estimating physician net income; that is, both physician compensation and total expenses were higher based on the revised method in response to public comments.

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TABLE 45: Final 2017-based MEI, Proposed 2017-based MEI and 2006-based MEI Cost Categories and Weights

Cost Category	Final 2017-based	Proposed 2017-based	Current 2006-based
MEI Total	**100.000%**	**100.000%**	**100.000%**
Physician Compensation	**47.522%**	**47.261%**	**50.866%**
Wages and Salaries	39.443%	39.226%	43.641%
Benefits	8.079%	8.034%	7.225%
Practice Expense	**52.478%**	**52.739%**	**49.134%**
Non-physician Compensation	**25.451%**	**24.716%**	**16.553%**
Non-physician Wages	**21.124%**	**20.514%**	**11.885%**
Non-health, non-physician Wages	10.858%	12.306%	7.249%
Professional and Related	1.312%	1.381%	0.800%
Management	2.101%	2.171%	1.529%
Clerical	6.750%	7.947%	4.720%
Services	0.695%	0.807%	0.200%
Health related, Non-physician Wages	10.266%	8.208%	4.636%
Non-physician Benefits	**4.327%**	**4.202%**	**4.668%**
Other Practice Expense	**27.027%**	**28.024%**	**32.582%**
Utilities	0.353%	0.366%	1.266%
All Other Products	1.981%	2.055%	2.478%
Telephone	0.455%	0.471%	1.501%
Postage	-	-	0.898%
All Other Professional Services	**13.419%**	**13.914%**	**8.095%**
Professional, Scientific, and Tech. Services	6.124%	6.350%	2.592%
Administrative & Waste Services	2.258%	2.341%	3.052%
All Other Services	5.037%	5.223%	2.451%
Capital	**7.473%**	**7.748%**	**10.310%**
Fixed Capital	5.331%	5.527%	8.957%
Moveable Capital (including medical)	2.142%	2.221%	1.353%
Professional Liability Insurance	**1.349%**	**1.398%**	**4.295%**
Medical Equipment	-	-	1.978%
Medical Supplies	1.997%	2.071%	1.760%

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3. Selection of Price Proxies for Use in the MEI

To select prices proxies for the proposed 2017-based MEI cost categories, most of the proxy measures we considered are based on BLS data and are grouped into one of the following four categories:

- Producer Price Indices (PPIs): PPIs measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indices (CPIs):* CPIs measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available or if the particular expenditure category is likely to contain purchases made at the final point of sale.
- *Employment Cost Indices (ECIs):* ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC). We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:
- *Reliability:* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness:* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The MEI levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent

data available to update the MEI. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- *Availability:* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that the MEI updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

As discussed in the proposed rule, we believe the proposed PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied. In this rule, we present a detailed explanation of the price proxies that we proposed for each cost category weight. We noted that many of the proxies that we proposed to use for the proposed 2017-based MEI (as shown in Table 36) are the same as those used in the 2006-based MEI except as noted below.

a. Physician Compensation

(1) Physician Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for Professional and Related Occupations (Private Industry) (BLS series code CIU20200001200000I) to measure price growth of this category in the proposed 2017-based MEI. We noted that we believe this price proxy reflects the wage pressures faced by physicians in that it captures wage trends in labor markets of skilled professional workers without being directly affected by trends in physician income that may be influenced by the ownership structure of physician practices. This price proxy also follows the recommendation of the MEI–TAP that the price proxy would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled ''Social Security Amendments of 1972,'' which stated that the index should reflect changes in practice expenses and ''general earnings''. This is the same proxy used in the 2006-based MEI.

(2) Physician Benefits

We proposed to continue to use the ECI for Benefits for Professional and Related Occupations (Private Industry) to measure price growth of this category in the proposed 2017-based MEI. The ECI for Benefits for Professional and Related Occupations is derived using BLS's Total Compensation for Professional and Related Occupations (BLS series ID CIU2010000120000I) and the relative importance of wages and salaries within total compensation. We believe this series is technically appropriate because it better reflects the benefit trends for professionals requiring advanced training. This is the same proxy used in the 2006-based MEI.

b. Practice Expense

(1) Non-Health, Non-Physician Wages and Salaries

- *Professional and Related:* We proposed to continue using the ECI for Wages and Salaries for Professional and Related Occupation (Private Industry) (BLS series code CIU20200001200000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.
- *Management:* We proposed to continue using the ECI for Wages and Salaries for Management, Business, and Financial (Private Industry) (BLS series code CIU20200001100000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.
- *Clerical:* We proposed to continue using the ECI for Wages and Salaries for Office and Administrative Support (Private Industry) (BLS series code CIU20200002200000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.
- *Services:* We proposed to continue using the ECI for Wages and Salaries for Service Occupations (Private Industry) (BLS series code CIU20200003000000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(2) Non-Physician, Health-Related Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for Hospital Workers (Private Industry) (BLS series code CIU20262200000000I) to measure the price growth of this cost category in the proposed 2017-based MEI. The ECI for Hospital workers has an occupational mix that approximates that of physicians' offices. This is the same proxy used in the 2006-based MEI.

(3) Non-Physician Benefits

We proposed to continue using a composite ECI for non-physician employee benefits in the proposed 2017-based MEI. The weights and price proxies for the composite benefits index are shown in Table 46, which lists the five ECI series and corresponding weights used to construct the proposed composite benefit index for non-physician employees in the proposed 2017-based MEI. We noted the ECI benefits series are derived based on BLS published data from the applicable Total Compensation ECI and Wages & Salaries ECI as BLS does not publish the ECI Benefit Indexes directly.

TABLE 46: Proposed 2017-based Composite Benefits Blend Cost Weights

	Price Proxy	2017	2006
Non-Health, non-physician Benefits		**60%**	**61%**
Professional and Related	ECI - Benefits for Private industry workers in Professional and related	7%	7%
Management	ECI - Benefits for Private Industry workers in Management, Business, and Financial	10%	13%
Clerical	ECI - Benefits for Private Industry workers in Office and Administrative Support	39%	40%
Services	ECI - Benefits for Private Industry workers in Service Occupations	4%	2%
Health related, non-physician Benefits	ECI - Benefits for All Civilian workers in Hospitals	**40%**	**39%**

(4) Other Practice Expense

(a) Utilities

We proposed to continue using the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(b) All Other Products

We proposed to use the PPI—Final demand—Finished goods less foods and energy (BLS series code WPUFD413) as the price proxy for this category. We believe that the expenses for the products that physicians purchase for use in providing physicians services are better reflected by purchases at the wholesale or producer level rather than at the consumer level and the growth in overall prices less food and energy provides a good approximation for the inflation pressures experienced for these expenses. The 2006-based MEI used several PPI and CPI series to proxy the price growth for the products reflected in this category.

(c) Telephone

We proposed to continue using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(d) Professional, Scientific, and Technical Services

We proposed to continue to use the ECI for Total Compensation for Professional, Scientific, and Technical Services (Private Industry) (BLS series code CIU2015400000000I) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(e) Administrative and Support Services

We proposed to continue to use the ECI for Total Compensation for Administrative, Support, Waste Management, and Remediation Services (Private Industry) (BLS series code CIU2015600000000I) to measure the price growth of this cost category in the 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(f) All Other Services

We proposed to continue to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

(g) Fixed Capital

We proposed to continue to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(h) Moveable Capital

We proposed to continue to use the PPI for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(i) Professional Liability Insurance

Unlike the other price proxies based on data from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. The MEI–TAP discussed the methodology of the CMS PLI index, as well as considered alternative data sources for the PLI price proxy, including information available from BLS and through State insurance commissioners. As detailed in the CY 2014 PFS final rule (78 FR 74271), the MEI–TAP ''believes the current index appropriately reflects the price changes in premiums throughout the industry.'' Accordingly, we proposed to continue using the CMS Physician PLI index to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(j) Medical Supplies

We proposed to continue using a blended index comprised of 50/50 blend of the PPI for Surgical Appliances (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). This is the same proxy used in the 2006-based MEI.

Table 47 shows the 2017-based MEI cost categories and price proxies.

TABLE 47: Proposed 2017-Based MEI Cost Categories and Price Proxies

Proposed 2017-based Medicare Economic Index	
Cost Category	**2017 Price Proxy**
MEI Total	
Physician Compensation	
Wages and Salaries	ECI - Wages and salaries for Private industry workers in Professional and related
Benefits	ECI - Total Benefits for Private industry workers in Professional and related
Practice Expense, including PLI	
Non-physician compensation	
Non-physician wages	
Non-health, non-physician wages	
Professional and Related wages	ECI - Wages and salaries for Private industry workers in Professional and related
Management wages	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial
Clerical wages	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support
Services wages	ECI - Wages and Salaries for Private Industry workers in Service Occupations
Health-related, non-physician wages	ECI - Wages and salaries for All Civilian workers in Hospitals
Non-physician benefits	Composite - ECI - Total Benefits for the 5 non-physician wage categories
Other Practice Expense	
Utilities	CPI - Fuels and utilities
All Other Products	PPI - Final demand - Finished goods less foods and energy
Telephone	CPI - Telephone Services
All Other Professional Services	
Professional, Scientific, and Technical Services	ECI - Total compensation for Private industry workers in Professional, scientific, and technical services
Administrative support & waste	ECI - Total compensation for Private industry workers in Office and administrative support
All Other Services	ECI - Total compensation for Private industry workers in Service occupations
Capital	
Fixed Capital	PPI - Industry - Lessors of nonresidential buildings
Moveable Capital	PPI - Commodity - Machinery and equipment
Professional Liability Insurance	**CMS - Professional Liability Insurance Index, physicians**
Medical supplies	Composite: PPI - Commodity - Medical and surgical appliances and supplies (50%), PPI - Commodity - Surgical and medical instruments (50%)

We did not receive any comments on the proposed price proxies used in the MEI and we are finalizing all price proxies as proposed. We note that the price proxies within the benefits blend are the same as proposed; however, the final weights for the composite benefits index have changed due to the revisions we are finalizing to the methodology for deriving compensation costs (that is, changes to the physician net income estimated expenses, the correction to classification of RN compensation expenses, and the inclusion of variation in average hours worked by occupation). These factors resulted in a change to the weights for the composite benefits blend relative to the proposed rule as shown in Table 48.

We are finalizing the continued use of a composite ECI for non-physician employee benefits in the 2017-based MEI; however, the relative shares for each of the ECI benefits series within the blend differ from those presented in the proposed rule because the final relative shares are updated to reflect the revisions to the methodology that we are finalizing in this final rule. The weights and price proxies for the composite benefits index are shown in Table 48, which lists the five ECI series and corresponding weights used to construct the final composite benefit index for non-physician employees in the 2017-based MEI. We noted the ECI benefits series are derived based on BLS published data from the applicable Total Compensation ECI and Wages & Salaries ECI as BLS does not publish the ECI Benefit Indexes directly.

TABLE 48: Final 2017-based Composite Benefits Blend Cost Weights

	Price Proxy	Final 2017	Proposed 2017	2006
Non-Health, Non-physician Benefits		**51%**	**60%**	**61%**
Professional and Related	ECI - Benefits for Private industry workers in Professional and related	6%	7%	7%
Management	ECI - Benefits for Private Industry workers in Management, Business, and Financial	10%	10%	13%
Clerical	ECI - Benefits for Private Industry workers in Office and Administrative Support	32%	39%	40%
Services	ECI - Benefits for Private Industry workers in Service Occupations	3%	4%	2%
Health-related, non-physician Benefits	ECI - Benefits for All Civilian workers in Hospitals	**49%**	**40%**	**39%**

4. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) total factor productivity (previously referred to as multifactor productivity) that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of economy-wide private nonfarm business labor productivity.

The MEI–TAP's Finding 5.1 states that, ''[t]he Panel reviewed the basis for the current economy-wide multifactor productivity adjustment (Private Nonfarm Business Multifactor Productivity) in the MEI and finds such an adjustment continues to be appropriate. This adjustment prevents ''double counting'' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

We proposed to continue to use the current method of applying a productivity adjustment to the full MEI increase factor in the proposed 2017-based MEI. As described in the CY 2003 PFS final rule with comment period, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We noted that we believe that using the 10-year moving average percent change in economy-wide total factor productivity is appropriate for deriving a stable measure that helps alleviate the influence that the peak (or a trough) of a business cycle may have on the measure. The adjustment would be based on the latest available historical economy-wide nonfarm business total factor productivity data as measured and published by BLS.

We did not receive any comments on the proposed productivity adjustment to the MEI, and therefore, we are finalizing the productivity adjustment as proposed.

5. Results of Rebasing and Revising of the MEI

Table 49 illustrates the results of the proposed update to the MEI cost weights for Physician Compensation, Practice Expenses (excluding PLI), and PLI from a 2006-based cost distribution, the proposed 2017-based cost distribution, and the final 2017-based cost distribution including all the revisions as a result of public comments as specified.

TABLE 49: Percent Distribution of Major Physician Expense Components: 2006-based MEI, proposed 2017-based MEI, and final 2017-based MEI

	Weights		
RVU Component	**Final 2017-based**	**Proposed 2017-based**	**Current 2006-based**
	2017	2017	2006
Physician Work	47.5%	47.3%	50.9%
Practice Expense	51.2%	51.3%	44.8%
Malpractice or PLI	1.3%	1.4%	4.3%
Total	100.0%	100.0%	100.0%

Table 50 shows the average calendar year percent change for CY 2016 to CY 2023 for the 2006-based MEI, the proposed 2017-based MEI, and the final 2017-based MEI. The final 2017-based MEI annual percent changes differ from the 2006-based MEI annual percent changes by 0.1 to 0.2 percentage point for any given year.

TABLE 50: Annual Percent Changes in the 2006-Based and the Proposed and Final 2017-based MEI

Update Year[1]	Final 2017-based MEI	Proposed 2017-based MEI	2006-based MEI
2016	1.4	1.4	1.2
2017	1.3	1.3	1.1
2018	1.5	1.5	1.4
2019	1.8	1.8	1.6
2020	1.9	1.9	1.8
2021	1.7	1.7	1.5
2022	2.1	2.2	2.1
2023	3.8	3.8	3.8
Average Change	1.95	1.94	1.81

[1]Update year based on historical data through the second quarter of the prior calendar year. For example, the 2023 change is based on historical data through the second quarter 2022.

As shown in Table 50, the percent change of the final 2017-based MEI, the proposed 2017-based MEI, and the 2006-based MEI for CY 2023 is an increase of 3.8 percent based on historical data through the 2nd quarter of 2022.

We did not receive any comments on the proposed updates as a result of rebasing and revising of the MEI, and, therefore, we are finalizing the update factor based on the most recent historical estimate of the MEI increase.

III. Other Provisions of the Final Rule

A. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§§ 414.902 and 414.940)

1. Background

Drugs and biologicals payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limit amounts for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are covered under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient.

Many drugs and biologicals (hereafter referred to as a drugs) payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often times, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for industry,[132] a single-dose container is designed for use with a single patient as a single injection or infusion. The FDA-approved labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the labeling instructs a provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (Drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B in order to more effectively identify and monitor billing and payment for discarded amounts of drugs.[133] [134] The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting. Additional details about this policy can be found in Chapter 17 of the Medicare Claims Processing Manual [135] and in the JW modifier frequently asked questions (FAQ) document.[136]

Medicare Part B data for discarded amounts of drug (based on the JW modifier) have been published on the CMS website annually for calendar years beginning in 2017.[137] Data for 2020 shows that Medicare paid nearly $720 million for discarded amounts of drugs from a single-dose container or single-use package (hereafter referred to as single-dose container [138]) paid under Part B with claims identifying the discarded amounts with the JW modifier. JW modifier data from 2020 is the most recent available at the time of this analysis. This data is comparable to 2017–2019 with regard to percentage of discarded amounts and total Medicare spending for discarded drugs each year, which ranged from approximately $700–750 million each year during that

[132] *https://www.fda.gov/media/117883/download.*

[133] CR6603: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf.*

[134] MLN Matters® Number MM9603: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf.*

[135] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.*

[136] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

[137] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

[138] *https://www.fda.gov/media/117883/download.*

time. More than half of Medicare spending for discarded amounts in 2020 represents about 40 billing and payment codes (that is, HCPCS codes), for which 10 percent or more of the total charges for the drug were for discarded units. A large proportion of single source drugs with 10 percent or more discarded units are dosed based on patient's body weight or BSA. We note that the JW modifier data published on the CMS website is limited to only billing and payment codes that are published on the ASP Drug Pricing File.[139] There are likely additional billing and payment codes payable under Medicare Part B available in single-dose containers that would be subject to the JW modifier policy and are not reflected in the data discussed above.

The calculated dose (based on weight or BSA) is drawn from one or more vials and any remaining amount of the drug is discarded. For example, if labeled dose of a drug is 20 mg/m², the dose for a patient with a BSA of 1.9 m² (the approximate average BSA of an adult male) would be 38 mg. If the drug is available in single-dose 60-mg vials, then 38 mg would be administered to the patient and 22 mg (36.67 percent) would be discarded. If the ASP payment limit amount (typically, ASP plus 6 percent) for this drug for a given quarter is $190 per 1 mg, the total payment for the amount of drug that was administered to the beneficiary would be $7,220 and for the amount of drug that was discarded would be $4,180. Both the amount of drug administered and the amount discarded (consistent with the discarded drug policy) are subject to the deductible and coinsurance. For a beneficiary who has already met the deductible, the coinsurance for the entire 60-mg vial would be $2,280. Since the vial in this example contains enough drug to provide a 20 mg/m² dose to an individual with a BSA of 3 m², the full amount of drug labeled on the vial would be used in a small subset of patients.

As discussed in the CY 2023 PFS proposed rule (87 FR 46055 through 46062), section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (hereinafter is referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. A refundable single-dose container or single-use package drug does not include a radiopharmaceutical or imaging agent, certain drugs requiring filtration, and certain new drugs. We proposed implementation of section 90004 of the Infrastructure Act including: how discarded amounts of drugs are determined; a definition of which drugs are subject to refunds (and exclusions); when and how often CMS will notify manufacturers of refunds; when and how often payment of refunds from manufacturers to CMS is required; refund calculation methodology (including applicable percentages); a dispute resolution process; and enforcement provisions. We also proposed regulatory changes to implement new section 1847A(h) of the Act at 42 CFR part 414, subpart K.

We note, subsequent to the publication of the CY 2023 PFS proposed rule, sections 11101 and 11102 of the Inflation Reduction Act (IRA) (Pub. L. 117–169), relating to inflation rebates by manufacturers of drugs covered under Medicare Parts B and D, were signed into law on August 16, 2022. These provisions are effective January 1, 2023. We believe implementation of the Parts B and D rebates mandated under the IRA should be considered together with the operational implications of discarded drug refund discussed in this final rule, because the refunds and rebates both require CMS to accept payments from drug manufacturers to the Federal Supplementary Medical Insurance (SMI) Trust Fund. In order to align the operation of these programs and minimize burden, we are declining to finalize some aspects for collection of discarded drug refunds. Specifically, we are declining to finalize the timing of the initial reports and which quarters' information will be included in each report; this is discussed below in section III.A.4. of this final rule. We are also declining to finalize specific dates associated with the dispute resolution process (discussed below in section III.A.7. of this final rule), which are impacted by the reporting dates. We intend to address these aspects in future rulemaking.

2. Discarded Amounts

The JW modifier has existed since 2003, and since 2017 its use has been required on claims for separately payable Part B drugs that include discarded amounts of single use vials or single use packages. Currently, there are no other modifiers to measure discarded units of Part B drugs. On the claim form, the amount of drug administered is billed on one line (reflected as billing units in the unit field); discarded amounts are billed on a separate line with the JW modifier (reflected as billing units in the unit field). The term ''billing unit'' is defined in section 1847A(b)(6)(B) of the Act as the identifiable quantity associated with a billing and payment code, as established by the Secretary. For example, in a circumstance where a single-dose container is labeled to contain 200 mg and the established billing unit for the billing and payment code is 2 mg, then there are 100 billing units in the vial. If 95 billing units (190 mg) are administered to the patient and 5 billing units (10 mg) are discarded, the 95 billing units are billed on one line, and the discarded 5 billing units are billed on another line using the JW modifier. Both line items are processed for payment.

The JW modifier must not be used to report discarded amounts of overfill, which is any amount of drug greater than the amount identified on FDA-approved labeling. Additional information on the overfill policy is available in the PFS final rule published in the November 29, 2010 **Federal Register** (75 FR 73466 through 70). Contents of a vial or package that are considered overfill are not included in the total billing units contained in the vial or package and also do not count toward the number of billing units that are discarded.

As discussed in the CY 2023 PFS proposed rule (87 FR 46056 through 46058), section 1847A(h) of the Act specifies that discarded amounts of refundable single-dose container or single-use package drugs are to be determined using a mechanism such as the JW modifier used as of the date of enactment of the Infrastructure Act or any successor modifier that includes such data as determined appropriate by the Secretary. For consistency with our current billing procedures and to minimize burden, we proposed to use the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of a billing and payment code (that is, the identifiable quantity associated with a billing and payment code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, that were discarded for dates of service during such quarter. We

[139] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

proposed to use the JW modifier (or any successor modifier that includes the same data) to identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act.

We explained, currently under the OPPS and Ambulatory Surgical Center (ASC) Payment System, hospital outpatient departments (HOPDs) and ASCs use the JW modifier to identify all separately payable drugs and biologicals for which there is an unused or discarded amount. For consistency with our current billing procedures we proposed that HOPDs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes that are assigned status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) or status indicator ''G'' (Pass-Through Drugs and Biologicals) under the OPPS. Specifically, we proposed that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, assigned status indicator ''K'' or ''G'' that were discarded for dates of service during such quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. Similarly, we proposed that ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes assigned payment indicator ''K2'' ('Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) under the ASC payment system. Specifically, we proposed that ASCs would be required to report the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, assigned status indicator ''K2'' that were discarded for dates of service during such quarter.

Consistent with section 1847A(h)(1)(C) of the Act, which excludes units that are packaged into the payment amount for an item or service and not separately payable, as well as current HOPD and ASC use of the JW modifier, we proposed that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable, such as drugs for which payment is packaged under the OPPS or ASC payment system or drugs administered in the FQHC or RHC setting. Specifically, in HOPD setting and the ASC setting, the JW modifier does not apply to drugs that are described by HCPCS codes assigned status indicator ''N'' (Items and Services Packaged into APC Rates) under the OPPS or assigned to a payment indicator of ''N1'' (Packaged service/item; no separate payment made) under the ASC payment system.

Similarly, we proposed to exclude from the refund amount those units of drugs for which payment is packaged into payment for a comprehensive ambulatory payment classification (C–APC) service under the OPPS. We proposed to exclude such drugs when payment is packaged into a C–APC service which is assigned to an OPPS status indicator of ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC) or ''J2'' (Hospital Part B Services That May Be Paid Through a Comprehensive APC). For example, if a drug under the OPPS is assigned to status indicator ''K'', reports the JW or similar modifier, but is then packaged into a C–APC service assigned to a status indicator of ''J1'' or ''J2'', we would exclude from the refund those units associated with the packaged drug.

We stated that section 1847A(h) of the Act requires manufacturers to provide refunds for discarded amounts of refundable single-dose container or single-use package drugs for which payment is made under Part B exceeding an applicable percentage of at least 10 percent of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter. Under our current discarded drug policy, no modifier is required when there are no discarded amounts from a single-dose container.[140] However, as discussed in the proposed rule, we are aware that the JW modifier is often omitted on claims, and it is unclear whether the absence of the JW modifier on a claim for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim. This has led to incomplete data describing quantities of discarded amounts and the associated Medicare payments. We explained that there are a number of possible reasons why the modifier might be incorrectly omitted on the claim form, including provider burden for documentation or lack of awareness of the policy. In addition, there may not be strong incentive for appropriate JW modifier use because Medicare pays for administered and discarded amounts of the drug. For instance, if a provider administers a portion and discards a portion of a single-dose container, but bills for the entire vial as administered (incorrectly omitting the JW modifier), the provider payment and beneficiary coinsurance amounts would be the same as if the provider had correctly billed for the administered amounts and the discarded amounts (using the JW modifier). The JW modifier FAQs state that claims that do not use the modifier correctly may be subject to review, but we do not have quantifiable numbers regarding how often the modifier is omitted or how many discarded units are not accounted for because of such omissions. Because JW modifier data is incomplete and because refund amounts would rely on this data, we proposed that for dates of service on or after January 1, 2023, the JW modifier be required on claims for all single-dose container or single use drugs for which any amount is discarded (as reflected in our current policy and proposed above), and a separate modifier be required on claims for these drugs when there are no discarded amounts. Specifically, we proposed to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. To align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. So, on all claims for single use vials or single use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We noted that we believe the proposed JZ modifier requirement would not increase burden on the provider because under the current JW modifier policy, the provider already needs to determine whether or not there are any discarded units from a single use vial or package, record discarded amounts in the patient medical record, and specify

[140] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

administered and discarded amounts on the claim form.

We sought comments on the proposals.

The following is a summary of the public comments received on the discarded amount provisions and our responses:

Comment: Several commenters expressed general support for the proposed policy. One commenter supported the requirement that manufacturers refund CMS for drug discards.

Another commenter supported a variety of policies to reduce costs related to discarded drugs, including the manufacturer refunds for discards, re-examining the weight-based dosing of drugs, requiring pharmaceutical companies to have vial sizes that more appropriately meet the range of standard dosing, developing more multiple-dose vials that can be shared across multiple patients, and utilizing closed-system transfer devices to extend beyond-use-dating time. One commenter stated the proposed policy may result in manufacturers acting to revise packaging methods and incentivize a reduction in waste across markets and programs. One commenter expressed their belief that the provision would reduce waste and spending in Medicare by discouraging manufacturers from including excessive amounts of drug single-dose containers. One commenter summarized their own analysis of drug discards at their facilities, noting that five chemotherapy drugs accounted for 59 percent of all chemotherapy drug discards, and that these drugs had discards about 3 to 7 times more than all studied drugs did on average.

Response: We thank commenters for their support of these proposals. We also thank commenters for their view on discarded amounts of drugs and how the proposed policies may incentivize a reduction in spending on discarded amounts of drugs. We also appreciate the thoughtful analysis of discarded amounts from the practitioner's perspective. We agree that the proposed policies will create such incentives for improved package sizes and presentations of drugs that will reduce amounts that are discarded.

Comment: Some commenters expressed general opposition to the implementation of the provision. Two commenters expressed concern that the proposal will disproportionately impact small biotech companies, who will either raise prices for patients or reduce research expenditures. One commenter stated that it is unreasonable to collect refunds for administration processes that generate discarded drug for which there are no or limited alternatives. One commenter expressed concern that the proposed policy would result in larger amounts of discarded drugs by compelling manufacturers to create more batches of smaller vials with the intention of reducing drug waste, but with the unintended consequence of creating more waste and added costs to undergo the process of retrofitting manufacturing facilities to produce different vial sizes. The commenter also expressed concern that the proposed policy would compel providers to spend effort learning how to administer drugs from new container and package configurations. Some commenters expressed concern that the proposed policy would increase operational burden by incentivizing container size reduction, for example by requiring providers to use more containers than had previously been needed to achieve an appropriate weight-based dose. Two commenters stated that the production of medications in multiple vial sizes would be costly for the manufacturer and inefficient in production. One commenter noted the cost and time required to develop and obtain regulatory approval for a new vial size, which they estimated to be about 2 years and $10 million. The commenter also noted that there are no assurances that if they gained approval for and distributed treatment in additional vial sizes to reduce discard amounts that providers would stock them. The commenter concluded that the effect of the provision's incentive to use a greater number of vial sizes would be increased treatment costs.

One commenter requested CMS examine the implications of the proposals on products commonly used in neurology. The commenter stated several products commonly used by neurologists are packaged in a way that results in significant amounts of discarded drug. One commenter noted concern that, in response to the discarded drug refund policy, manufacturers may raise the price of certain drugs to compensate for the cost of any refund payments. The commenter urged CMS to ensure that implementation is closely monitored, and that appropriate action is taken to dissuade any manufacturer from compensating for lost revenue with a price increase.

Response: With regard to commenters that are generally opposed to the implementation of section 90004 of the Infrastructure Act or generally opposed to CMS collecting a refund, we do not have discretion on whether or not to implement the provision. Regarding small biotech companies being disproportionately affected, we address concerns about exemptions and unique circumstances in the respective discussions below. This provision does not include any special treatment specifically for small biotech companies.

With regard to the increased burden on manufacturers to potentially manufacture different vial sizes and to providers who would have to adjust to stocking and administering new vial sizes, we acknowledge these concerns, but note that the statute requires payment of refunds for single-dose containers for which the amount discarded exceeds the applicable percentage. We note that the 2020 data showed that Medicare Part B spending on discarded drugs is weighted heavily toward a small number of drug products. With regard to the possibility that the implementation of the provision could lead to increases in discarded drug amounts, we do not have any data that suggests this may be the case. On the contrary, we have seen at least one case in which discarded amounts of a drug decreased after the manufacturer began packaging the drug in an additional smaller vial size: Kyprolis® (carfilzomib) introduced a 10 mg vial in June 2018 in addition to its 60 and 30 mg vials, and its discard percentages were 14.27 percent in 2017, 12.68 percent in 2018, and 5.95 percent in 2019, suggesting the new vial size led to a decrease in the discard percentage below 10 percent. In response to the comments that manufacturers may pass on costs from the investigation and manufacture of new vial sizes, or of refunds to patients, we do not speculate on drug manufacturer pricing strategies. We plan to continue to monitor the discarded amounts and trends with regard to this data; this will be for all drugs payable under Medicare Part B and not specific to any condition, such as neurology. We plan to track associated prices of such drugs and assess discretionary aspects of the policy over time and will undertake additional rulemaking, if warranted. In addition, as noted above, the Inflation Reduction Act was signed into law subsequent to the publication of the CY 2023 PFS proposed rule. Sections 11001 and 11101 establish the Secretary's authority to negotiate prices with drug manufacturers for select Part B and Part D drugs and require manufacturers to pay rebates to the Federal SMI Trust Fund for amounts Part B drug prices exceed inflation-adjusted amounts, respectively.

Comment: One commenter stated that the impact of this new requirement is unclear and could potentially increase

the cost of health care delivery, including drug acquisition costs and overhead and labor costs. The commenter requested we actively monitor potential downstream outcomes and mitigate any adverse impacts, as necessary.

Response: We plan to continue engaging with manufacturers as we implement the drug discard refund provision to ensure we understand how implementation affects operations, pricing, and costs of healthcare delivery. In addition, section 1847A(h)(9) of the Act requires OIG to consult with CMS and FDA and report to several Congressional committees by November 15, 2024, the impact of this provision on the licensure, market entry, market retention, or marketing of biosimilar biological products. We also intend to monitor effects on other drugs and biologicals impacted by these policies in a similar manner, including but not limited to the ASP of such drugs and discarded units reported using the JW modifier. We already review quarterly ASP data for the calculation of payment allowances, so we will observe trends in the ASP for drugs subject to refunds.

Comment: One commenter noted the proposal does not account for discards that occur due to clinical reasons, such as when a physician reduces the dosage of an administered drug if the patient has a heart condition or other comorbidities.

Response: Although there may be situations in which there are increased discarded amounts due to clinical circumstances, there is no mechanism on a claim to denote discarded units for a change in clinical circumstance. Section 1847A(h)(3)(B)(i)(I) of the Act requires the refund amount to be the amount above an applicable percentage of 10 percent of the total allowed charges for a drug. We believe that this threshold allows for a certain amount of drug to be discarded for various factors, including clinical reasons, without being subject to a refund. As we noted above, the most recent JW modifier data indicates that drugs with discarded amounts exceeding 10 percent is isolated to a small number of products. There are many drugs provided in single-dose containers with historical discarded amounts below 10 percent, including many chemotherapy drugs, which have specific instructions for reduced dosage in cases of toxicity experienced from the chemotherapy. For example, ixabepilone dosage is based on BSA and the drug is provided in a single-dose vial. The dose modifications indicated in the label direct clinicians to reduce the dose of the drug in certain clinical situations (the dose reduction could range from 20 to 50 percent depending on the clinical circumstance). Based on the 2020 JW modifier data,[141] this drug had just under 8 percent of units discarded, which is below the applicable percentage of 10 percent, and the manufacturer would not owe a refund if this data were to be for dates of service on or after the effective date of January 1, 2023.

Comment: Two commenters stated the statutory construction of section 90004 of the Infrastructure Act requires CMS to define ''unused'' to complete the statute's definition of ''discarded'' referenced in section 1847A(h)(1)(B) of the Act, as the commenters noted that the two are not interchangeable terms. Several commenters requested CMS not include in the definition of ''unused'' amounts that are required to safely administer a drug, such as liquid amounts in a vial that are needed to assure the appropriate dose is withdrawn into an injector. These commenters stated that determining discarded amounts is a two-step process: first that a drug amount was discarded, and second that the amount did not serve a useful purpose. One commenter noted that the same interpretation of the term ''unused'' is applied in the hydrogel example (section III.A.6.a of the CY 2023 PFS proposed rule (87 FR 46061 through 46062) in the discussion of unique circumstances) in which we stated that 35 percent would be an appropriate applicable percentage. Several commenters stated that we should consider liquid amounts required to express a needle (or that otherwise gets lost or stuck in the container or administration devices) and to account for dead volume in the transfer or priming of drug administration as useful and not as unused or as discards, in alignment with FDA's thinking on amount of liquid required in vial fills. Commenters stated these liquid amounts effectuate clinical outcomes. Another commenter suggested CMS define ''discarded amount subject to refund'' to exclude amounts left over when the product contains the minimum fill required for clinicians to draw up the appropriate labeled therapeutic dose.

One commenter requested that we exclude units administered as part of a drug's induction or loading dose(s), which are initial dose(s) of a drug therapy that may differ from the subsequent maintenance dosing regimen. The commenter stated that induction and loading doses may involve variable dosing depending on the patient's specific circumstances. The commenter suggested we use a modifier to identify such doses in claims. This commenter also requested that we exclude units of drugs administered in combination with other drug therapies. The commenter explained that when drugs are used in combination, the dosing of each drug is likely to vary based on factors such as the disease/condition being treated and adjustments for potential adverse events, and it makes little sense to manufacture container sizes to take all such combinations into account. The commenter added a request that we establish a claims modifier to identify drugs administered in combination with others.

Response: As we stated in the proposed rule, when a provider must discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

We clarify how we interpret ''the amount of such drug that was unused and discarded,'' with respect to that which should be reported as discarded based on section 1847A(h)(1)(B) of the Act, as any amount that is not a part of the dose and is not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. This is contemplated by the statute as evidenced by the exclusion of drugs requiring filtration during the preparation process as described in section 1847A(h)(8)(B)(ii) of the Act, and by the treatment of drugs that have unique circumstances in section 1847A(h)(3)(B)(ii) of the Act. If the amount of drug lost during filtration was not considered to be an unused and discarded amount, this exclusion would not be necessary. Similarly, with regards to the treatment of drugs with unique circumstances, the statute says the Secretary may, through notice and comment rulemaking, increase the applicable percentage in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section

[141] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units/data.*

1847A(h)(8)(B)(ii) of the Act, which describes the loss due to filtration. Since the statute prescribes that amounts lost in a manner similar to filtration during preparation may be considered a unique circumstance (and may warrant an increased applicable percentage), these amounts are generally considered unused and discarded for the purposes of determining discarded amounts. Otherwise, such amounts would not be required to be billed using the JW modifier, and an increased applicable percentages would not be needed. Based on this, generally, we consider the amount that is unused and discarded to be the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug).

As examples, we consider labeled amounts remaining in the vial, amounts remaining in the syringe hub, and amounts remaining in the syringe that are not a part of the dose intended for therapeutic effect (as reflected in the product label or that would be reflected on a provider's prescription for the drug) to be unused and discarded. As discussed above, such amounts are similar to situations where filtration is required during preparation, and therefore, are contemplated by the statute to be unused and discarded amounts. In addition, we believe that this approach is the simplest for providers to determine on claims forms and in the medical record.

With regard to the request to exclude units administered as part of a drug's induction or loading dose and the request to exclude units of drugs administered in combination with other drug therapies, we disagree that such discarded amounts as a result of such doses should be excluded from being reported using the JW modifier, because the statute allows for a certain amount to be discarded (that is, the minimum applicable percentage of 10 percent). When an induction or loading dose is administered, there may subsequently be larger amounts of drug left in the single-dose container when compared with the amount of drug left in the container if a typical dose had been administered. As described above, we consider amounts left in the vial to be unused and discarded because they were not part of the dose that was intended for therapeutic effect. We disagree that an additional modifier is needed to report amounts administered in these circumstances because, as discussed above, the threshold of an applicable percentage of 10 percent, as required in section 1847A(h)(3)(B)(i)(I) of the Act, allows for a certain amount of discarded drug. This 10 percent threshold allows for circumstances when a loading dose or induction dose is administered, or when a drug is administered in combination with other drug therapies, before a refund would be required.

Comment: Three commenters supported CMS's proposal to exclude overfill amounts from being taken into consideration when determining the number of units that are discarded, but two of these commenters requested that the regulatory text be updated to clearly reflect this. The commenters stated that without this clarification, physicians may mistakenly report overfill amounts as discarded amounts, leading to inaccurate refund amounts. Commenters stated that while the preamble and guidance is clear, the regulatory text is confusing because some providers may interpret a ''billing unit'' to also reference overfill units. Commenters recommended revisions to the proposed regulatory text changes at § 414.940(a)(1)(iii) and (c)(1)(i). One commenter requested clarification about whether providers should report discards of overfill. One commenter encouraged provider education that the JW modifier should not be used to report discarded amounts of overfill.

Response: We disagree that changes to the regulatory text are needed for clarification. As stated in our longstanding JW modifier FAQs, the JW modifier must not be used to report discarded amounts of overfill, which is any amount of drug greater than the amount identified on FDA-approved labeling. We reiterate the overfill policy, as stated in the CY 2011 PFS final rule (75 FR 73466 through 73470), that contents of a vial or package that are considered overfill are not included in the total billing units contained in the vial or package, and also do not count toward the number of billing units that are discarded.

Comment: Two commenters requested that we clarify that drug discard refunds under section 1847A(h) of the Act are excluded from ASP, average manufacturer price (AMP), and the Medicaid best price calculations.

Response: We do not consider the discarded drug refund to be a price concession that is described in section 1927 of the Act. Since these Part B refunds represent reimbursement by manufacturers to Medicare for a discarded amount that is ''otherwise unsalable returned goods'' manufacturers may exclude these Part B discarded drug refunds from determinations of best price and AMP (including 5i AMP). Section 1927(k)(1)(B)(i)(III) of the Act states that AMP shall exclude reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing. We implemented this statutory language in regulations for the determination of AMP (see 42 CFR 447.504(c)(16) and (e)(7)), and the determination of best price (see § 447.505(c)(14)).

We note that manufacturers typically have established internal policies regarding returned purchases, and to the extent that the reimbursement by the manufacturer for returned goods is consistent with the requirements of section 1927 of the Act and applicable federal regulations, such reimbursement made by the manufacturer shall be excluded from AMP. Standard industry practices and manufacturer policies should govern the determination of what is unsalable, provided such practices are consistent with section 1927 of the Act and applicable federal regulations. What is ''unsalable'' can vary by the product, and manufacturers should rely upon prevailing business standards to determine circumstances when their products are unsalable.

Section 1847A(c)(2)(A) of the Act states that sales exempt from the inclusion in the determination of Medicaid best price are also excluded from the calculation the manufacturer's ASP. Since discarded drug refunds are considered to be ''otherwise unsalable returned goods'' and manufacturers may exclude discarded drug refunds from determination of best price, manufacturers may also exclude such refunds from the calculation of ASP.

Therefore, with regard to the calculation of ASP, AMP, or the Medicaid best price, the refund amounts may be excluded from such determinations.

Comment: Several commenters expressed support for our proposal to require the use of the JZ modifier to attest that there are no discarded amounts. One of the commenters expressed support for methods that could increase JW reporting. One commenter expressed support for our proposal to require institutional providers and ASCs to report the JW modifier, or any successor, on Part B medication claims.

Response: We thank the commenters for their support. We believe that the JZ modifier requirement will improve the completeness of the discarded drug data to effectively implement section 90004 of the Infrastructure Act.

Comment: Many commenters opposed our proposal to require the JZ modifier when no amount is discarded from a single-dose container. Commenters considered its use unnecessary for documenting discarded amounts, overly burdensome, and potentially confusing. Commenters stated that the JW modifier on its own is sufficient to calculate discarded amounts for drugs and biological products subject to this provision. A few commenters expressed the belief that providers are correctly reporting JW modifier data on claims, and that we have no evidentiary basis for believing our JW data is incomplete. Other commenters acknowledged that providers sometimes omit the JW modifier, and suggested several reasons for underreporting, including administrative resource constraints, the lack of incentives for its use, and inability to measure discard amounts. One commenter opposed the requirement to use the JZ modifier on the grounds that the burden of identifying drugs administered with no discarded amounts should fall on CMS or manufacturers, rather than the provider.

Response: We disagree with the assertion that the JZ modifier is unnecessary and that we lack evidence to show that reported JW modifier data fails to convey a full account of drug discard data. The National Academies of Sciences, Engineering, and Medicine provided an analysis conducted by the Committee on Implications of Discarded Weight-Based Drugs [142] which indicates low compliance with the JW modifier requirement. Their analysis of Medicare claims found that the level of compliance is variable among providers, and that nearly two-thirds never used the modifier at all. In addition, providers who use the modifier do not do so consistently, and they vary in their reporting from one drug to another, and across claims for the same patient and drug. Based on these findings, we believe current data for discarded drug amounts are underestimates due to omission of the JW modifier when it should be used, even though reporting the JW modifier has been required since 2017. Accordingly, we believe that more complete data is needed. We believe the most practicable method for improving our data quality is by requiring providers filing claims for drugs from single-dose containers to report either a JW modifier when there are discarded amounts, or JZ modifier when no amount is discarded. We continue to believe providers are the only party that can obtain complete and accurate information on used and discarded amounts of variably dosed drugs. While we acknowledge that, in some situations, it may be difficult to quantify discarded quantities of drugs and associate the specific amount with a single beneficiary, we believe that, in most situations, there are no practical impediments that would prevent billing providers or other staff, such as nurses or pharmacists, from incorporating the measurement of discard amounts into the process of preparing and administering the drug. We also believe that the observation and recording of no discard amounts using the JZ modifier does not add additional burden beyond the existing requirement of measuring discarded amounts by use of the JW modifier. If a provider is already required to determine whether there are discarded amounts from single-dose packages, then they are already assessing and documenting what is needed for the JZ modifier. Since the assessment is already required, the only additional action needed by the provider is to add JZ on the claim form when there are no discarded amounts. Thus, we believe the burden for reporting the JZ modifier is minimal and justifiable.

Comment: Commenters requested that we take care to minimize administrative burden in the implementation of section 90004 of the Infrastructure Act, and many suggested several alternatives to the JZ modifier. Several commenters recommended that we enhance education efforts and outreach to providers on JW modifier use instead of requiring the use of the JZ modifier. One commenter requested that we instead amend our claims policy to state that the absence of reporting the JW modifier on claims for single-dose containers is an attestation that there is no amount of discarded drug. Several commenters suggested we only require JW and JZ modifier use for drugs associated with significant discards and refund obligations while focusing data collection efforts on JW data for those drugs. Two commenters recommended that instead of requiring the use of the JZ modifier, we develop a new claims modifier for drugs subject to the refund which, in conjunction with JW modifier data, would produce the information set we need to issue refund obligations.

Response: As noted above, since the JW modifier is underreported, the absence of the modifier cannot be relied upon to signify that there is no amount of discarded drug.

In response to the request that we require the use of the JW and JZ modifiers only for drugs that are associated with high discard amounts in recent quarters, or any other subset of separately payable Part B drugs from single use vials or single use packages, we believe that approach is likely to lead to confusion among providers and billers, who may mistake which drugs are included or excluded from the relevant subset from one quarter to the next. Additionally, we do not see the practicality of establishing a separate modifier for drugs for which manufacturers will have refund obligations, particularly as the set of refundable drugs will likely shift across quarters.

Comment: One commenter stated their current billing software cannot currently add either the JW or JZ modifier, so under the proposed modifier requirements for claims covered by the proposed policy, modifier codes would both have to be handwritten in by non-clinical staff that smaller facilities cannot afford to recruit. The commenter added that billing software is space-limited and requested CMS only require the use of modifiers that provide the most information.

Two commenters stated that the addition of new claims requirements not paired with increased reimbursement or other incentives would exacerbate strains on provider resources at a time of staffing shortages. One commenter expressed concern about the additional workload collecting discard data would impose on pharmacists and pharmacy technicians. The commenter requested compensatory reimbursements for such pharmacists and pharmacy technicians for the work involved with collecting discard data. In addition, the commenter urged CMS to adopt a mechanism for calculating discard amounts that can be incorporated into existing processes and use as much automation as possible. One commenter requested that we assess administrative impacts the implementation of section 90004 of the Infrastructure Act will have on provider practices.

Response: The JW modifier policy has been in place since 2017, and we are codifying it without change in this final rule. Providers should currently be reporting the JW modifier on their claims, as well as documenting the discarded amounts in the beneficiary's medical records. We understand that providers do not currently have the capability to accept or report the JZ

[142] National Academies of Sciences, Engineering, and Medicine. 2021. Medications in single-dose vials: Implications of discarded drugs. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25911*. National Academies of Sciences, Engineering, and Medicine. 2021. *Medications in Single-Dose Vials: Implications of Discarded Drugs.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25911*.

modifier. We expect that a 6-month delay in the requirement to use the JZ modifier would allow providers sufficient time to incorporate necessary updates to their claims systems to report JZ data. If a provider cannot report the JW or JZ modifiers as required by October 1, 2023, they should hold their claims until they are able to do so. Claims submitted without required modifier data will not be accepted. If the provider has any other technical issues with submitting the required modifier data, we expect the provider to work with their Medicare Administrative Contractor (MAC) on an acceptable approach to submitting claims.

We also understand that providers and administrative staff spend substantial time on recordkeeping and submitting claims, and adding claims requirements without removing requirements of equal burden places strain on provider practices. However, providers have been required to identify discarded amounts of drugs from single-dose containers since 2017, so providers should already have established processes for making these assessments and recording JW data as appropriate.

In response to whether a method can be developed by CMS for the automated calculation of discard amounts, we are not in a position to know which vial or container size of a drug or biological a physician has selected for a patient nor the amount that has been discarded. For assistance in calculating discard amounts, we recommend providers and billers work with drug manufacturers to develop methods for assessing discard amounts in the easiest manner.

Comment: One commenter requested clarification on all documentation elements of our proposal. The commenter expressed concern about documentation burdens, including documentation that proves that prepared and administered drug amounts match what was billed, as well as documentation that reports white-bagged or specialty drugs provided as patient assistance. The commenter added that this documentation is done manually.

Response: The JW modifier policy has been in place since 2017, and we are codifying it without change in this final rule. In the JW modifier FAQ, it states that the JW modifier policy applies to providers and suppliers who buy and bill drugs and is intended to track discarded amounts of drugs that occur as a result of the preparation of a drug dose for administration to a beneficiary. Also, providers and suppliers must document the amount of discarded drugs in Medicare beneficiaries' medical records. The document also states that CMS expects that providers and suppliers will maintain accurate (medical and/or dispensing) records for all beneficiaries, as well as accurate purchasing and inventory records for all drugs that were purchased and billed to Medicare. General guidance on documentation is available in MLN Matters SE 1316. Providers and suppliers should also check with the MAC that processes their Part B drug claims for any additional information on billing and documentation is available at the local level.

With regard to the JZ modifier, it must be used on the claim line with the billing and payment code of the drug when no amounts were discarded. CMS will not require that the provider note in beneficiary's medical record when no amounts are discarded. We will update the JW modifier FAQ document to clarify billing and documentation requirements consistent with this final rule.

With regard to documentation for ''white bagged'' or specialty drugs that a provider does not purchase, such drugs are not payable under Part B, are not subject to the JW/JZ modifier policy, and are not subject to the discarded drug refund.

Comment: Several commenters requested a delay in the requirement to use the JZ modifier in claims to account for the time needed to develop, test, and implement changes to claims processing systems, as well as for provider education and adoption. One commenter requested the effective date of the provision to be delayed one year, to January 1, 2024, to accommodate software modifications to support the reporting of the JZ modifier. The commenter stated that it is not realistic to expect software development and adoption to occur by January 1, 2023.

Several commenters expressed concern that confusion and errors in use of the JZ modifier by providers may cause billing errors, including claims denials, and could slow claims processing and provider revenues. One commenter expressed concern over general risks associated with noncompliance with the JZ modifier requirement.

One commenter stated providers may experience confusion on correct JZ modifier use when billing for the administration of generic drugs.

Several commenters urged that we undertake adequate educational efforts on JW and JZ reporting requirements, including the issuance of guidance and collaboration with provider communities. Several other commenters offered to collaborate with us on outreach and education efforts for the JW and JZ reporting requirements.

Response: We thank the commenters for their feedback and note that they highlighted several constraints in the implementation of any new billing and coding elements. After consideration of these comments, we acknowledge that incorporating the new coding modifier by January 1, 2023 may not be feasible for many providers. Therefore, the JZ modifier will be effective starting January 1, 2023, but not required until July 1, 2023. For dates of service beginning July 1, 2023 or after, providers will be required to use the JZ modifier on claims for single-dose containers when there are no discarded amounts, but CMS will not perform claims processing edits on its use. Then, beginning October 1, 2023, we will begin edits for correct use of both the JW and JZ modifiers for billing and payment codes that are required to use the modifiers based on the policy we are finalizing in this final rule. We expect this 9-month transition period will allow providers, billing software vendors, and MACs enough time to adjust billing and claims review processes before providers are at risk for noncompliance, as CMS typically posts updates to the Medicare Claims Processing Manual 5 months prior to implementation. Following the publication of this final rule, we will work to engage providers on claims coding requirements, including through the Medicare Learning Network, Changes Requests and associated CMS internet Only Manual sections, and updating the JW modifier FAQ document [143] to reflect the new JZ modifier requirement, and the issuance of technical guidance to MACs. We will take any opportunity to engage with interested parties to improve our outreach and education efforts.

We understand commenters' concerns that confusion about JW and JZ modifier use could cause compliance issues and, when edits for the modifies are implemented, delays to provider payments. We expect the delay in the compliance date for JZ modifier use to July 2023, as well as the delay in edits for both the JW and JZ modifiers to October 2023, will give providers time to become familiar with our educational resources on the new requirement, adopt necessary changes to their claims processing software, and adjust recordkeeping and billing practices accordingly.

[143] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

In response to the commenter's concern regarding the correct use of the JZ modifier on claims for the administration of generic drugs, we are clarifying that we are finalizing the requirement to code either the JW or JZ modifier on claims for drugs from all single-dose containers payable under Medicare Part B, regardless of whether the drug meets the definition of refundable single-dose container or single-use package drug; this includes both single source and multiple source drugs. This is consistent with our proposal to align the policy for the JZ modifier with the current JW modifier policy. That is, the JZ modifier would be required when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. As the requirement to use the JW modifier to report discarded amounts has been our policy since 2017, we are finalizing in this rule that providers must report the JW modifier in all outpatient settings beginning January 1, 2023, but as discussed, we are delaying the compliance date for the JZ modifier to July 1, 2023. Although we will only calculate manufacturer refunds with JW modifier data from single source drugs and biologicals, discarded drug data for drugs that do not meet the definition of refundable single-dose container or single-use package drug will provide us with useful information about drug discards in the Medicare program generally.

Comment: Several commenters requested guidance on appropriate JW and JZ modifier use. A few inquired about application and proper use of the modifiers as they relate to claims for drugs that fall under one or more of the exclusions provided in section 90004 of the Infrastructure Act, drugs that are packaged for payment, drugs from pre-filled syringes, ''cellular and/or tissue-based products for skin wounds'', and drugs from single-dose containers that are used for multiple patients, as may occur with repackaged or compounded drugs.

One commenter asked how the MACs will process claims that omit both the JW and JZ modifiers. One commenter requested clarification whether the billing provider should use the vial size purchased or smallest vial size available that could have been used to treat the patient as the basis for calculating discarded amounts. One commenter asked that we address confusion related to JW modifier policy as stated in MLN Matters article SE1316, issued August 1, 2013, that discarded drug amounts reported with the JW modifier ''must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any wastage.'' The commenter stated that providers have difficulty identifying what is the smallest dose vial available for purchase for which they are required to report wastage.

Response: As discussed above, we are finalizing that beginning January 1, 2023, use of the JW modifier will be required in claims for all drugs separately payable under Part B that are designated as a single-dose container on the FDA-approved label or package insert for which amounts of the drug are discarded. Similarly, beginning no later than July 1, 2023, the use of the JZ modifier will be required for all drugs separately payable under Part B that are designated as a single-dose container on the FDA-approved label or package insert for which there are no discarded amounts. Claims for drugs subject to this provision that do not report the JW or JZ modifier on or after July 1, 2023, may be subject to provider audits. Claims that do not report the modifiers as appropriate on or after October 1, 2023, will be returned as un-processable until claims are properly resubmitted.

With regard to what vial size should be used to calculate discarded amounts, discarded amounts should be calculated using the labeled amount of the product that is actually purchased to prepare the dose, not the labeled amount of the smallest vial size that could have been purchased. The guidance referenced in MLN Matters article SE1316 is no longer effective, as it has been superseded by MLN Matters article MM9603, which was issued on June 9, 2016, and effective January 1, 2017. This article notified providers of updates to JW modifier instructions in Claims Processing Manual 100–04, Chapters 17, in which providers are instructed to use the JW modifier line to bill for discarded amounts from the single use vial or other single use package of the drug or biological administered to the patient.

As stated above, we will update our JW modifier FAQ, Change Requests and associated IOM guidance, and issue a new MLN article, to reflect the coding changes finalized in this rulemaking.

Comment: One commenter requested direction on how to measure discard amounts of drugs from small container sizes, such as those with fill volumes of one mL or less.

Response: As described in the proposed rule, when a provider must discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. We clarified that above that, generally, we consider the dose (as described, for example, in the dosage and administration section of the FDA-approved labeling) as the administered amount and any other amount as discarded. This applies to determining discarded amounts from all vial sizes, including vial sizes less than 1 mL. The provider would bill the number of billing units that represent the dose administered on one line of the claim form and, on a separate line, bill the number of billing units of the drug that were discarded. The unused and discarded amount can be calculated by determining the labeled amount on the vial and subtracting the dose that was administered to the patient.

Comment: Several commenters stated that the required use of the JZ modifier contradicts congressional intent in the drafting of this provision.

Response: We disagree with the commenters. The statute specifies that we use a mechanism such as the JW modifier to collect data on discarded amounts. The use of the JZ modifier is consistent with such a mechanism because it will complement the use of the JW modifier and will likely increase the accuracy of JW modifier data.

Comment: One commenter requested we extend the requirement to report discarded drug data with the JW modifier to additional drugs to obtain more information on discarded amounts and related costs in Parts B and C. The commenter requested the additional JW data be publicly reported.

Response: At this time, we are only finalizing that JW and JZ modifiers be used for billing drug separately payable under Part B that are designated as a single-dose container on the FDA-approved label or package insert. Medicare data on Part B discarded amounts is available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units*. While we did not consider expanding the scope of discarded drug reporting in this rulemaking, we look forward to further feedback from the public on methods to identify and reduce unnecessary costs in the Medicare program.

After consideration of public comments, we are finalizing our proposal to codify our existing policy and require that billing providers report the JW modifier for all separately

payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. We are also finalizing our proposal to require billing providers to report the JZ modifier for all such drugs with no discarded drug amounts beginning no later than July 1, 2023, and we will begin claims edits for both the JW and JZ modifier beginning October 1, 2023.

3. Refundable Single-Dose Container or Single-Use Package Drug

As discussed in the CY 2023 PFS proposed rule (87 FR 46058 through 46059), section 90004 of the Infrastructure Act added section 1847A(h)(8) of the Act, which defines in subparagraph (A) of such section the term ''refundable single-dose container or single-use package drug'' as a single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act) or a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act) for which payment is made under Part B and that is furnished from a single-dose container.

For the purposes of section 1847A(h) of the Act, we proposed that the definition of ''refundable single-dose container or single-use package drug'' would apply to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a ''single-dose'' container or ''single-use'' package based on FDA-approved labeling. This definition also includes drugs described in FDA-approved labeling as a part of a ''kit'' that is intended for a single dose or single use. We noted that the JW modifier data published on the CMS website is limited to only billing and payment codes that are published on the ASP Drug Pricing File. Therefore, there are likely billing and payment codes payable under Medicare Part B that would meet the proposed definition of refundable single-dose container or single-use package drug that are not found on the ASP drug pricing file or the JW modifier data published on the CMS website.

We stated that in our analysis of drugs that meet this definition, there may be a need to revise existing billing and payment codes or establish a new billing and payment codes for the purposes of implementing these provisions because estimated total number of units discarded and total allowed charges must be determined at the billing and payment code level for the purpose of calculating refund amounts. For example, if there is a drug that meets the definition of refundable single-dose container or single-use package drug that does not have a unique billing and payment code, a new code may be needed for the purposes of estimating the total number of units that were discarded during such quarter and the total allowed charges.

We also stated that there may be drugs for which there are national drug codes (NDCs) of single-dose containers and NDCs of multiple-dose containers under the same FDA approval, and these NDCs are assigned to the same billing and payment code. We proposed that for a drug to meet the definition of ''refundable single-dose container or single-use package drug,'' all NDCs assigned to the drug's billing and payment code must be single-dose containers, as described in each product's labeling.

We explained that section 1847A(h)(8)(B) of the Act specifies that the term ''refundable single-dose container or single-use package drug'' excludes drugs that are either radiopharmaceuticals or imaging agents, drugs that require filtration during the drug preparation process, and drugs approved on or after the date of enactment of the Infrastructure Act (that is, November 15, 2021) for which payment under Part B has been made for fewer than 18 months.

a. Exclusions for Radiopharmaceuticals and Imaging Agents

Section 1847A(h)(8)(B)(i) of the Act excludes a drug or biological that is either a radiopharmaceutical or an imaging agent. We proposed to identify radiopharmaceuticals (including therapeutic or diagnostic radiopharmaceuticals) and imaging agents (including contrast agents) [144] for purposes of the exception at section 1847A(h)(8)(B)(i) of the Act by language describing them as such in FDA-approved labeling.

We proposed to codify the exclusion of radiopharmaceuticals and imaging agents from the definition of ''refundable single-dose container or single-use package drug'' at § 414.902.

b. Exclusions for Drugs Requiring Filtration

Section 1847A(h)(8)(B)(ii) of the Act excludes from the definition of refundable single-dose container or single-use package a drug approved by FDA for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. As the statute states, for the purposes of this exclusion, the filtration must occur prior to dilution and administration. Therefore, for example, the definition excludes those drugs requiring filtration in order to remove the product from a vial, such as drugs contained within ampules or certain liposomal products that require filtration when removing the product from the manufacturer's vial consistent with FDA labeling. However, drugs that require in-line filters only as part of the drug administration process would not meet this exclusion. We proposed that, consistent with section 1847A(h)(8)(B)(ii) of the Act, requirement for filtration must be present on FDA labeling in order for the drug to be excluded.

Additionally, consistent with our longstanding interpretation of the distinction between multiple source drugs and single source drugs (see program instructions available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), we are proposing if there is any NDC under a single New Drug Application (NDA) or Biologics License Application (BLA) that requires filtration as described in section 1847A(h)(8)(B)(ii) of the Act, then all NDCs of such drug or biological (that is, any billing and payment code to which any such NDCs are assigned) would be excluded from the definition of refundable single-dose container or single-use package drug, even if other products under the relevant approval and assigned to that billing and payment code do not require such filtration. We noted that this is appropriate because drugs and biologicals payable under Medicare Part B are billed at the level of the billing and payment code (not with the NDC of the individual product). If some products that require filtration and some products that do not require filtration are assigned to the same billing and payment code, we would not be able to distinguish (based on JW modifier data) which discarded amounts were from the filtered product and which were from the non-filtered product.

c. Exclusions for Drugs for Which Payment Under Medicare Part B has Been Made for Fewer Than 18 months

Section 1847A(h)(8)(B)(iii) of the Act excludes from the definition of refundable single-dose container or single-use package drug approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months. Typically, if their use is reasonable and

[144] *https://www.fda.gov/media/72295/download.*

necessary and all other coverage requirements are met, FDA-approved drugs become payable under Medicare Part B on the date which they are marketed in the United States. However, we are not able to reliably determine the exact date on which the first Part B claim was paid for a particular new drug because they are usually first billed using an unclassified drug or biological billing and payment code. Therefore, our ability to accurately determine when payment for a new drug has been made under Part B for 18 months is exceedingly limited. Because of the operational challenges with identifying the date of when the first Part B claim was paid for a new drug and because this exclusion would be operationally difficult to implement if the 18-month period ends in the middle of a calendar quarter, we noted that we believe it is appropriate to measure the 18-month period using the first day of the calendar quarter following the date of first sale as reported to CMS, which is a required field for reporting ASP data.[145] That is, for purposes of this exclusion, we proposed to consider the 18-month period to begin on the first day of the calendar quarter following the date of first sale as reported to CMS for the drug. Because 18 months is the equivalent of 6 calendar quarters, under our proposed approach, refundable single-dose container or single-use package drugs approved or licensed by FDA on or after November 15, 2021 would be excluded from the definition of refundable single-dose container or single-use package, and thus, not subject to a refund, for the first 6 full calendar quarters following the date of first sale for any NDCs of such drug. Thereafter, that is, beginning with dates of service after the last day of the sixth full sales quarter, the drug would no longer be excluded from the definition of refundable single-dose container or single-use package drug. For example, if a drug that would otherwise meet the definition of refundable single-dose container or single-use package drug is approved by FDA in June 2023 and the first date of sale is June 20, 2023, the first day of the calendar quarter following the date of first sale for such drug would be sales occurring in the third calendar quarter of 2023 (July 1, 2023 through September 30, 2023), and we would consider the drug to be excluded from the definition for the next 6 quarters (that is, through December 31, 2024). As of January 1, 2025, the drug would no longer be excluded from the definition of refundable single-dose container or single-use package drug and would be subject to applicable refunds.

We proposed that exclusion would apply only once for a drug. That is, it would apply for the first NDC of such drug assigned to a billing and payment code and paid under Medicare Part B. If additional NDCs in the same billing and payment code, such as a new vial size or ready-to-use syringe, were subsequently approved under the same FDA approved application (for example, under the same approved NDA or BLA number), marketed, and paid under Part B, these subsequent NDCs would not start a new 18-month exception period. We noted that we believe this proposed approach is appropriate to prevent a drug from periodic or continual exemption from reports and refunds due to new NDCs that are marketed under the same FDA-approval.

We proposed to add a new definition at § 414.902 of ''refundable single-dose container or single-use package drug,'' which would be defined to mean a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container based on FDA-approved labeling or product information, except as otherwise specified. We welcomed comment on the proposed implementation of these statutory exclusions.

The following is a summary of the public comments received on the refundable single-dose container or single-use package drug provisions and our responses:

Comment: Several commenters requested CMS add additional exclusions from this provision for various drugs or drug categories. One commenter stated that implementation of this provision will likely have disproportionately negative impacts to small biotech companies that received FDA approval through expedited development and review programs. The commenter explained that under expedited programs such as Breakthrough Therapy Designation (BTD),[146] it is more challenging for manufacturers to determine optimal vial size for the purpose of Medicare payment when focus is primarily on rapid clinical testing. The commenter stated for breakthrough therapy, the vial size is developed in a manner that would best match the dosage needed by most trial participants, while also promoting efficient care delivery. The commenter stated that in an expedited program using a single vial size is more efficient from a resource, compliance, and complexity standpoint. The commenter requested that CMS specifically exclude products from small biotech companies that received BTD and FDA Priority Review. The commenter noted that the Inflation Reduction Act has a similar exception for small biotech companies in its price negotiation provision.

Two commenters requested that we exclude orphan drugs because such drugs have differing manufacturing conditions because of the smaller scale of demand and production. One of these commenters stated that failure to exempt orphan drugs from refunds could have the detrimental effect of stifling innovation and limiting development of new rare disease treatments that may require weight-based dosing. One commenter added that even if an orphan drug were produced in multiple vial sizes, the supply of each vial size may be limited or providers may not stock all sizes due to the rarity of the condition being treated. One commenter requested that we exclude all biosimilar biological products. The commenter stated that they believe this would be justified because FDA regulations require that biosimilar biologicals have the same dosage form and packaging as their reference biologicals. In addition, the commenter noted that biosimilar biological manufacturers cannot make changes to factors such as vial size that are not first made by the reference product's manufacturer.

Two commenters requested we exclude all ophthalmic drugs or drugs with small volumes administered (1 mL or less). Similarly, four commenters asserted that the exceptions for small vials are necessary because of unique circumstances. We discuss the unique circumstances of drugs with small volumes and vial sizes below in section III.A.6.a. of this final rule.

One commenter requested we establish a unique modifier to signal the exclusion of drugs administered via ''microdose dispensing.''

Response: We appreciate commenters' insight to the variety of manufacturers and products that may be affected if a product meets the definition of refundable single-dose container or single-use package drug and does not meet a statutory exclusion. The statute defines refundable single-dose container or single-use package drug broadly, makes limited exceptions to the definition, and directs the use of JW

[145] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.*

[146] *https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy.*

modifier or similar mechanism to calculate the refunds owed. Drugs with BTD and FDA priority review and ophthalmic drugs with small vial sizes are not addressed by any of the statutory exclusions and are thus subject to the JW and JZ modifier policy. This JW modifier data will be used to calculate refund obligations as required by statute.

Comment: One commenter suggested CMS consider excluding any off-label use of applicable drugs from the annual report and calculations of the discarded drug refund, because off-label use could involve significantly different dosing that varies greatly from the tailored vial size that was designed for the labeled indication(s).

Response: When a provider bills for a drug, it is reported using the drug's billing and payment code, which does not allow for particular designation regarding the indication (or whether the drug was used off-label). Therefore, there is no way to indicate on a claim that a drug from a single-dose container was used for an off-label use. Thus, the drug would still be subject to the JW and JZ modifier policy and that JW data would be used to determine refund obligations.

Comment: One commenter stated that the discarded drug provision may interrupt access for some patients to certain treatments. This commenter stated that CMS should allow manufacturers additional time to comply with the provision to prevent supply interruptions, and suggested that CMS should temporarily exempt manufacturers from the refund while they develop new vial sizes for approval by the FDA. The commenter also suggested that CMS develop a process for exemption requests and the provision of temporary relief from compliance for the requesting party. In addition, the commenter suggested that CMS seek comment on other drug exceptions to the provision, such as when compliance would negatively impact patient access.

One commenter requested CMS consider a broader, transparent exemption policy that would consider the wide range of reasons for which certain amounts of product may be unused (for example, an interrupted procedure, changes in clinical circumstance), including a detailed exemption request process. The commenter recommended that CMS strike a balance in providing exclusions to allow provider discretion when additional drug is needed.

Response: CMS does not have discretion to delay the effective date of this provision, and therefore, cannot allow for an alternative effective date. As stated above, the statute defines refundable single-dose container or single-use package drug broadly, makes limited exceptions to the definition, and directs the use of JW modifier to calculate the refunds owed. We are not considering an exemption policy at this time outside of the exclusions specified in statute. We have discretion, under the statute, to consider unique circumstances and increased applicable percentages, which are discussed further below.

Comment: Several commenters stated that the proposed rule inappropriately applies the provision to drugs administered in hospital outpatient departments and ambulatory surgical centers, which would cause inappropriate refund obligations. In support of this argument, the commenters stated that the provision was placed within, and the statutory language only references calculations and payments under, section 1847A of the Act and does not reference section 1833(t) of the Act. These commenters stated that the lack of reference to payments under section 1833(t) of the Act precludes counting units paid under the OPPS or ASC payment system. One commenter stated the application of this provision is particularly inappropriate if future cuts to hospital reimbursement for 340B drugs are implemented. One commenter expressed concern about the possibility of an overlap between refunds calculated under this provision and discounts made available to covered 340B entities. The commenter asked CMS to develop a policy or process to ensure such layered price concessions do not occur, which could be done by stating that OPPS units are not included in the discarded drug refund calculation.

Response: New section 1847A(h)(2) of the Act requires the manufacturer of a refundable single-dose container or single-use package drug to provide to the Secretary a refund that is equal to the amount specified in paragraph (3). Section 1847A(h)(8)(A) of the Act defines a refundable single-dose container or single use package drug for which a refund is owed as a single source drug or biological or a biosimilar biological product ''for which payment is made under this part'' meaning Medicare Part B. Payment is made for drugs furnished in hospital outpatient departments and ASCs under Medicare Part B. See section 1841(g) of the Act; see also section 1847A(h)(1)(A) of the Act (requiring use of a mechanism, such as the JW modifier, which applies to OPPS and ASC drugs, to determine the total number of units).

We also note that section 1847A(h)(1)(C) of the Act excludes ''units that are packaged into the payment amount'' from the refund calculation. This language also suggests that manufacturers are required to pay refunds for OPPS and ASC drugs by excluding packaged drugs, which is a common phenomenon under the OPPS and ASC payment system. Regarding the commenter's concern about future reductions in OPPS payment for 340B drugs, we note that, for CY 2023, we are finalizing a policy to pay for separately payable drugs at a default rate that is generally ASP plus 6 percent under the OPPS, regardless of whether a drug is acquired under the 340B program.

Therefore, we are finalizing our proposal that HOPDs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes that are assigned status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) or status indicator ''G'' (Pass-Through Drugs and Biologicals) under the OPPS. We are finalizing that ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) under the ASC payment system. We are finalizing that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable, such as drugs for which payment is packaged under the OPPS or ASC payment system or drugs administered in the FQHC or RHC setting.

Comment: One commenter requested that CMS clarify that the definition of refundable single-dose container or single-use package drug does not apply to vaccines described in section 1861(s)(10) of the Act. The commenter explained that the payment amount of those vaccines is not determined under section 1847A of the Act, and that section 1847A of the Act is explicitly limited to payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act, which explicitly excludes vaccines described in section 1861(s)(10)(A) or (B) of the Act.

Response: CMS grounds its interpretation of this provision on language in new section 1847A(h) of the

Act that refunds are owed on refundable single-dose container or single-use package drugs which are or drugs ''for which payment is made under this part,'' which would include vaccines described in section 1861(s)(10) of the Act. However, we discuss below that we are finalizing that for a drug to meet the definition of ''refundable single-dose container or single-use package drug,'' all NDCs assigned to the drug's billing and payment code must be single-dose, as described in each product's labeling. Many vaccines in section 1861(s)(10) of the Act are available in both single-dose containers (usually prefilled syringes) and multiple-dose containers, and therefore, would not meet the definition of ''refundable single-dose container or single-use package drug''.

In addition, we clarify that, with regard to the JW/JZ modifier policy, we will not require those modifiers for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID–19 vaccines specified in section 1861(s)(10) of the Act are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines. In addition, section 1847A(h)(1)(A)(i) of the Act describes that data reported by a claims modifier, such as the JW modifier, are the appropriate measure for determining discarded amounts. Since such vaccines would not be subject to the JW and JZ modifier policy, we would not expect to have discarded amount data for these billing and payment codes for the purposes of calculating the discarded drug refund.

Comment: Two commenters requested we exempt drugs paid for under the End-Stage Renal Disease (ESRD) bundled payment. One commenter expressed concern regarding how implementation of the discarded drug refund might inadvertently impact ESRD products, including those used by home dialysis patients (for example, Extraneal, a peritoneal dialysis solution). The commenter noted the language in the proposed rule provided a limited number of examples of drugs that are not separately payable (for example, drugs for which payment is packaged under the OPPS or ASC payment system or drugs administered in the FQHC or RHC settings). The commenter requested that we clarify that this is not an exhaustive list and that drugs for which payment is packaged under the Medicare ESRD Prospective Payment System (PPS) is another example of drugs that are not separately payable and are, therefore, excluded.

Response: We agree with the commenter and clarify that units for drugs that are packaged under the Medicare ESRD PPS are not subject to the JW modifier policy or the discarded drug refund.

Comment: One commenter requested clarification on whether ''cellular and/or tissue-based products for skin wounds'' are subject to the provisions in section 90004 of the Infrastructure Act.

Response: If a product is a single source drug or biological for which payment is made under Medicare Part B (including any items, services, supplies, or products that are paid under Medicare Part B as a drug or biological), is from a single-dose container based on the FDA-approved labeling or product information, and is not otherwise excluded, then it meets the definition of refundable single-dose container or single-use package drug. If the product is also subject to billing using the JW and JZ modifier as described above, this data will be used to calculate refund obligations. Therefore, if a product is a single source drug or biological as defined in section 1847A(c)(6)(D) of the Act and meets these other requirements, then it is subject to the refund obligations under this provision.

Comment: One commenter requested that if we finalize the proposal to create new billing and payment codes for circumstances in which a billing and payment code today is assigned to both single-dose and multiple-dose containers, we only create new billing and payment codes that include products that meet the 10 percent threshold, or a 5 percent threshold, to minimize administrative and billing disruption and workload. According to the commenter, many shared billing and payment codes that include a single-dose container are associated with less than 1 percent discard each year. The commenter also expressed concern that creating new billing and payment codes in these circumstances would create challenges determining ''who is responsible,'' in addition to issues related to ASP calculations and pricing.

Response: We stated in the proposed rule that there may be a circumstance in which we need to revise existing billing and payment codes or establish a new billing and payment codes for the purposes of implementing these provisions because estimated total number of units discarded and total allowed charges must be determined at the billing and payment code level for the purpose of calculating refund amounts. This statement was separate and apart from our proposal that for a drug to meet the definition of ''refundable single-dose container or single-use package drug,'' all NDCs assigned to the drug's billing and payment code must be single-dose, as described in each product's labeling. As we discussed in the proposed rule, if there is a drug that meets the definition of refundable single-dose container or single-use package drug and does not have a unique billing and payment code by which the discarded units can be tracked for the purposes of the refund calculation, we may revise a code or create a new code for the drug.

Comment: One commenter disagreed with our proposal to only include billing codes for which all NDCs are single-dose containers because in some circumstances, a manufacturer may sell predominantly single-dose containers and some, but very few, multiple-dose containers of a drug. The commenter stated that we instead include single-dose containers that are in billing codes that contain multiple-dose containers, and proposed that, since Medicare Part B does not bill drugs by NDC, we should instead calculate the refund by using: 10 percent of total charges for the billing and payment code (including all utilization regardless of whether single-dose or multiple-dose NDCs) or 10 percent of total charges for single-dose container NDCs in the billing code (based on the presence of JW or JZ modifiers).

Response: We thank the commenter for their input regarding billing and payment codes to which both single-dose and multiple-dose containers are crosswalked. There are several operational challenges to applying the discarded drug refund to such billing and payment codes. Since the JW modifier would not be required for the multiple-dose product, the percentage of units discarded for the billing and payment code as a whole would be skewed. If a multiple-dose product is included in a billing and payment code along with single-dose products, there will be an underestimate for the percent discarded from the single-dose products. For example, if 100 billing units of the drug from a multiple-dose vial were billed under a billing and payment code and 100 billing units of the drug from the single-dose vial were billed under the same billing and payment code, but some was discarded (for example, 70 units administered and 30 units discarded and billed using the JW modifier), then the percentage discarded overall for the billing and payment code would be 15 percent. We

are not able to distinguish billing units from multiple- or single-dose containers on claims when they are assigned to the same billing and payment code.

Based on our analysis of JW modifier data from CY 2020, we did not identify any billing and payment codes that have both multiple-dose and single-dose containers crosswalked to it for which 10 percent or more of billed amounts were discarded. Therefore, we believe this circumstance would not be common and we are finalizing that, for a drug to meet the definition of ''refundable single-dose container or single-use package drug,'' all NDCs assigned to the drug's billing and payment code must be single-dose, as described in each product's labeling. However, if we find at a later time (particularly with expected improved data after implementation of the JZ modifier) that several products are excluded from the definition of refundable single-dose container or single-use package drug due to a multiple-dose product being crosswalked to the code, and the manufacturer would otherwise owe refunds for discarded amounts, we may find it necessary to revisit this policy in the future.

Comment: Several commenters requested that, if there are drugs subject to the policy that are not currently found in the public ASP Drug Pricing File or JW modifier data published on the CMS website,[147] that CMS begin publishing ASP and JW modifier data on those drugs. One commenter requested we publish and update quarterly a list of all known drugs that fall into a statutory exclusion from the discarded drug refund process. The commenter expressed concern that the lack of clarity regarding how CMS will identify excluded drugs may lead to confusion, and stated that such a publication would allow manufacturers the opportunity to anticipate valid or erroneous reports. One commenter requested that CMS issue guidance explaining the exclusions of drugs from the definition of refundable single-dose container or single-use package drug, as providers and manufacturers, particularly in the case of new drugs, may not know whether a drug falls under one of the exception categories. Another commenter requested that CMS clarify the process by which we identify excluded drugs.

Response: With regard to publishing ASP data, CMS does not publish an ASP payment limit or crosswalk for all drugs that are reported by manufacturers. A number of factors, including but not limited to the setting in which the drug is used and the volume of use in Medicare Part B, are considered before a decision about national pricing is made. Since the refunds are determined after claims are submitted and processed, the specific billing and payment codes that will be subject to refund obligations will not be known at the time the annual ASP Drug Pricing File is published. Therefore, the information that would be required to publish a payment allowance for all drugs subject to the discarded drug policy would not be available at the time the annual ASP file is published and, thus, it would not be feasible for CMS to include that information.

We thank commenters for their input regarding their request that CMS publish a quarterly list of all known drugs that fall into a statutory exclusion, and their request for CMS guidance to explain the exclusion of drugs from the definition of refundable single-dose container or single-use package drug. We will consider developing lists of drugs that fit a statutory exclusion as part of the operational process of implementing this provision.

Comment: Two commenters requested that CMS exclude Part B drugs that are not administered by the billing supplier, including DME drugs that are administered by the beneficiary, from the discarded drug refund. One commenter stated that reporting, audit, and civil money penalties described in the proposed rule are inappropriate when drug products are administered outside the chain of custody once in the possession of the beneficiary. Three commenters requested that we clarify that drugs administered via an item of DME, and any other drug billed to the DME MACs, are not subject to the discarded drug refund provision. Commenters stated that such drugs are typically self-administered by patient or caregiver in their home, administered over a period that spans several days, and dispensed by suppliers that have no visibility into discarded drug provision. They stated that reporting discarded units in these circumstances would present an increased burden for all parties involved. One of these commenters requested that we clarify that drugs whose FDA-approved labels indicate that they are intended for self-administration by the patient or their caregiver are not subject to the discarded drug provision. The commenter noted that this would ensure that the applicability of the discarded drug refund requirement does not depend on self-administered drug (SAD) list. The commenter suggested we develop a claims modifier to identify such self-administered drugs in claims.

Two commenters requested clarification on the application of the JZ modifier to drugs not administered by the billing supplier, such as drugs administered via a covered item of DME or those that are self-administered by patients.

Response: In the proposed rule, we proposed that, to align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts.

At this time, we do not believe it would be appropriate to collect data about discarded amounts from beneficiaries. Section 1847A(h)(1)(A)(i) of the Act describes that data reported by a claims modifier, such as the JW modifier, are the appropriate measure for determining discarded amounts. Discarded amounts (as identified by the JW modifier) are submitted by the billing provider and not the patient, typically before the patient administers the drug. Therefore, the JW and JZ modifiers are not required for refundable single-dose container or single-use package drugs that are self-administered by a patient or caregiver in the patient's home.

Comment: One commenter expressed support for proposed exclusions from the discarded drug refund policy. Several commenters expressed support for the exclusion of radiopharmaceuticals. One commenter noted approval for our proposal to identify diagnostic and therapeutic radiopharmaceuticals and imaging agents eligible for the exclusion based on their FDA-approved labeling. Two commenters requested CMS explicitly confirm that the exclusion of imaging agents includes contrast agents.

Two commenters stated that the drug, Susvimo™ (ranibizumab injection), which is for intravitreal use via ocular implant, meets the criteria for the filtration exclusion, both with its ocular implant initial fill and refill-exchange procedure. The drug's filtration step for the initial fill procedure is described in the dosage and administration instructions in the label and occurs during the drug preparation process; filtration occurs prior to dilution and administration; and the unused portion after filtration is discarded along with the filtration needle. The commenter stated that, exactly like the initial fill procedure, the refill-exchange procedure also includes filtration in a

[147] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

manner that is consistent with the filtration exclusion criteria. One commenter stated that the drug, Onpattro® (patisiran injection), meets the criteria for the filtration exclusion. The dosage and administration instructions in Onpattro's FDA-approved prescribing information expressly state that the drug must be filtered and diluted prior to intravenous infusion, and practitioners must discard any unused portion of the drug after filtration.

With regard to the exclusion for drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months, three commenters expressed support for this exclusion. One commenter suggested CMS extend the exclusion by running the 18-month period from the start of the effective date of this provision (January 1, 2023) for any new drug with an FDA approval date on or after July 1, 2021, and creating a data field to collect the estimated date for Part B reimbursement thereafter for any new drugs that are approved by the FDA after January 1, 2023. The commenter stated that this would simplify CMS' burden for monitoring manufacturer compliance with the new drug exclusion and is consistent with congressional intent for the grace period for new drugs on the market. One commenter suggested CMS exclude new drugs for 24 months following the first sale reported in order to provide adequate time to operationalize, shift resources, and properly train personnel. The commenter stated that CMS' proposal to exclude new drugs for 6 calendar quarters following date of first reported sale does not take into consideration certain factors, such as the fact that a provider's first prescription of a new drug is entirely dictated by the needs of the patient population served. Also, with manufacturers' drug timelines starting at different points, the health information technology requirements needed to modify claims may also come at different times.

Response: With regard to the exclusion of radiopharmaceuticals and imaging agents, we recognize contrast agents as a category of imaging agents as described in FDA's Guidance for Industry referenced in the proposed rule.[148] Therefore, we clarify that contrast agents are excluded from the definition of refundable single-dose container or single-use package drug.

With regard to Susvimo and Onpattro and the commenters' assertion that these drugs are excluded from the definition of refundable single-dose container or single-use package drug based on filtration steps described in each drug's FDA-approved labeling, upon review of the labeling, we agree that both drugs would fit exclusion criteria as described in section 1847A(h)(8)(B)(ii) of the Act. In both circumstances, the labeling requires filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

With regard to the exclusion for drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months, we disagree that a data field to collect the estimated date for Part B payment in the ASP online collection system is needed. The proposed approach to measure the 18-month period using the first day of the calendar quarter following the date of first sale as reported to CMS is adequate for the purposes of measuring when the 18-month period should begin for this exclusion because of the limitations of identifying the first date for which payment is made under Part B (as discussed in the proposed rule) and because of the quarterly nature of the ASP Drug Pricing File publications.

Comment: One commenter requested clarification on the impact to current billing policy for unused and discarded amounts of the excluded products specified in statute. The commenter interpreted the exclusion of certain products to mean that manufacturers are not required to refund Medicare for the discarded amount of product, though providers can still bill for the amount discarded using the JW modifier for these drugs.

Response: We agree with the commenter and clarify that even if a drug is excluded from the definition of refundable single-dose container or single-use package drug (and not subject to refunds), for example, multiple source drugs, claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers in accordance with the policy we are finalizing in this final rule. In addition, as we describe below, although such drugs described in section 1847A(h)(8)(B)(iii) of the Act are excluded from the definition of refundable single-dose container or single-use package drugs for an 18-month period of time, we agree with the comment below that providing information regarding discarded amounts from such drugs would be beneficial to the manufacturers during the exclusion period. Therefore, for drugs meeting this time-limited exclusion, we plan to provide information on the total number of units of the billing and payment code that were discarded for calendar quarters during the 18-month exclusion period. Requiring the JW and JZ modifier for all single-dose container drugs will allow us to provide such information during the exemption period.

After consideration of the public comments, we are finalizing the definition of ''refundable single-dose container or single-use package drug'' as proposed, to be codified at § 414.902.

4. Provision of Information to Manufacturers

In the CY 2023 PFS proposed rule (87 FR 46059 through 46060), we stated that section 1847A(h)(1) of the Act requires the Secretary to provide each manufacturer of a refundable single-dose container or single-use package drug (as defined in section 1847A(h)(8) of the Act) with a report, for each calendar quarter beginning on or after January 1, 2023, that includes the following information:

- The total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The refund amount that the manufacturer is liable for pursuant to section 1847A(h)(3) of the Act.

We proposed to use the definition of manufacturer at section 1847A(c)(6)(A) of the Act, which is codified at § 414.802 and defines manufacturer as any entity that is engaged in the following (this term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

We proposed to identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable single-dose container or single-use package drug. If such product does not have an NDC, we proposed to use manufacturer

[148] *https://www.fda.gov/media/72295/download.*

information included on the ASP data submission for the product.

We proposed that there be a lag between the date of service quarter and the date we send reports to manufacturers to allow for claims maturity from the date of service. To operationalize reports to manufacturers, we must consider the timing with regard to the availability of JW modifier data. Providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, so a lag exists between the date of service when a drug is administered and when the claim is submitted and adjudicated. Because of this lag in finalized claims, there may also be a lag in available JW modifier data for any given date of service quarter. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months, 99.83 and 100 percent of the claims, respectively, were considered to be final.

We stated that section 1847A(h)(1) of the Act does not specify the interval by which reports for each calendar quarter must be sent to manufacturers. We proposed that CMS provide an annual report to manufacturers with information for each calendar quarter. Sending reports (with information for each calendar quarter) annually would reduce the operational resources needed to implement this provision and would streamline the dispute resolution process. We proposed to send reports to manufacturers no later than October 1 of each year. We proposed that the report reflect claims data that is finalized by the end of the second calendar quarter (that is, June 30) of the year in which the report is sent. We noted that this would allow time for CMS to analyze the data and calculate refund amounts to provide reports to manufacturers no later than October 1. In addition, we proposed that annual reports would include any additional lagged claims data not included for the quarters first reflected in the prior year's report.

In an effort to implement this provision in a timely manner, we proposed to send the first report to manufacturers no later than October 1, 2023. Under our proposal, this first report would contain information only for the first calendar quarter of 2023, because that would be the only quarter for which we would have a substantial amount of claims data that is finalized by the end of the second calendar quarter of the year in which the report is sent. We proposed to send the second annual report no later than October 1, 2024, and this report would include information for the second, third, and fourth quarters of 2023 and the first calendar quarter of 2024. It also would include any additional lagged claims for dates of service in the first calendar quarter of 2023 that were not included in the first report. Subsequent annual reports would be done in this manner, meaning that they would provide the information required under section 1847A(h)(1) of the Act for the last 3 quarters of the prior year, the first quarter of the current year, and lagged claims data not reflected for the last 3 quarters of the year that is 2 years prior and the first quarter of the prior year (that is, the quarters first reflected in the previous year's report). This means that reports (except for those in 2023 and 2024) would include information for 8 calendar quarters: 4 new calendar quarters and 4 quarters with additional information for claims that were not yet finalized for those dates of service in the previous year's report. As proposed, we explained that we would expect to capture JW modifier data and total allowed charges from over 99 percent of claims for dates of service in a given quarter. For example, the report sent to manufacturers in 2025 would include information for dates of service in the second, third, and fourth quarters of 2024 and the first quarter of 2025 plus additional lagged claims that were not included in the report sent in 2024 (that is, information for dates of service in the second, third, and fourth quarters of 2023 and the first quarter of 2024).

We noted that when lagged claims data is evaluated, any changes in the refund amount owed for those quarters and not already accounted for in the previous year's report would be calculated as described in section III.A.6. of the proposed rule.

The following is a summary of the public comments received on the provision of information to manufacturers and our responses:

Comment: One commenter expressed support for the transmittal of annual reports containing information on discards and refund amounts for each calendar quarter.

Response: We thank the commenter for their support.

Comment: One commenter requested that we clearly distinguish the calendar quarter associated with all discard amount claims data.

Response: We thank the commenter for their feedback. The organization of discarded amount claims data by the date of service calendar quarter was part of our proposal for the provision of information to manufacturers. We are finalizing our proposal to send annual reports to manufacturers containing information described in section 1847A(h)(1)(A) of the Act, broken down by calendar quarter.

Comment: One commenter requested that we provide quarterly estimates of projected payment obligations rather than reporting manufacturer obligations on an annual basis. The commenter expressed that more frequent notices would help manufacturers better budget their outlays. Another commenter stated that we should issue preliminary calculations of refund amounts to manufacturers in order to permit engagement between CMS and the manufacturer prior to the issuance of the report.

Response: We appreciate the interest of manufacturers in having additional advance notice of their refund obligations, and agree with the commenter that CMS and manufacturers should have time to engage and address potential disagreements related to discard amounts and refund calculations before obligations are due. As we discuss below, we are not finalizing the date we will send the first report to manufacturers in this final rule and will revisit the timing of the first report to manufacturers in future rulemaking. However, we believe that it will be beneficial to provide manufacturers an opportunity to engage with us on discard amount data in the first year of this provision's implementation, and therefore, we plan to issue a preliminary report on estimated discarded amounts based on available claims data from the first 2 quarters of CY 2023 no later than December 31, 2023. This preliminary report will not reflect any final determinations of the number of discarded units, percentage of discarded units, or calculations of the refund amount obligations. That information will be sent in the initial report at a date that will be determined through future rulemaking.

Comment: Several commenters stated that we should provide manufacturers all information we use to calculate refund amounts to allow them to validate the accuracy of our calculations, including claims for all drug units billed to Medicare, along with associated modifier data. One commenter requested claims-level information be provided to manufacturers in the annual report, or at the very least, following the initiation of the dispute process. One commenter suggested that manufacturers would not be able to engage meaningfully in the dispute process without seeing claims-

level data. The commenter cited reasoning related to sharing claims level data used in 2015 and 2020 Medicaid guidance CMS issued regarding measures to reduce discount disputes in the 340B program, as well as a 2014 OIG report with the same emphasis.

Response: We agree with commenters that they should have access to claims information to verify our refund calculations, including number of allowed claims, allowed charges, amounts administered, and reported discard amounts, to the extent that they do not violate the privacy of any beneficiary. Aggregate HCPCS code claims data are available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview*. In addition, aggregate discarded drug data for all separately payable Part B drugs from single use vials or other single use packages is available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units*. Though our proposal only considered including some version of the aggregated data sets available on those websites in the manufacturer reports, our aforementioned decision to not finalize the date we will issue the first reports allows us time to take the request for claims-level data under advisement. We will consider the inclusion of claims-level data in manufacturer reports in future rulemaking.

Comment: One commenter requested that the CMS include information on the use of the JW modifier for drugs approved by FDA on or after the date of enactment of section 90004 of the Infrastructure Act, and with respect to which payment has been made under this part for fewer than 18 months drugs in its annual reports to manufacturers while exempting them from the refund requirement.

Response: Although such drugs described in section 1847A(h)(8)(B)(iii) of the Act are excluded from the definition of refundable single-dose container or single-use package drugs, we agree that providing information regarding discarded amounts from such drugs would be beneficial to the manufacturers during the 18-month exclusion period. Therefore, we plan to provide information on the total number of units of the billing and payment code of drugs meeting this exclusion (and not meeting any other exclusion in section 1847A(h)(8)(B) of the Act) that were discarded during the 18-month exclusion period.

Comment: One commenter requested that we develop and specify a mechanism for manufacturers to validate the provider billing practices underlying reported discarded drug amounts.

Response: The JW modifier FAQ defines discarded amounts as the amount of a single use vial or other single use package that remains after administering a dose/quantity of the drug to a Medicare beneficiary. We clarified this definition above as amounts that remain after administering a dose/quantity of the drug to a Medicare beneficiary. We will update our guidance documents to reflect this definition and we will work with provider groups to guide them to correctly report discarded amounts.

Comment: One commenter requested CMS review sample data sets, propose validation mechanisms, and build the infrastructure needed to implement the provision with minimal risk of error in calculation of refund amounts.

Response: We thank the commenter for their feedback. We will review these aspects of implementation and consider these ideas for future rulemaking.

Comment: Several commenters requested we place a limit on how far back lagged discarded drug data may be included in the annual report to manufacturers.

Response: Due to the enactment of the Inflation Reduction Act on August 16, 2022, and our efforts to efficiently implement two statutory provisions that require reporting and deposit mechanisms, we are not finalizing our proposal on the timing of the refund reports, which was to send the first report to manufacturers no later than October 1, 2023, and subsequent reports no later than October 1 of each year following. As previously mentioned, the discarded drug refunds are to be deposited into the Federal SMI Trust Fund. Similarly, the Part B and Part D rebates described in the Inflation Reduction Act also are to be deposited into the Federal SMI Trust Fund. We aim to coordinate the collection of these funds in order to minimize the administrative burden on both manufacturers and CMS. This requires an alternative timeline for sending reports to manufacturers and different dates on which funds would be due and, therefore, we decline to finalize our proposal that the initial reports under the discarded drug refund provision to be sent no later than October 1, 2023. In addition, since the date that the initial report is sent will impact the number of quarters with mature claims data available, we also decline to finalize the policy regarding the inclusion of additional lagged data in reports in this final rule. We will revisit the date of the initial report and the inclusion of lagged discarded drug data in future rulemaking.

Although we are not finalizing a date for the transmittal of reports in this final rule, we are finalizing our proposal to send reports to manufacturers containing discard information for each calendar quarter on an annual basis. We are also finalizing that we will send reports to all manufacturers of refundable single-dose container or single-use package drugs. We intend to address the timing of these reports in future rulemaking. We also note that we will issue a preliminary report on estimated discarded amounts based on available claims data from the first 2 quarters of CY 2023 no later than December 31, 2023.

5. Manufacturer Provision of Refund

As discussed in the CY 2023 PFS proposed rule (87 FR 46060), section 1847A(h)(2) of the Act states that, for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund for such quarter. As described in the previous section, we proposed to issue reports for each calendar quarter on an annual basis. Section 1847A(h)(4) of the Act states that refunds under section 1847A(h)(2) of the Act must be paid in regular intervals as determined appropriate by the Secretary. We proposed that refunds be paid in 12-month intervals (that is, annually) to align with the proposal to issue reports for each calendar quarter on an annual basis. Additionally, we noted that we believe requiring refunds to be paid on an annual basis is operationally optimal because it allows for some claims runout while administering reports in a timely manner following the date of service and leaves more time for dispute resolution, which we believed would be important for refund calculation accuracy. Including lagged claims data from the previous year's report allows more time for claims to be finalized for a given calendar quarter, consequently represent a more accurate estimate of discarded units, and result in a more accurate refund calculation. Therefore, we proposed to specify that the regular interval for the payment of refunds is annual and that refund amounts for the quarters reported in an annual report must be paid no later than December 31 of the year in which the report was sent to the manufacturer except in circumstances where a dispute is pending. In the case of a dispute,

payment of the refund is due no later than 30 days after the resolution of the dispute. As discussed in more detail in the next section, we noted that we believe December 31 is an appropriate deadline because it would allow manufacturers to review their annual reports and initiate dispute resolution if needed. We proposed to require manufacturers owing refunds to transmit payment in a form and manner specified by CMS.

We proposed to codify these provisions at § 414.940.

The following is a summary of the public comments received on the manufacturer provision of refund provisions and our responses:

Comment: One commenter stated manufacturers should have 3 months after the receipt of the report to remit refund obligations.

Response: We appreciate the commenter's feedback. Our proposal to issue reports to manufacturers by October 1 and require refund obligations to be paid by December 31 of the year in which reports are issued reflects the commenter's preference. However, as stated in the previous section, we are not finalizing the timing for reports to be sent or for refund obligations to be paid in this final rule. We will revisit the process and timeline for manufacturers' provisions of refunds in future rulemaking. Although we are not finalizing the proposed timing for reports sent to manufacturers, the effective date of the provision remains January 1, 2023, as required by statute, and reports will be sent for calendar quarters beginning on or after this date.

6. Refund Amount

As discussed in the CY 2023 PFS proposed rule (87 FR 46060 through 46062), section 1847A(h)(3) of the Act provides, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, that the refund for which the manufacturer is liable is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The payment limit amount for the refundable single-dose container or single-use package drug;

- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

We stated that section 1847A(h)(3) of the Act specifies that the applicable percentage is 10 percent, but authorizes us to increase this percentage as appropriate, through notice and comment rulemaking, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act.

We proposed to calculate the refund required under section 1847A(h)(1) of the Act using the number of discarded units for dates of services in the same calendar quarter to which the payment limit amount applies. We proposed to estimate the total allowed charges during the quarter by multiplying the drug's payment limit amount for the quarter by the total number of units of the billing and payment code of such drug that were subject to JW modifier reporting including those for which the JZ modifier would be required if no units were discarded. As specified in section 1847A(h)(1)(C) of the Act, the total number of units of the billing and payment code of a refundable single-dose container paid during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), exclude such units that are packaged into the payment amount for an item or service and are not separately payable.

We illustrated how the refund would be calculated, if 2,000 units of a billing and payment code for a given drug were unused and discarded during dates of service in the first calendar quarter of 2023, that number would be multiplied by the drug's payment limit amount for the first calendar quarter of 2023. If the payment limit amount was $100, that would be multiplied by 2,000 (the number of discarded units) to equal $200,000. If Medicare paid for 15,000 units of the billing and payment code subject to the JW modifier with dates of service in the first quarter of 2023, that would be multiplied by the same payment limit amount ($100) to determine the total allowed charges during the quarter ($1,500,000). Then, the applicable percentage (in this example, 10 percent) of those total allowed charges ($150,000) would be subtracted out to determine the refund amount. For the sake of this example, that would be $200,000 (the amount described in section 1847A(h)(3)(A)(i) of the Act) minus $150,000 (the amount described in section 1847A(h)(3)(A)(ii) of the Act) to equal a refund amount of $50,000 for the first calendar quarter of 2023.

We noted that section 1847A(h)(3)(A) of the Act states that the refund amount is equal to an estimated amount, and that the refund amount is the difference between: (1) the product of the estimated allowed charges and applicable percentage; and (2) the product of the total number of discarded units of a drug form a single-dose container during a given quarter and the payment limit for that drug during that quarter. Exact amounts are likely not attainable for these numbers because of, for example, lagged claims data, appeals, or reversals in the case of an audit. To obtain the most accurate estimates possible, we proposed to provide information and determine any refund amount for discarded refundable single-dose container or single-use package drugs annually, and to include additional lagged claims data not included in the previous year's report. Based on claims maturity data, we expect this approach would capture over 99 percent of claims for a given date of service quarter in an effort to make the most accurate estimates possible for the purposes of calculating refund amounts. We explained that if the assessment of lagged claims data increases the refund amount for a quarter, the manufacturer would be liable for that additional refund amount, which would be reflected in the report. If the assessment of lagged claims data decreases the refund amount for a quarter, we proposed that any overpayment be corrected. In the event that an assessment of lagged claims data for a calendar quarter causes the product of total discarded units and the payment limit amount to fall below the applicable percentage, which would result in no refund due from that manufacturer for the given quarter, we proposed that any overpayment be corrected. We solicited comments on the operational process of overpayment correction.

We proposed to codify these provisions at § 414.940.

a. Increased Applicable Percentage for Drugs With Unique Circumstances

In the CY 2023 PFS proposed rule (87 FR 46061), we stated that section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary.

We did not propose an increase of the applicable percentage for any drugs

with unique circumstances. We noted that we expected that for most drugs supplied in single-dose containers, the amount of drug indicated on the vial or container reflects the amount of drug that could potentially be administered to a patient. This is consistent with FDA regulations at 21 CFR 201.51(g), which provide that for drugs in ampules or vials intended for injection, the declaration of net quantity of contents on the label is considered to express the minimum quantity of contents and that variation above the stated measure must comply with the excess volumes set forth in the United States Pharmacopeia (USP). FDA guidance for industry [149] explains that USP General Chapter 1151 *Pharmaceutical Dosage Forms* provides excess volume recommendations for mobile and viscous liquids in a range of fill volumes, noting that the excess volumes recommended are usually sufficient to permit withdrawal and administration of the labeled volumes. In this guidance, FDA recommends that single-dose vials should not contain a significant volume beyond what would be considered a usual or maximum dose for the expected use of the drug product.

We noted that we recognized there may be very rare cases in which, as part of a drug's FDA-approved preparation and administration in labeling, the amount of drug identified on the package or labeling far exceeds the amount administered to a patient, thus leading to a substantial percentage of drug that is discarded. For example, in the case of a drug that is reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, there is substantial amount of reconstituted hydrogel that adheres to the vial wall during preparation.[150] In this instance, the drug adhering to the vial wall (and not able to be extracted from the vial) must be discarded, which leads to a higher percentage of discarded units billed with the JW modifier. If the labeled amount of the package is 80 mg and the maximum extracted amount from the vial guarantees delivery of the maximum dose of 60 mg, then there would be at least 25 percent discarded units. We noted that in the case that a patient does not require the maximum dose, the percent of discarded units would be even higher. In this circumstance, an applicable percentage of 35 percent may be appropriate because it would allow for the amount drug diluted in hydrogel that adheres to the vial wall (25 percent) plus an additional 10 percent to align with the applicable percentage for drugs without a unique circumstance.

We also noted that we considered whether we should adopt a higher applicable percentage for a drug in this circumstance. We welcomed comments on specifying a higher applicable percentage for drugs that are diluted in hydrogel and administered via the pyelocaliceal route, and we welcome comments on whether an applicable percentage of 35 percent would be appropriate in this circumstance. We welcomed comments on whether there are other drugs with unique circumstances as described under section 1847A(h)(3)(B)(ii) of the Act that may warrant an increase in the applicable percentage.

The following is a summary of the public comments received on the refund amount provisions and our responses:

Comment: Several commenters supported our proposal to calculate the refund amount based on claims for each calendar quarter, as well as our proposal to present aggregate discard information for each quarter. Commenters stated that using actual claims would capture reductions in discarded drug amounts due to changes in manufacturers' container or package configuration.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern about cases in which a refund amount would be based on a higher amount than the provider or supplier was actually paid for the drug or biological. Commenters requested that we use the actual payment limit used to reimburse providers and suppliers for each claim to calculate refund amounts, particularly the 340B ceiling price or the rate drugs are reimbursed in the event of sequestration.

Response: Section 1847A(h)(3)(A)(i) of the Act states that the refund amount must be the product of the number of discarded units and the amount of payment determined under either section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological product, or section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product. In most cases, the former provides for a payment limit of 106 percent of the average sales price and the latter provides for a payment limit of the sum of the average sales price and 6 percent of the average sales prices of the reference biological product, or 8 percent for qualifying biosimilars during an applicable 5-year period. These statutory provisions do not account for other payment amounts not specified in section 1847A(b)(1)(B) or (C) of the Act. We identified an error in our proposed regulation text, and we are making changes in this final rule to correct the language in regulation at § 414.940 to reflect payment amounts specified in section 1847A(b)(1)(B) or (C) of the Act.

Comment: One commenter stated that manufacturers should have the option of excluding refund claims that are missing data elements such as provider ID, prescription number, total units billed, or the amount paid in order to ensure that CMS has verifiable information for the calculation of refund payments.

Response: We appreciate the commenter's concern about the data quality used in discard amount and refund calculations. We agree that claims lacking certain information are unusable for the purposes of calculating discard and refund amounts and it is important the MACs do not adjudicate claims that omit those key data elements. Several of the data elements cited by the commenter, such as the billing provider's name and National Provider Identifier, the claims service date, HCPCS code and applicable modifier, and units of service are required and without which a claim would be returned to the provider. A full list of data elements institutional providers, physicians, and suppliers must include on claims submissions can be found in Claims Processing Manual 100–04, Chapters 25 and 26, respectively. Those chapters are available here at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf.* In this final rule we are codifying the requirement to use the JW modifier, which has been required since 2017, and we are adopting a requirement to use JZ modifier beginning no later than July 1, 2023. However, several of the data elements cited by the commenter, such as the amount paid for the drug in question and the paid date, are populated by a MAC's claims processing system when a claim is finalized. Other elements cited by the commenter, such as the prescription number or NDC, are not necessary for accurate claims processing or the calculation of refund amounts and are generally not required on a Medicare Part B claim for payment.

Comment: One commenter requested that we clarify our process for adjustments to discarded amount and refund calculations after audits find errors in underlying claims. Another commenter requested that we clarify our process for reconciling refund

[149] *https://www.fda.gov/media/88138/download.*

[150] *https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3d3d5053-5427-4a68-a40b-edb60699521e.*

obligations in subsequent reports to manufacturers after claims from calendar quarters contained in the previous report have matured.

Response: We recognize that Medicare, through claims audits, may adjust claims based on audit findings, and this could occur after the payment of the discarded drug refund. However, since we are not finalizing the timing for reports to be sent or for refund obligations to be paid in this final rule, we will revisit the interaction of claims audits and lagged claims data in future rulemaking.

Comment: One commenter requested that we exclude from the refund calculation any amounts billed for dually eligible beneficiaries, so that manufacturers are not required to pay both the discarded drug refund and rebates under the Medicaid Drug Rebate Program.

Response: Section 1847A(h)(1) of the Act does not exclude units that are paid for dually eligible beneficiaries that would be subject to the rebates under the Medicaid Drug Rebate Program.

Comment: With regard to consideration of a unique circumstance in the case of a drug that is reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, several commenters supported increasing the applicable percentage to 35 percent, because a substantial amount of product adheres to the vial wall and cannot be extracted from the vial. Many commenters specifically expressed support for the adoption of an increased applicable percentage for drugs diluted in hydrogel and administered via ureteral catheter or nephrostomy tube, specifically Jelmyto® (mitomycin for pyelocaliceal solution). Many commenters requested that CMS finalize a 35 percent applicable percentage described in the proposed rule's example for Jelmyto®, because its viscosity makes a portion of the drug stick to the vial wall. One commenter requested that we consider whether an applicable percentage greater than 35 percent be applied to such hydrogel products because providers do not know until drug administration (after the hydrogel has been prepared by the pharmacy) the value of the patient's kidney volume, which determines what amount of drug administered.

Response: We thank commenters for their input on the discussion in the proposed rule about the case discussed in the regarding a drug reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, in which there is a substantial amount of reconstituted hydrogel that adheres to the vial wall during preparation. We agree with the commenters that such a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics (for example Jelmyto® (mitomycin for pyelocalyceal solution)), should be considered to have a unique circumstance as described in section 1847A(h)(3)(B)(ii) of the Act that would warrant an increased applicable percentage. We also thank commenters for input on whether an applicable percentage of 35 percent (10 percent applicable percentage plus 25 percent to account for drug that cannot be extracted from the vial) may be appropriate for such a drug. We agree with the vast majority of commenters that 35 percent is a reasonable applicable percentage that would be appropriate in this case. We disagree that an applicable percentage greater than 35 percent should be applied to such hydrogel products, because we believe that 35 percent accounts for the hydrogel that adheres to the vial, and because we have allowed for an additional 10 percent of drug to be discarded before any refund would be owed.

After consideration of public comments, we are adopting an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics. At this time, we have only identified one product, Jelmyto® (mitomycin for pyelocalyceal solution), that would fit this unique circumstance.

Comment: Many commenters requested an increased applicable percentage for certain drugs or certain drug categories that may have unique circumstances other than the circumstance pertaining to the drug reconstituted in hydrogel. Several commenters requested that CMS specify increased applicable percentages for drugs that have highly variable dosing, such as drugs dosed by patient weight, or skin surface area, or wound size. One commenter specifically requested an increased applicable percentage for weight-based drugs, because it is impractical to manufacture many different vial sizes for such drugs, and even if mutable vial sizes were available, it would be unreasonable to expect facilities and pharmacies to keep a broad variety of vial sizes in stock. One commenter requested that CMS develop a process for examining each weight-based drug individually in order to determine the appropriateness of an applicable percentage, and to only include outlier cases under the discard refund policy.

Another commenter suggested that CMS consider delaying implementation of a final rule or delay implementation for reconstituted products in order to evaluate why the provision disproportionally impacts reconstituted products. The commenter observed that 9 out of the 10 highest refund examples that CMS calculated from the 2020 claims data in the proposed rule were reconstituted products.

Several commenters requested CMS use higher applicable percentages for drugs packaged with small vial fill amounts or low-volume products (those less than 1 mL). These commenters noted that, in some cases, the small volume of drug contained in the vial often represents the minimum necessary to safely and effectively prepare and administer the target dose volume. One commenter added that there are practical limits on providers' ability to measure such small amounts as the basis for refunds, as well as manufacturers' ability to produce smaller vials to prevent discarded amounts. One commenter suggested the applicable percentage of products with small vial fill amounts be product-specific and calculated using the difference between the labeled amount of product and the appropriate labeled therapeutic dose for those products that contain the minimum necessary fill required to draw up the labeled therapeutic dose. Alternatively, the commenter suggested such products have an increased applicable percentage, on a sliding scale based on volume, to account for the increased relative percentage lost in the vial and syringe with low-volume products. Three commenters requested 100 percent applicable percentage for all products with vial fill volumes smaller than 1 mL

One commenter stated that although the product, Susvimo™ (ranibizumab injection), qualifies for the filtration exclusion, the drug also has a unique circumstance because of the preparation process, which would justify an applicable percentage of 80 percent. The commenter explained that, though this percentage is appropriate because the label instructs that the entire contents of the vial must be removed to ensure the proper dose is administered, up to 80 percent of the vial contents are lost in the process of filtration, removing air bubbles from administration device, and removing bubbles from the implant. This loss in the preparation and administration procedure occurs in both the initial fill of the ocular implant and the refill-exchange procedures. The commenter added that, because the volume of drug provided in the

Susvimo™ vial is significantly less than the smallest packaging recommendations provided in USP General Chapter 1151 Pharmaceutical Dosage Forms, it is not feasible to determine in an individual case how much volume is discarded after administration other than by deduction from the labeled instructions and amounts.

One commenter requested an increase applicable percentage for Dexycu® (dexamethasone intraocular suspension), because the entire contents of the vial are mixed with a drug delivery vehicle, Verisome®, to create a suspended product. The commenter stated that, because of this process, there is no unused product. In addition, the commenter stated that this drug has unique circumstances that could warrant an increased applicable percentage because of the small vial size with less than 1 mL fill; the viscosity of the suspension created in the vial resulting in some product adhering to the vial walls; the minimum depth of material in the vial is needed in order for providers to be able to pull the product into the 18-gauge needle and the vial; and that providers' withdrawal 0.2 mL leaves 0.3 mL of contents in the vial.

One commenter requested an applicable percentage of at least 30 percent for Visudyne® (verteporfin for injection) on the grounds that all of the active ingredient is reconstituted and, therefore ''there is no unused product.'' In addition, the commenter stated that the drug is dosed based on BSA and the package amount is designed to account for varying body sizes. A 30 percent applicable percentage would account for the difference between doses for average-sized and larger individuals. The commenter stated that it is not practical to create multiple vial sizes.

One commenter requested an applicable percentage of 20 percent for Elzonris™ (tagraxofusp-erzs) due to the weight-based nature of its dosing, the small patient population its treatment is used for (300 people annually), and because of the leakage inherent in its storage, distribution, and administration beyond overfill that should not be considered discarded drug amounts. Another commenter suggested an increased applicable percentage for Vyvgart® (efgartigimod alfa injection) due to its weight-based dosing and required dilution prior to administration.

One commenter requested an applicable percentage of 70 percent for Zynrelef® (bupivacaine and meloxicam solution), a local anesthetic used in surgical procedures, on the basis of highly variable dosing based on wound size. The commenter stated that although it produces multiple vial sizes, providers only stock two vial sizes due to storage limitations. In addition, providers have difficulty estimating how much of the product will be needed to cover the area inside the wound site. The commenter also stated Zynrelef should be considered to have a unique circumstance because it is a non-opioid pain management treatment.

Another commenter requested an increased applicable percentage for eight of its products used for the treatment or care of wounds (ranging from 23 to 70 percent). The commenter stated that, because wounds come in an infinite number of sizes, shapes, and depths, it is not possible to manufacture an individual product sized for each potential wound. Such products must be tailored to fit the specific wound, and therefore, there will be discarded amounts every time the product is used.

One commenter stated that the drug pegcetacoplan, an intravitreal injection that is under FDA Priority Review, has a 75 percent overfill amount in the vial due to the high viscosity of the product. They stated that their scientists determined that this was the appropriate amount to safely administer the dose amount without air bubbles.

Four commenters requested that CMS utilize its discretion to increase the threshold for discarded unit refund requirements for cell, gene, and immunotherapies. Commenters explained that, because these therapies are unique and need to be given to a patient all at once, the maximum potentially needed amount of product must be available for each administration. Therefore, cell and gene therapies should have a 100 percent applicable percentage. Two commenters suggested instructing providers to use the JZ modifier for all claims for cell and gene therapy.

Two commenters requested that the applicable percentage for small biotech companies that received Breakthrough Therapy Designation (BTD) and FDA Priority Review during the NDA approval process be increased to 30 percent. One commenter requested that CMS establish a review policy to adjust the applicable percentage for orphan drugs associated with large discarded amounts.

Two commenters requested that CMS use increased applicable percentages for products that require complex delivery methods and necessarily use variable product volume, including those based on the following factors: mechanisms that deliver drugs to tiny anatomical spaces of the body, multiple procedures or steps for administration, variable and unpredictable patient characteristics, specialized equipment or equipment variability due to physician or facility preference, and immunogenicity concerns. The commenters requested CMS base the applicable percentage off of the maximum amount of drug utilized for successful administration. One commenter added these techniques often utilize extra product to ensure proper dosage. One commenter stated products used during complex administration procedures should be given a 100 percent applicable threshold or be given guidance to use the JZ modifier.

Several commenters requested that CMS provide a list of criteria defining unique circumstances that justify an increased applicable percentage (for example, classes of products, modes of administration, or disease states) to guide manufacturers. Several commenters requested that CMS establish a formal process for requesting an increased applicable percentage based on particular circumstances and characteristics of their drugs. One commenter stated that such a process should, at minimum, include subregulatory guidance and standardized forms that outline the information that CMS deems necessary in order to assess whether an increased applicable percentage should be applied. The commenter stated the process should have an established timeline with deadlines for requests to be included in proposed rules, consideration of comments on the proposed rule, and the opportunity to appeal decisions. One commenter stated such a process would increase transparency and facilitate discussions more effectively between manufacturers and CMS to assess drugs and their discarded amounts. Another commenter suggested that, if an administrative process is developed, CMS do outreach to ensure that manufacturers are aware of the process and publish guidance on any applicable requirements or deadlines for submitting a request for an increased applicable percentage. In addition, one commenter recommended that such a process should include methods for CMS and manufacturers to consult with relevant expert agencies and other organizations, including FDA and the United States Pharmacopeia. One commenter requested CMS take patient safety into account when considering increased applicable percentages for variable-dose drugs (for example, regulatory review of new vial sizes, distribution and inventory constraints for multiple vial sizes).

Response: We value the input commenters provided and the scope of drugs that may have unique circumstances. We recognize that there are products that may indeed have a unique circumstance, and an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking as required by the statutory provision. Therefore, we are not adopting increased applicable percentage for any additional products in this final rule. After considering the public comments, we plan to collect additional information about drugs that may have unique circumstances along with potential increased applicable percentages that might be appropriate for each circumstance. We also plan to collect additional information about a process to identify unique circumstances based on manufacturer input. We will revisit additional increased applicable percentages for drugs that have unique circumstances, and a process to identify such circumstances, through future notice and comment rulemaking.

Comment: One commenter expressed concern that, because they are a small biotech company, their refund obligation under the proposed rule would amount to about 10 percent of their net revenue, and that the refund would have a substantial impact on their capacity for research.

Response: We understand the commenter's concern; however, section 1847A(h) of the Act does not exempt drugs produced by small biotech companies from the refund requirement. We have discretion in section 1847A(h)(3)(B)(II) of the Act to determine increased applicable percentages for drugs with unique circumstances involving loss of product similar to ones that require a filtration process through notice and comment rulemaking. While we only discussed an increased applicable percentage for one unique circumstance in the proposed rule and are finalizing an increased applicable percentage for it in this final rule, we plan to consider additional unique circumstances in future rulemaking.

Comment: One commenter requested clarification on the process for manufacturers of new drugs with unique circumstances to request higher applicable percentages.

Response: A drug that is exempt from the definition of ''refundable single-dose container or single-use package drug'' because it was approved by FDA on or after the date of enactment of the Infrastructure Act (that is, November 15, 2021), for which payment under Part B has been made for fewer than 18 months, may still be considered for an increased applicable percentage for unique circumstances during the 18-month time period in which the drug is are exempt. We believe that this would actually be an efficient approach because, when the 18-month time period has ended (and if the drug otherwise meets the definition of refundable single-dose container or single-use package drug), consideration will have already been given to any potential unique circumstances and any appropriate increases in the applicable percentage in advance of the refund requirement.

After consideration of the public comments, we are finalizing the manner in which the refund amount will be calculated as proposed at § 414.940, with the addition of an increased applicable percentage of 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics.

7. Dispute Resolution

In the CY 2023 PFS proposed rule (87 FR 46062), we explained that, as a part of implementing this section 90004 of the Infrastructure Act, we recognized the need to establish a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. Although a dispute resolution process is not expressly required by section 1847A(h) of the Act, we noted that we believed proactively establishing such a process will aid in the successful implementation of this provision. We proposed that each manufacturer have an opportunity to dispute the report by submitting an error report as described in this section.

We proposed that to assert that there have been one or more errors in a report, a manufacturer must submit a dispute with each asserted error. We proposed that the dispute must include the following information: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

We proposed that in order to dispute a report, manufacturers must assert any basis for contesting its refund calculation during the 30-day period following the issuance of the report. We noted that we would evaluate error reports and would decide whether the information (such as number of discarded billing units or refund amount calculation) requires correction based on the information provided. We proposed that we would provide manufacturers who have submitted a dispute a response to each dispute and inform manufacturers of the final refund amount no later than 30 days after receipt of the dispute. We proposed that if we find that a different refund amount is owed than what was stated on the report, we would issue a new report with updated discarded amounts and/or refund. We proposed that if we disagree with the dispute, we would notify the manufacturer that refund amount on the report is still owed and should be paid as described above in section 5 (no later than December 31 of the year in which the report was sent). We welcomed comment on whether CMS should develop an appeal mechanism, which we will consider for future rulemaking.

We proposed to codify the dispute resolution process at § 414.940.

The following is a summary of the public comments received on the dispute resolution provisions and our responses:

Comment: Several commenters expressed support for our dispute resolution proposal. One commenter expressed support for its simplicity and formal character.

Response: We thank the commenters for their support.

Comment: One commenter requested the effective date of the provision be delayed until after a ''detailed'' dispute resolution process is implemented.

Response: We do not have the flexibility to delay the effective date of the provision of January 1, 2023, which is specified in statute. We may consider an appeal process in future rulemaking.

Comment: Several commenters requested that we broaden the dispute resolution process to cover disputes related to manufacturer requests for higher applicable percentages or exclusions for particular drugs. Commenters offered that we could make these determinations as part of the annual rulemaking process and that the window for these disputes could immediately follow the issuance of the final rule.

Response: We appreciate the commenters' suggestion. At this time, we are not establishing a separate process for requesting higher applicable percentages or disputing unique circumstance or applicable percentage determinations. Since the determination of unique circumstances or increased applicable percentages requires notice and comment rulemaking, all interested parties would have an opportunity to comment on these determinations through the rulemaking process.

Comment: Several commenters requested that the window for manufacturers to file disputes be extended, with some suggesting an extension from 30 days to either 60 or 90 days. Several commenters suggested that, as an alternative to a longer filing window, we provide manufacturers with preliminary estimates of refund obligations. One commenter explained that preliminary estimates would be useful in allowing manufacturers a second opportunity to raise concerns about discard and refund calculations, which could be of significant help to manufacturers, since we proposed to include limited information in manufacturer reports. Commenters stated the proposed timeline does not allow enough time for engagement with the agency, particularly those with small regulatory staffs. A few commenters stated that manufacturers should not have to pay refund obligations when refund amounts are in dispute, and one requested that they have 90 days after dispute resolution to remit refund payments.

Several commenters stated that the dispute resolution process should include an appeal process. One commenter requested an appeals process overseen by a third-party arbiter. One commenter suggested we incorporate an appeal process in regulatory text, in order to mirror the Parts A and B claims appeals process.

Response: We disagree with commenters about the amount of time needed to file a dispute, and we continue to believe that 30 days is a sufficient filing period. The information provided in the report is required by statute to include two numbers: (1) the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter; and (2) the refund amount for which the manufacturer is liable. We do not expect that the formulation of a dispute regarding these two numbers should take longer than 30 days, since the calculations are straightforward. In addition, the 30-day dispute period is similar to the dispute period for several other CMS programs. Specifically, many of the Quality Reporting Programs have 30-day ratings preview periods, including the Quality Payment Program.[151] As noted above, we are not finalizing the date that we will issue the first reports, and we will revisit in future rulemaking other mechanisms that can ensure that manufacturers have enough time to process and validate discard data. As stated above, we plan to issue a preliminary report to manufacturers for the first 2 quarters of 2023 no later than December 31, 2023. With regard to amounts due while a dispute is ongoing, as we noted above, we clarify that our intent was to propose that manufacturers have until 30 days following the resolution of the dispute to pay the refund if dispute resolution results in an amount due, which was included in another part of the proposed rule. We are finalizing this payment deadline for disputed amounts.

We thank the commenters for their feedback on the potential benefits and structure of an appeals process. We will take this input under advisement and we plan to revisit the topic in future rulemaking.

Comment: Commenters offered several suggestions and requests regarding the operational aspects of the dispute resolution process. One commenter requested that the dispute process be simple and easy to for manufacturers to use. One commenter had several suggestions on the process operations, including that we permit manufacturers to dispute as many errors as needed in each dispute, rather than having to file separate disputes. The commenter also suggested that the process be conducted through a web-based portal, that we employ dedicated staff to administer the dispute resolution process, and that we issue program instruction on the dispute process, including information on factors we consider in evaluating disputes. Several commenters requested that we state that the dispute resolution process is confidential, so that no manufacturer's confidential proprietary information is disclosed to the public. One commenter requested that we clarify that we will credit manufacturers in refund calculations in the case of disputes resolved in a manufacturer's favor. One commenter requested that we remain engaged with stakeholders while developing the dispute resolution process.

Response: We agree that the dispute process should be simple and of minimal burden on manufacturers, and to that end, we will build as much as possible on data sets already familiar to the public. We will further address the dispute resolution process in future rulemaking. With regard to the number of errors that a manufacturer may submit in one filing, we clarify that we did not propose a limit; we proposed that a manufacturer would be able to identify as many errors as they need for each manufacturer report that they dispute. Should a manufacturer receive two reports for two drugs and the manufacturer would like to dispute both, the manufacturer would need to file two disputes, regardless of how many errors they identify in each. We believe that this aligns with the commenter's request. We would maintain the confidentiality of a manufacturer's proprietary information consistent with applicable law.

At the conclusion of the process, if we agree that information presented by the manufacturer reveals errors in our original refund calculation, we will make appropriate adjustments to our calculation and issue a new report to the manufacturer. A report may indicate either that the manufacturer owes no refund obligation, or some amount that would be due to the agency within 30 days of the dispute resolution. If we conclude that information submitted in the dispute does not affect our original calculation, the manufacturer would owe the amount specified in the original manufacturer report within 30 days of the dispute resolution.

We welcome continued engagement with commenters on all aspects of the dispute process.

After consideration of public comments, we are finalizing our proposal to establish a dispute resolution process through which manufacturers can challenge refund calculations and underlying data in their section 1847A(h)(1)(A) of the Act manufacturer reports in § 414.940(d). We are finalizing that manufacturers will have 30 days after receipt to file a dispute of their report or reports and that, if following resolution of the dispute we affirm our original calculation, or if we resolve to issue a revised manufacturer report that specifies a new discard refund amount, the manufacturer will be required to pay the refund within 30 days of the dispute resolution. We are not finalizing the payment of the refund by December 31 of the year the report was issued, since we will be revisiting the timing of reports in future rulemaking. We will also revisit the issue of an appeals process in future rulemaking.

[151] *https://content.govdelivery.com/accounts/USCMS/bulletins/2fe564d.*

8. Enforcement

a. Audits

As discussed in the CY 2023 PFS proposed rule (87 FR 46062), section 1847A(h)(6)(A)(i) of the Act requires that we perform periodic audits on each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under section 1847A(h) of the Act with respect to such drug and such refunds. We proposed to specify at 414.940(e) that we periodically audit manufacturers of refundable single-dose container or single-use package drugs consistent with this requirement. We welcomed comments about what such audits should entail, which we will consider for future rulemaking.

We stated that section 1847A(h)(6)(A)(ii) of the Act requires us to conduct periodic audits of claims submitted under Medicare Part B with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) of the Act. Under the JW modifier policy, claims for dates of service on or after January 1, 2017 containing billing for discarded drugs that do not use the JW modifier may be subject to review.[152] We proposed that our review contractors would periodically review Part B medication claims to ensure the JW modifier, JZ modifier (if adopted), and discarded drug amounts are billed appropriately consistent with our normal claims audit policies and protocols.

b. Civil Money Penalty

We noted that provisions in section 1847A(h)(6)(B) of the Act give the Secretary authority to impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who fails to comply with the requirement under section 1847A(h)(2) of the Act for such drug for a calendar quarter.

As set forth in section 1847A(h)(6)(B) of the Act, the civil money penalty would be an amount equal to the sum of—

- The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and
- 25 percent of such amount.

We proposed to codify the civil money penalty at § 414.940.

The following is a summary of the public comments received on the enforcement provisions and our responses:

Comment: Several commenters requested that the focus of manufacturer audits be limited to the manufacturers' responsibilities under section 1847A(h) of the Act, namely, the payment of obligations specified in CMS reports to manufacturers. The commenters also requested that the audits only be triggered by patterns of unusual payments, rather than being regularly scheduled. One commenter requested we engage with manufacturers as we develop the manufacturer audit process, and that we develop a system that is transparent, predictable, and minimally burdensome. The commenter requested a 60-day notice in advance of audits and that we provide instructions on the audit process and remedial measures. Several commenters requested more information on the lookback period, frequency, and scope of manufacturer audits, as well as remedial measures.

One commenter requested that manufacturer audits be performed remotely.

Response: We agree with the commenters, and at this time, we do not intend to conduct audits under section 1847A(h)(6)(A) of the Act beyond determinations they have either paid refund obligations or not. The remedial measure for nonpayment of refund obligations is the civil money penalty specified under section 1847A(h)(6)(B) of the Act, as discussed below. These determinations will be made following the issuance of the report to manufacturers, but as we are not finalizing the date we will issue the first report, we cannot finalize timing for determinations of nonpayment. Finally, this determination can be performed remotely.

Commenter: One commenter suggested we conduct post-claims reviews for providers with unusual JW and JZ modifier reporting patterns. One commenter, while generally supporting our proposal for provider audits, requested a process for those audits that allows manufacturers to guide audit efforts by suggesting particular issues or trends that warrant attention. One commenter supported our proposal to not significantly increase the volume of post-payment claims reviews to identify claims submitted without the JW or JZ modifiers.

Response: We agree with the commenter that provider audits should focus on unusual JW and JZ modifier reporting patterns. We also agree that engagement with manufacturers on potential issue areas in discard reporting practices can make the provider audit process more targeted and effective. In response to the comment about audits specifically for identifying claims without the JW or JZ modifiers, we are finalizing that we will continue the JW reporting requirement and that the JZ modifier will be required for dates of service beginning July 1, 2023. In addition, we will begin editing for the use of both the JW and JZ modifiers beginning October 1, 2023.

Comment: One commenter stated that CMS's actions following adverse manufacturer audit findings should start with an opportunity for education and correction prior to any enforcement action or penalties.

Response: We disagree with the commenter. We proposed to impose civil money penalties only on manufacturers who fail to remit refunds to CMS in a timely manner. We clarify our proposal on the amount of time manufacturers have to pay a refund if, after the resolution of a dispute, we find that the provider owes a refund. Although in one part of the proposed rule we stated that manufacturers have until 30 days following the resolution of the dispute to pay the refund, in another part of the proposed rule we stated refunds would be due December 31 of the year in which a report is issued to manufacturers even if the amount is under dispute. We are finalizing the former, as discussed above in section III.A.7 of this final rule. We continue to believe this is ample time for manufacturers to comply with a report for refund obligations.

Comment: One commenter stated that the imposition of civil money penalties should not be set before a manufacturer has had the opportunity to meaningfully engage CMS in a dispute process.

Response: We agree with the commenter that civil money penalties should not be imposed while the window for disputing a refund amount is still open, when the dispute process is ongoing, and not before a reasonable amount of time has passed since either the report was first sent to the manufacturer or the dispute process concluded with a decision finding that the manufacturer has a refund obligation.

After consideration of the public comments, we are finalizing the regulations of § 414.490(e) that at this time, manufacturer audits will be limited to determinations that they have paid refund obligations or not and will revisit timing of those determinations in future rulemaking. We are also finalizing that provider audits of Part B medication claims will be conducted periodically to determine whether the JW modifier, JZ modifier, and discarded drug amounts are billed appropriately consistent with our normal claims audit policies and protocols. Finally, we are

[152] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

finalizing that we will impose a penalty of 125 percent of the fund amount owed if the manufacturer fails to remit refund obligations.

Comment: We received public comments that were outside the scope of the discarded amount refund proposals included in the CY 2023 PFS proposed rule. These comments were related to: guidance to FDA on encouraging or requiring manufacturers to use more efficient drug packaging, the impacts of the policy on drug and biological research and development and market participation, the review burden imposed on FDA by the refund policy, the Medicare program's use of the refund revenues, the impact of the refunds for Medicare beneficiaries, and comparative billing reports to providers focusing on JW modifier reporting.

Response: We consider these public comments to be outside the scope of the proposed rule, and therefore, we are not addressing them in this final rule. We may consider these public comments for possible proposals in future rulemaking.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to new payment limits on the AIR, and this limit will be determined for each RHC in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

b. Care Management Services in RHCs and FQHCs

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to separately recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

A separate payment was established in the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088) for RHCs and FQHCs that furnish Chronic Care Management (CCM) services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule with comment period (82 FR 53169 and 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018. We also initiated the use of HCPCS code G0511, a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. In the CY 2019 PFS final rule (83 FR 59683), we explained for CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised G0511 were CPT code 99490 (20 minutes or more of CCM services), CPT code 99487 (60 minutes or more of complex CCM services), and CPT code 99484 (20 minutes or more of BHI services).

We also explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487 (83 FR 56983). Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2020 PFS final rule with comment (84 FR 62692), we established a separate payment for Principle Care Management (PCM) services under the PFS. PCM services include

comprehensive care services for a single high-risk disease or complex condition, typically expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065. HCPCS code G2064 is for at least 30 minutes of PCM services furnished by physicians or nonphysicians during a calendar month. HCPCS code G2065 is for at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or non-physician during a calendar month.

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that since the requirements for the new PCM codes were similar to the requirements for the services described by HCPCS code G0511, we added HCPCS code G2064 and G2065 to G0511 as a general care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS G2064 and G2065). Finally, we note that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the current payment rate for HCPCS G0511 is the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (CPT codes 99424 and 99425).

Additional information on care management requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html* and on the CMS RHC and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*.

2. New Care Management Codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)

As discussed in the CY 2023 PFS proposed rule (87 FR 46064 through 46065), under the PFS we proposed two new HCPCS codes to describe CPM and the proposed CPM codes would be created to separately pay for a specified set of pain management and treatment services, specifically including the administration of validated rating scales, and a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes.

(1) HCPCS codes G3002: *Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month.* (When using G3002, 30 minutes must be met or exceeded.)

(2) HCPCS code G3003: *Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month.* For G3002, CPM services, we are requiring a face-to-face visit of at least 30 minutes provided by a physician or other qualified health professional, per calendar month to a beneficiary who has a diagnosis of pain that has lasted more than 3 months, which could be the result of an underlying medical disease or condition. HCPCS code G3003 will apply to up to three units of an additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (listed separately in addition to HCPCS code G3002). The new codes for CPM would be valued using crosswalks to the CY 2023 PCM services, CPT codes 99424 and 99425.

We also discussed proposed new coding and payment under the PFS for general BHI services. That is, the new HCPCS code (G0323): *(Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with an/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team)* describing general BHI services performed by clinical psychologists (CPs) and clinical social workers (CSWs). As proposed, the payment rate for the new General BHI code would be based on the payment rate for the current general BHI code, 99484. We noted that CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs, as described by § 405.2411(a)(6).

We explained the requirements for the CPM service (that is, HCPCS code G3002) would be similar to the requirements for the general care management services furnished by RHCs and FQHCs and as such, we believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or underserved populations served by RHCs and FQHCs. The pain management coordination included in services, such as office visits, do not always adequately describe the non-face-to-face pain management services involved in primary care.

Allowing separate payment for CPM services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. We did not propose to utilize the add-on HCPCS code G3003 for RHC/FQHC payments because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners, as is the case for practitioners under the PFS. In an effort to be consistent with the new services that were proposed for practitioners billing under the PFS, we proposed to include CPM services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code G3002 would be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, we did not propose a change to the average used to calculate the HCPCS code G0511 payment rate.

In addition, as explained in the proposed rule, since CPs and CSWs are

statutorily authorized to furnish services in RHCs/FQHCs, we clarified that when CPs and CSWs furnish the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511.

We noted that if finalized as proposed, RHCs and FQHCs that furnish the new CPM and GBHI services furnished by CPs and CSWs would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023. The payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC and FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) and PCM codes (CPT codes 99424 and 99425) and would be updated annually based on the PFS amounts for these codes.

We also noted that we may consider other approaches in future rulemaking for calculating the rate of HCPCS code G0511 as the number of services is growing each year. For example, we could value HCPCS code G0511 using a weighted average of the services that comprise HCPCS code G0511 or using the national average of the top three services comprising HCPCS code G0511. We welcomed comments on potential methodologies.

Finally, we note that the codes GYYY1, GYYY2, and GBHI1 in the proposed rule were placeholder codes and that the final code numbers will be HCPCS code G3002, G3003, and G0323 respectively and corresponding discussions have been updated.

The following is a summary of the public comments received on the new care management codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI) and our responses:

Comment: The majority of the commenters supported our proposal to allow RHCs and FQHCs to furnish CPM services; however, they would like CMS to treat HCPCS code G3002 as an encounter and reimburse these services at the RHC AIR or at the FQHC PPS rate, instead of bundling the services under the general care management code, HCPCS code G0511. The commenters noted that the definition of an RHC or FQHC encounter is a face-to-face encounter between a patient and an RHC or FQHC practitioner during which a qualified service is furnished. They explained that the proposed codes require a face-to-face visit for at least 30 minutes with a RHC or FQHC practitioner, therefore clearly meeting the definition of an RHC or FQHC encounter.

Response: We appreciate the feedback from commenters regarding the addition of CPM services and the proposed reimbursement for these services. We agree that the description of HCPCS code G3002 includes a face-to-face component. As explained in the CY 2023 PFS proposed rule (87 FR 45936 through 45937), to value CPM, we compared the proposed services to codes that involve care management. In doing so, we concluded that the CPM services were similar in work (time and intensity) to that of PCM in that both the PCM codes and proposed CPM codes reflected services that have similar complexities, possible comorbidities, require cognitive time on the part of the practitioner, and may involve coordination of care across multiple practitioners. Therefore, in an effort to pay the same for similar services, and for RHCs and FQHCs we pay PCM using HCPCS code G0511, we did not believe it is appropriate to pay CPM as a visit.

After consideration of public comments, we have reconsidered our approach to billing CPM services. Many Medicare beneficiaries have multiple chronic conditions, and many of these conditions could involve chronic pain. We believe it is reasonable to assume that in many instances, the RHC or FQHC practitioner could be spending time with the Medicare patient discussing health and wellness related to a variety of conditions that a person may be experiencing, or expect to experience, and that interaction might also have a focus on the chronic pain aspects of the person's care. Addressing chronic pain as part of a visit would complete the face-to-face component of CPM. Billing of HCPCS code G0511 would address the non-face-to-face components of CPM. Therefore, both the face-to-face visit and the non-face-to-face components of CPM as an add-on service(s) could be on the same day if all requirements to report each service are met, without time or effort being counted more than once. We believe having the ability to bill both a face-to-face visit and a non-face-to-face CPM add-on service on the same day mitigates concerns from the commenters since payment for the RHC or FQHC visit accounts for the face-to-face component and payment for non-face-to-face CPM services accounts for the additional time and resources necessary for the unique components of care coordination for non-face-to-face CPM services furnished outside of the face-to-face visit with an RHC or FQHC practitioner. Therefore, we are finalizing as proposed to include non-face-to-face CPM services described in HCPCS code G3002 in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs.

Comment: A few commenters encouraged CMS to permit RHCs and FQHCs to provide CCM and GBHI to a patient in the same calendar month and receive the separate reimbursement for each service.

Response: We note that we did not specifically make any proposals in the CY 2023 PFS proposed rule to simultaneously bill CCM or BHI service in the same calendar month. In the CY 2021 PFS final rule with comment (86 FR 84699), we finalized a policy that general care management services furnished in RHCs and FQHCs can only be billed once per month per beneficiary when at least 20 minutes of CCM services, at least 30 minutes of PCM services, or at least 20 minutes of general BHI services have been furnished and all requirements have been met. Therefore, if the requirements for each of these care management services are met, then HCPCS code G0511 can be billed more than once in a calendar month, either alone or with other payable services and the same would apply for CPM and GBHI.

Comment: One commenter recommended CMS to further designate if separately reportable procedures are able to be billed during the proposed 30-day CPM management period, and if CMS allows for separately reportable procedures (for example, injections, dry needling, acupuncture, PT/OT) to be performed during the same billing period, then CMS should define any limitations on which ones are, or are not, separately billable.

Response: We appreciate the commenter's feedback. Procedures, such as injections, dry needling, acupuncture, and PT/OT, may be furnished by auxiliary personnel ''incident to'' an encounter with an RHC or FQHC practitioner in a medically appropriate timeframe, as described by §§ 405.2413 and 405.2415. More than one ''incident to'' service or supply can be provided as a result of a single encounter with an RHC or FQHC practitioner. However, they cannot be separately billed as separate visits.

Comment: One commenter requested that CMS allow RHCs and FQHCs to bill for the new HCPCS code G3003 which applies up to three units of an additional 15 minutes of CPM per month.

Response: We appreciate the feedback from the commenter regarding the new CPM HCPCS code that describes the additional time spent by practitioners. We did not propose to utilize the add-

on HCPCS code G3003 for RHC/FQHC payments because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners, as is the case for practitioners paid under the PFS. As we stated in the CY 2016 PFS final rule (80 FR 71086) when we added CCM, we explained that additional minutes as follows: the service period for billing CCM services in RHCs and FQHCs is one calendar month, and we expect the RHC or FQHC to continue furnishing services during a given month as applicable even after the 20-minute time threshold to bill the service is met. The RHC or FQHC could bill for the CCM service after completion of at least 20 minutes of qualifying CCM services during the service period, or any time after that until the end of the month. This is consistent for other care management services included in HCPCS code G0511 and now extends to CPM services. RHCs and FQHCs must meet the minimum of 30 minutes in order to bill HCPCS code G0511 for CPM services.

Comment: Generally, commenters were supportive of the clarification that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511 as statutorily authorized RHC and FQHC practitioners.

Response: We appreciate the support received from commenters.

Comment: Commenters urged CMS to create billing codes that reflect the complexities between RHC and FQHC patients and provide variable reimbursement rates that reflect the varying levels of care management services provided. Commenters opined that adding CPM and GBHI services further dilutes the reimbursement to RHCs and FQHCs under HCPCS code G0511 drawing attention to the fact that not every patient is the same as the level of providers needed to treat the patient and time spent may vary.

Response: We appreciate the feedback in response to our comment solicitation on potential methodologies for calculating the rate of HCPCS code G0511 and will take this information into consideration for future rulemaking.

After consideration of the public comments, and in an effort to be consistent with the new services finalized in section II.E of this final rule for practitioners billing under the PFS, we are finalizing as proposed to include CPM services described by HCPCS code G3002 in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. Since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there is no change to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services. This is in addition to the face-to-face visit component of CPM services. We note as discussed in section II.E of this final rule, we are finalizing the descriptor of HCPCS code G3002 as follows, with the two modifications shown in italics: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, *and/or* maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, for example, physical therapy and occupational therapy, *complementary and integrative approaches,* and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using HCPCS code G3002, 30 minutes must be met or exceeded.)

In addition, CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs, and therefore, we are finalizing the clarification that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511.

RHCs and FQHCs that furnish CPM and GBHI services are able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023. The payment rate for HCPCS code G0511 will continue to be the average of the national non-facility PFS payment rates for the RHC and FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) and PCM codes (CPT codes 99424 and 99425) and will be updated annually based on the PFS amounts for these codes. In addition, we will take into consideration the comments we received in response to our comment solicitation on potential methodologies for calculating the rate of HCPCS code G0511 for future rulemaking.

3. Conforming Technical Changes to 42 CFR 405.2463 and 405.2469

Last year in the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

We also revised the regulation under § 405.2469, FQHC supplemental payments, to state that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or

audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. At § 405.2469, we also revised paragraph (d) to describe the same in-person visit requirement referenced in § 405.2463.

As discussed in the CY 2023 PFS proposed rule (87 FR 46065), the Consolidated Appropriations Act, 2022 (Pub. L. 117–103) (CAA, 2022) signed into law on March 15, 2022, included the extension of a number of Medicare telehealth flexibilities established during the PHE for a limited 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. Specifically, section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE. We explained that payment would continue to be made under the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. We noted that we did not believe it was necessary to conform the regulation for this temporary provision.

We also discussed section 304 of the CAA, 2022 which delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. We noted this change required conforming regulatory text. For RHCs and FQHCs, in-person visits will not be required until the 152nd day after the end of the PHE for COVID–19. We noted that while the extensions of mental health telehealth visits under section 304 of the CAA, 2022 were placed into paragraphs of section 1834 of the Act applicable only to hospice patients served by RHCs and FQHCs, the overall intent of the amendments made by section 304 of the CAA, 2022 appear to be to provide an exception to the limitations otherwise in place on payment for mental health visits that are not in-person visits. Therefore, we proposed to apply the 151-day extension of non-in-person visits to all RHC and FQHC mental health visits.

We proposed to make conforming regulatory text changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we proposed to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we proposed to amend paragraph (d) to include the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19.

In the CY 2023 PFS proposed rule we listed the several other provisions of the CAA, 2022 that apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. These provisions are also listed in the following paragraphs.

Section 301 of the CAA, 2022 amended section 1834(m)(4)(C) of the Act to add a new clause (iii) expand the originating site requirements to include any site in the U.S. at which the beneficiary is located, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID–19. It also prohibits an originating site facility fee from being paid unless the site is a setting included on the originating site list in section 1834(m)(4)(C)(ii) of the Act, excluding the home of an individual.

Section 305 of division P, title III, subtitle A of the CAA, 2022 amended section 1834(m) of the Act to extend coverage and payment of telehealth services that are furnished via audio-only telecommunications system for the 151-day period beginning on the first day after the end of the PHE for COVID–19.

Section 309 of division P, title III, subtitle A of the CAA, 2022 authorized the Secretary to implement the Medicare telehealth provisions via program instruction or otherwise.

The following is a summary of the public comments received on the conforming technical changes to §§ 405.2463 and 405.2469 our responses:

Comment: All commenters supported our proposal to make conforming regulatory text changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' and at § 405.2469 ''FQHC supplemental payments'' to reflect the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19. One commenter stated the delay of the in-person requirements would ensure consumers and caregivers have time to plan how they will attend an in-person visit, including arranging for childcare or transportation, and meeting other logistical challenges. Several commenters expressed concern that the in-person requirements would pose a challenge for some beneficiaries due to various social determinants of health and would like CMS to permanently remove the in-person requirements.

Response: We appreciate the feedback from commenters regarding the impact in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology may have on access to care. Regarding concerns that the in-person requirements would pose a challenge for some beneficiaries due to various social determinants of health, we would like to direct you to § 405.2463(b)(3) that describes the exceptions to the in-person visit requirements. An in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient.

Comment: Commenters supported the Medicare telehealth extensions, but urged CMS to permanently allow RHCs and FQHCs to become distant sites for medical visits furnished using interactive, real-time, audio and video telecommunications, or audio-only interactions. Several commenters noted CMS has the authority to revise the definition of a medical visit for RHCs and FQHCs and should do so prior to the end of the COVID–19 PHE to avoid consequential gaps in care for some of the most vulnerable Medicare patients.

Response: In response to comments that CMS permanently allow RHCs and FQHCs to become distant sites for medical visits, we note that the use of telecommunications technology by RHCs and FQHCs to furnish medical visits was not within the scope of this proposal. However, we anticipate that the extension of payment for distant site telehealth services furnished by RHCs and FQHCs for a 151-day period after the end of the PHE, as established in the CAA, 2022, would mitigate concerns regarding gaps in care since it could

provide time for transitioning patients to come into the RHC or FQHC.

Comment: Commenters also provided comments on the following issues: Allowing RHCs and FQHCs to bill separately for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services; recognizing pharmacists, DSMT providers, licensed professional counselors (LPCs) and licensed marriage and family therapist (LMFTs) as RHC and FQHC practitioners; and allowing RHCs and FQHCs to bill psychiatric collaborative care codes (G2214, 99492–99494).

Response: We appreciate the feedback from commenters. Since we did not specifically make any proposals associated with these subjects in the CY 2023 PFS proposed rule, the comments are considered to be out of scope. We note that while we recognize that pharmacists, DSMT providers, LPCs, and LMFTs can be a valuable part of the health care team, we do not have the statutory authority to add providers to the list of RHC and FQHC practitioners whose services are included in the statutory definition of RHC and FQHC services, as specified in section 1861(aa)(1) and (3) of the Act, respectively. However, incidental services furnished by auxiliary personnel are allowed incident to an encounter with and RHC or FQHC practitioner if furnished in a medically appropriate timeframe, as described by 42 CFR 405.2413 and 405.2415. As for allowing RHCs and FQHCs to bill RPM and RTM services separately and allowing RHCs and FQHCs to bill psychiatric collaborative care codes, we will continue to evaluate and may consider these in future rulemaking.

After consideration of the comments received, we are finalizing our proposal to make conforming regulatory text changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X. Specifically, we are finalizing revisions at §§ 405.2463 and 405.2469 to reflect the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19 as proposed.

4. Specified Provider-Based RHC Payment-Limit Per-Visit

a. Background

As discussed in the CY 2023 PFS proposed rule (87 FR 46065 through 46066), beginning April 1, 2021, provider-based RHCs that meet qualifications in section 1833(f)(3)(B) of the Act are entitled to the special payment rules described in section 1833(f)(3)(A) of the Act. In order avail themselves of this exception, instead of utilizing the national statutory payment limit set out at section 1833(f)(2) of the Act, such RHCs have to meet the following specified criteria set out at section 1833(f)(3)(B)(i) of the Act:

- As of December 31, 2020, the provider-based RHC was in a hospital with less than 50 beds and after December 31, 2020 in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the PHE for COVID–19); and one of the following circumstances:

++ As of December 31, 2020, was enrolled in Medicare (including temporary enrollment during the PHE for COVID–19); or

++ Submitted an application for enrollment in Medicare (or a request for temporary enrollment during the PHE for COVID–19) that was received not later than December 31, 2020.

In accordance with section 1833(f)(3)(A)(i)(I) of the Act, beginning April 1, 2021, for provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or (2) the national statutory payment limit for RHCs per visit. We noted, the MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264) and we are finalizing to rebase and revise the MEI for CY 2023 as detailed in section II.M of this final rule.

In a subsequent year (that is, after 2021), the provider-based RHC's payment limit per visit shall be set at an amount equal to the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs.

As stated in the CY2022 PFS final rule (86 FR 65200), in accordance with section 1833(f)(3)(A)(i)(II) of the Act, beginning April 1, 2021, for provider-based RHCs that met the specified criteria under section 1833(f)(3)(B) of the Act, but did not have a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit would be set at an amount equal to the greater of: (1) the per visit payment amount applicable to the provider-based RHC for services furnished in 2021; or (2) the national statutory payment limit for RHCs.

In a subsequent year (that is, after 2021), the provider-based RHCs payment limit per visit will be the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs.

Once a provider-based RHC meets the qualifications of section 1833(f)(3)(B) of the Act, it will lose its designation if the hospital does not continue to have less than 50 beds, beyond the exemptions provided for the COVID–19 PHE. If this occurs the provider-based RHC would be subject to the statutory payment limit per visit applicable for such year and will not be able to regain the specified provider-based payment limit.

In the CY 2022 PFS final rule (86 FR 65204), we discussed the provisions in section 1833(f) of the Act [153] and finalized conforming regulations under § 405.2462. On March 16, 2021, we issued Change Request 12185, Transmittal 10679, to instruct the Medicare Administrative Contractors (MACs) to establish the provider-based RHC payment limits per visit in accordance with section 1833(f)(3)(A) of the Act, beginning April 1, 2021. Change Request 12185, Transmittal 10679, was rescinded and replaced by Transmittal 10780 issued on May 4, 2021.[154] Change Request 12489, Transmittal 11130, issued on November 19, 2021, implemented the RHC payment limits for CY 2022.[155]

b. Clarification to the RHC Payment Limit for Specified Provider-Based RHCs

As we discussed in the CY 2023 PFS proposed rule (87 FR 46066 through 46068), section 1833(f)(3)(A) of the Act instructed CMS to set payment limits per visit for specified provider-based RHCs under certain payment rules. For specified provider-based RHCs that had a per visit payment amount (that is, an AIR) established for services furnished in 2020, beginning April 1, 2021,

[153] As amended by Division CC, section 130 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260, December 27, 2020). Section 2 of H.R. 1868 (Pub. L. 117–7), enacted April 14, 2021, provided a technical correction to section 1833(f) of the Act. The amendments made by this technical correction took effect as if included in the enactment of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260).

[154] *https://www.cms.gov/files/document/r10780OTN.pdf.*

[155] *https://www.cms.gov/files/document/r11130cp.pdf.*

section 1833(f)(3)(A)(i)(I) of the Act requires the payment limit per visit to be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 or; (2) the statutory payment limit per visit as described in section 1833(f)(2)(A) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, the payment limit per visit shall be set at an amount equal to the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in the MEI or; (2) the statutory payment limit described in section 1833(f)(2) of the Act as applicable.

For specified provider-based RHCs that *did not* have an AIR established for services furnished in 2020, beginning April 1, 2021, section 1833(f)(3)(A)(i)(II) of the Act requires the payment limit per visit shall be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2021 or; (2) the statutory payment limit per visit as described in section 1833(f)(2)(A) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, the payment limit per visit shall be set at an amount equal to the greater of: (1) the amount established in the previous year increased by the percentage increase in the MEI or; (2) the statutory payment limit described in section 1833(f)(2) of the Act as applicable.

In the CY 2022 PFS final rule (86 FR 65201), we interpreted the ''per visit payment amount'' to align with the interim rate process the MACs use in determining an RHC's AIR.[156] That is, as explained in § 405.2464(a) the AIR is determined by the MAC using the most recently available cost report. Therefore, using the RHCs discussed in section 1833(f)(3)(A)(i)(I) of the Act as an example, we interpreted the term ''services furnished in 2020'' to mean the period at which the services were furnished in 2020 and that costs for those services were reported. We acknowledged that there may be more than one cost report that reports costs for services furnished in calendar year 2020 and explained that since section 1833(f)(3)(A)(i)(I)(aa) of the Act requires the ''per visit payment amount'' to be increased by the CY 2021 MEI, if a provider has a cost reporting period that differs from a calendar year time-period (that is, January 1, 2020 through December 31, 2020) then the MACs should use data based on the relevant cost report period ending in 2020.

We noted that in the CY 2022 PFS final rule (86 FR 65200), we received comments from interested parties expressing concern about how the payment limit per visit is established for specified provider-based RHCs. To be appropriately reflective of an individual clinic's true costs, one commenter stated that grandfathered, clinic specific, upper payment limits should be based on the final cost settled amount for cost reporting periods that end in 2020, or 2021 (for grandfathered RHCs that did not have cost reporting period that end in 2020), not an interim rate. If an interim final rate is necessary for the time period before final cost settled rates are adjudicated, the commenter suggested that CMS set interim clinic-specific upper limits only until such time that a final rate is established. In our response to these comments, we agreed, and stated that what the commenter described was aligned with the statute and how we implemented the payment limit per visit for specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, had their payment limit per visit based on their AIR determined from their final settled cost report ending in 2020 increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 (CY 2021 MEI of 1.4 percent). However, if the product of those two numbers (AIR established for services furnished in 2020 * 1.014) were less than the national statutory payment limit of $100, their payment limit per visit was established at $100. With regard to a specified provider based RHC that did not have an AIR established for services furnished in 2020 and received an interim rate until the MAC accepted and finalized the RHC's initial cost report, we again agreed with the commenter. We believed that what the commenter described also aligned with the statute and how we implemented the payment limit per visit for these specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that did not have an AIR established for services furnished in 2020, would have their payment limit per visit established based on their AIR determined by MACs using the RHC's final settled cost report ending in 2021. The interim rate estimate would be reconciled at cost report settlement for the cost reporting period ending in 2021 which is used to establish the RHC's payment limit per visit for services furnished in 2021.

In the proposed rule, we stated that since publication of the CY 2022 PFS final rule, interested parties requested clarification regarding the timing of cost reports, specifically if the payment limit could be set using a short cost report (less than 12 consecutive months). We noted that in the CY 2022 PFS final rule (86 FR 65198 through 65202), we did not specifically address requiring the cost report to span a full 12-consecutive month period or whether MACs, following their interim rate setting process, could establish the payment limit using a specified RHC's short period cost report (less than 12 consecutive months). Since many questions were raised subsequent to the publication of the CY 2022 PFS final rule regarding the use of short-period cost reports (less than 12 consecutive months) versus 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs, in the proposed rule, we provided a discussion of the issue and provided clarification.

For purposes of establishing the payment limit effective April 1, 2021 for specified provider-based RHCs defined in section 1833(f)(3)(A)(i)(I) of the Act, that is, had an AIR established for services furnished in 2020, we proposed that MACs use the cost report ending in 2020 that reports costs for 12 consecutive months. If the RHC does not have a 12-consecutive month cost report ending in 2020, the MACs should use the next most-recent final settled cost report that reports cost for 12 consecutive months. We explained that the proposal would impact specified provider-based RHC's that had an established AIR for services furnished in 2020 but submitted a short cost report (less than 12 consecutive months) ending in 2020 since that period would have been used by MACs for determining the RHC's payment limit per Change Request 12185, Transmittal 10679.

The payment limit per visit is based on each specified provider-based RHC's AIR determined from their final settled cost report ending in 2020 when such cost reporting period is for 12 consecutive months. If a 12-consecutive month cost report ending in 2020 is not available, we proposed that the MAC

[156] Note: A discussion of the interim rate process is provided in section III.A.2 of the CY 2022 PFS final rule (86 FR 65198 and 65199).

use the next available 12-consecutive month cost report that reports costs for RHC services furnished in 2020, (for example, a cost reporting period October 1, 2020 through September 30, 2021 would be acceptable).

We considered the idea of combining cost report data that spans from the end of one year into the next year to equal a 12-consecutive month cost report (for example, a cost report that consists of 3 months ending December 31, 2020 plus a cost report that ends July 31, 2021) and prorating the rates from the time services were furnished in both years. We decided against combining cost report data to equal a 12-consecutive month cost report because prorating may result in an inaccurate AIR. We sought comment on whether we should combine cost report data that spans from one year into the next year to equal a 12-consecutive month cost report.

Consequently, for purposes of establishing the payment limit effective April 1, 2021 for specified provider-based RHCs defined in section 1833(f)(3)(A)(i)(II) of the Act (that is, those that did not have an AIR established for services furnished in 2020), we proposed that MACs use the cost report ending in 2021 that reports costs for 12 consecutive months. We noted that if the RHC does not have a 12-consecutive month cost report ending in 2021, the MACs should use the next most-recent final settled cost report that reports cost for 12 consecutive months.

In addition, we noted that for those specified provider-based RHCs who did not have an AIR established for services furnished in 2020, the 2021 MEI percentage increase would not be applied. As discussed in the CY 2022 PFS final rule (86 FR 65200), for those specified provider-based RHCs, the payment limit per visit would be at an amount equal to the greater of: (1) the per visit payment amount applicable to the provider-based RHC for services furnished in 2021; or (2) the national statutory payment limit for RHCs, and since the MEI is already built in the rate for services furnished in 2021 adding an MEI update would be duplicative. Therefore, those specified provider-based RHCs that did not have an AIR established for services furnished in 2020 would receive the CY 2023 percentage increase in the MEI. For CY 2023, we proposed to rebase and revise the MEI to a 2017-base year as discussed in section II.M. of this final rule, we are finalizing the 2017-based MEI for CY 2023, with technical modifications based on public comments.

We noted that we believe the 12 consecutive months of cost report data would more accurately reflect the costs of providing RHC services and would establish a more accurate base from which the payment limits will be updated going forward. We sought comment on the proposed interpretation.

The following is a summary of the public comments received on the specified provider-based RHC payment-limit per-visit provision and our responses:

Comment: We received a few comments on our proposal to use 12-consecutive month cost reports versus short-period cost reports (less than 12 consecutive months) to establish the payment limit for specified provider-based RHCs. Commenters were generally supportive of the use of 12 consecutive month cost reports to establish the payment limit for specified provider-based RHCs.

Response: We appreciate commenters' support of the use of 12 consecutive month cost reports to establish the payment limit for specified provider-based RHCs.

Comment: We received a few comments on our proposal to rebase and revise the Medicare Economic Index (MEI) from a 2006-base year to a 2017-base year. One commenter thanked CMS for rebasing and revising the MEI in such a way that it reflects more accurate payments to RHCs, however, the commenter urged CMS to explore its authority to ensure that rural practitioners are reimbursed a rate that reflects the current economic reality. Another commenter acknowledged and appreciated CMS' proposal to rebase the MEI for CY2023, but encouraged CMS to remain attentive to the inflationary impacts on providers now and over the coming years and to address the MEI formula accordingly. Another commenter urged CMS to establish a requirement to rebase the payment every 3 years or sooner as the market inflation costs will quickly fall below reimbursement rates.

Response: As we noted in the CY 2023 proposed rule (87 FR 46067) and as discussed in section II.M. of this final rule, the MEI is authorized under section 1824(b)(3) of the Act. The MEI reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. CMS calculates the MEI for several statutory and other purposes, which includes the RHC payment policies. As discussed in section II.M of this final rule, we are finalizing the 2017-based MEI for CY 2023 with technical modifications in response to public comments. The CY 2023 MEI update is 3.8 percent based on historical data through the 2nd quarter of 2022, of the finalized 2017-based MEI.

Comment: One commenter encouraged CMS to consider a more sustainable payment policy because they noted that over the years the RHC reimbursement policy has evolved to include a variety of different methodologies and systems patched together, which has led to increasingly complicated RHC billing and coding rules.

Response: We reiterate that in this year's proposed rule, we focused on providing clarification regarding the timing of cost reports, specifically, the use of short-period cost reports (less than 12 consecutive months) versus 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs. We note that in the CY 2022 final rule (86 FR 65199–65201), we discussed section 130 of the Consolidated Appropriations Act, 2021, which explained the implementation of the national statutory payment limit for RHCs, where RHCs will receive an increase in their payment limit per visit, over an 8-year period, with a prescribed amount for each year from 2021–2028. Then, in a subsequent year, at the limit established for the previous year increased by the percentage increase in the applicable MEI. We believe the intent of section 130 of the CAA was to provide sustainable payment for RHCs. The commenter did not provide examples of complicated billing and coding rules and we look forward to further engagement on these concerns.

After consideration of the public comments, we are finalizing our proposal to use 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs as proposed.

C. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions, and Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of

all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016 through June 30, 2016. The first data reporting period occurred from January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties (CMPs) for failure to report applicable information with respect to the initial data reporting period.[157]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand their experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage (MA) plan payments under Part C from the denominator of the Medicare revenues threshold calculation, in an effort to broaden the types of laboratories qualifying as applicable laboratories. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as applicable laboratories (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period. Because MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount than what they would have been compared to if MA plan payments remained in the denominator. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as applicable laboratories and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019 through June 30, 2019, and the next data reporting period was scheduled to take place from January 1, 2020 through March 31, 2020, with the next update to the Medicare payment rates for these tests based on that reported applicable information scheduled to take effect as of January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502.

Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website.[158]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, enacted on December 20, 2019), and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, enacted on March 27, 2020), revised the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs under section 1834A of the Act. Additionally, the CARES Act revised the phase-in of payment reductions under section 1834A of the Act. Specifically, section 105(a)(1) of the

[157] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

[158] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

FCAA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2021 through March 31, 2021; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period of January 1, 2021 through March 30, 2021 would be the period of January 1, 2019 through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the CARES Act further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022 through March 31, 2022. As amended by the CARES Act, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that: (i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2021; (ii) reporting is required during the period beginning January 1, 2022, and ending March 31, 2022; and (iii) reporting is required every 3 years after the period described in clause (ii).

The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2022 through March 31, 2022) would have been based on the data collection period of January 1, 2019 through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2022 through 2024, instead of CYs 2021 through 2023.

In the CY 2021 PFS rulemaking (85 FR 50210 through 50211 and 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we finalized revisions to § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019. We also revised § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, enacted on December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023 through March 31, 2023; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023 through March 31, 2023) will continue to be based on the data collection period of January 1, 2019 through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

5. Conforming Regulatory Changes

In accordance with section 4(b) of PMAFSCA, in the CY 2023 PFS proposed rule (87 FR 46068 through

46070), we proposed to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we proposed to revise § 414.502 to update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2023. In addition, we proposed to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4(b) of PMAFSCA. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We noted that the CYs 2022 and 2023 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016 through June 30, 2016. We explained that under current law, the CLFS payment rates for CY 2024 through CY 2026 for these tests will be based on applicable information collected during the data collection period of January 1, 2019 through June 30, 2019 and reported to CMS during the data reporting period of January 1, 2023 through March 31, 2023.

The following is a summary of the public comments received on the proposed conforming regulatory changes and our responses:

Comment: Several commenters supported our proposal to revise §§ 414.502, 414.504 and 414.507 to conform with the current statutory provisions governing data reporting and payment for CDLTs on the CLFS.

Response: We appreciate the commenters' support for these regulatory changes that reflect the recent statutory revisions required by section 4 of PMAFSCA.

Comment: One commenter requested that the CLFS data collection period be revised to January 1, 2022, through June 30, 2022, from the current data collection period of January 1, 2019, through June 30, 2019. The commenter asserted that such a change would serve to better reflect the current market conditions and private payor rates for laboratory tests.

Response: We note that section 4 of PMAFSCA did not modify the data collection period that applies to the next data reporting period for CDLTs that are not ADLTs. Therefore, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023, through March 31, 2023) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502. Because this requirement is statutory, we are unable to modify the data collection period.

Comment: Several commenters suggested that CMS delay implementation of the phase-in of payment reductions under the CLFS for CY 2023 and instead utilize a 0.0 percent payment reduction for CY 2023.

Response: We note that the phase-in of payment reductions to the CLFS payment amounts is statutory; therefore, we are unable to delay implementation and apply 0.0 percent payment reduction for CY 2023. The statute expressly states that there will be a 0.0 payment reduction for CY 2022 and, for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

In consideration of these public comments and in accordance with section 4(b) of PMAFSCA, we are finalizing the proposed conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G, as proposed.

6. Laboratory Specimen Collection Fee and Travel Allowance Policies

As discussed in the CY 2023 PFS proposed rule (87 FR 46070 through 46074), section 1833(h)(3) of the Act generally requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), in addition to the amounts provided under the Medicare CLFS. We proposed to codify our longstanding specimen collection fee policies at § 414.523(a)(1) and our travel allowance policies at § 414.523(a)(2), as well as certain changes to modify or clarify those policies.

a. Background on Laboratory Specimen Collection Fee Policy

Medicare Part B, which includes a variety of outpatient services, generally covers medically necessary CDLTs when a doctor or non-physician practitioner orders them. Medically necessary CDLTs generally are not subject to coinsurance or deductible. Section 1833(h)(3)(A) of the Act provides that, in addition to the amounts provided under fee schedules (for tests furnished before January 1, 2017) or under section 1834A of the Act (for tests furnished on or after January 1, 2017), the Secretary shall provide for and establish a nominal fee to cover the appropriate costs in collecting the sample on which a CDLT was performed and for which payment is made under Medicare Part B, except that not more than one such fee may be provided with respect to samples collected in the same encounter. As detailed in the proposed rule, we provided manual instructions regarding payment of the nominal specimen collection fee in the Medicare Claims Processing Manual Pub. 100–04, chapter 16, section 60.1,[159] but we have not reflected these general policies in our regulations.[160] The HCPCS codes for the nominal specimen collection fees currently listed on the CLFS (HCPCS codes 36415, P9612, and P9615 [161]) have a payment rate of $3. Neither the annual deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection fees or travel allowance for laboratory tests.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1834A(b)(5) to the Act, which increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a specimen collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a HHA. Therefore, effective April 1, 2014, the nominal fee that would otherwise apply for a specimen collected from an individual in a SNF or by a laboratory on behalf of a HHA is $5, and the relevant HCPCS code is G0471.[162] We

[159] The Medicare Claims Processing Manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS018912*.

[160] In 1993, we proposed to implement the payment methodologies for the specimen collection fee and travel allowance in the regulations, see 53 FR 43837 through 43838, but did not finalize those proposals.

[161] HCPCS codes and long descriptors: 36415 (Insertion of needle into vein for collection of blood sample); P9612 (Catheterization for collection of specimen, single patient, all places of); P9615 (Catheterization for collection of specimen(s) (multiple patients)).

[162] HCPCS code and descriptor: G0471 (*Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled*

implemented this provision in our regulations at § 414.507(f). However, as we discussed in the proposed rule, we proposed to codify our specimen collection fee policies in § 414.523(a)(1), including moving that provision from § 414.507(f) to § 414.523(a)(1)(iv).

In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), which appeared in the **Federal Register** on April 6, 2020 (85 FR 19230), we established that Medicare would pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 CDLTs for homebound and non-hospital inpatients (85 FR 19256 through 19258). Under this policy, the nominal specimen collection fee for COVID–19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a SNF and individuals whose samples are collected by laboratory on behalf of an HHA is $25.46. We indicated in that IFC that this specimen collection fee policy was established for the duration of the PHE for COVID–19 (85 FR 19256) and noted in that IFC and subsequent rules (86 FR 39309; 86 FR 65327) that this policy will end once the PHE for the COVID–19 pandemic has ended.

In the CY 2022 PFS proposed rule (86 FR 39310), we requested broad comments on our policies for specimen collection fees for consideration for possible updates to those policies in the future through notice and comment rulemaking. We requested comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), how specimen collection practices may have changed as a result of, or from insight gained during, the PHE for COVID–19, and what additional resources might be needed for specimen collection for COVID–19 CDLTs and other tests after the PHE ends, as well as comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients. In the CY 2022 PFS final rule (86 FR 65327 through 65328), we described the comments received and provided responses to those comments. We expressed appreciation for the comments regarding the nominal specimen collection fees for the collection of specimens for COVID–19 CDLTs and acknowledged that the types of resources utilized and supplies needed for specimen collection have been influenced by the PHE for COVID–19. We stated that although we would not extend the increased payment amount beyond the PHE, we would take the feedback received from the comment solicitation into consideration for possible future rulemaking and guidance.

b. Longstanding Laboratory Specimen Collection Fee Policies and Practices

In the CY 2023 PFS proposed rule (87 FR 46071 through 46073), we explained that CMS has longstanding policies and practices regarding the statutory requirements under section 1833(h)(3)(A) of the Act for the laboratory specimen collection fee, which are currently described in the Medicare Claims Processing Manual Pub. 100–04, chapter 16, § 60.1. However, we do not have corresponding regulations text related to the manual guidance and some of the manual guidance is no longer applicable. The manual guidance specifies when a specimen fee is allowed and not allowed. In particular, the manual provides guidance on the following topics: (1) specimen drawing by a physician; (2) specimen drawing by an independent laboratory; (3) specimen drawing for a dialysis patient; and (4) the coding requirements for specimen collection. We noted that laboratory services, including specimen collection and travel for specimen collection, paid under the CLFS must be reasonable and necessary as required under section 1862(a)(1)(A) of the Act.

Specifically, the guidance provides that a specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (that is, inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for a throat culture or a routine capillary puncture for clotting or bleeding time. Additionally, the specimen fee will not be paid to anyone who has not extracted the specimen. The manual guidance addresses the number of specimen collection fees allowed for each specimen type per patient encounter. The manual also addresses how to treat a series of specimens; when a series of specimens is required to perform a single test (for example, a glucose tolerance test), the series is treated as a single encounter.

The Medicare Claims Processing Manual (chapter 16, § 60.1.1) describes specimen collection fees for physicians. Specifically, the manual states that Medicare allows a specimen collection fee for physicians only when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.

We noted that, in reviewing the specimen collection criteria for physicians to be paid for this service, we had concerns regarding outdated terminology and the eligibility criteria for these suppliers to bill Medicare for a specimen collection fee. For example, we found that these criteria were established prior to January 1, 1992, which is when Medicare began to pay for physicians' services under section 1848 of the Act (56 FR 59502). Since that time, the provision of laboratory services and physicians' services have evolved. Therefore, we evaluated those criteria as they would apply today. In consideration of current standards of practice, we analyzed utilization of the specimen collection Current Procedural Terminology (CPT®) codes to determine if the physician office setting is billing for this fee. We found that, in 2019, office-based physician and nonphysician practitioners had 67.4 million claims billed with specimen collection, comprising 31.1 percent of all specimen collection claims.

We also looked to the PFS to see if there are similar services that physicians and nonphysician practitioners can bill and be paid for under section 1848 of the Act. We found that there are codes available that address collection of blood, for example, CPT® codes 36410 (Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture)). These findings confirmed specimen collection occurs in the physician's office setting and there are coding options to bill for that service via the PFS when applicable. Therefore, we noted that we believed the criteria currently included in the manual for physician eligibility for the CLFS specimen collection fee no longer apply. We stated that we would not reflect those policies in regulation and would remove this section of the manual accordingly.

The Medicare Claims Processing Manual (chapter 16, § 60.1.2) describes policies for specimen drawing by independent laboratories. Specifically, the manual states the following:

nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)).

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another. Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. Payment for the specimen collection fee is made based on the CLFS. The technician must personally draw the specimen, for example, venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is: (1) not confined to the facility; or (2) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, for example, urine or sputum, a specimen pickup service would not be considered medically necessary. The manual then refers to the Medicare Benefit Policy Manual, Chapters 7 and 15 of Pub. 100–02, for a discussion of ''homebound'' and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.

Under sections 1814(a) and 1835(a) of the Act, an individual shall be considered to be ''homebound'' or ''confined to his home'' if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered ''confined to his home,'' the condition of the individual should be such that there exists an inability to leave home such that leaving home requires a considerable and taxing effort by the individual. Moreover, § 424.22(a)(1)(ii) describes homebound for the purposes of the provision of Medicare home health services as home health services are or were required because the individual is or was confined to the home, as defined in sections 1835(a) and 1814(a) of the Act, except when receiving outpatient services. Additionally, chapter 15 of the Medicare Benefit Policy Manual [163] Section 60.4.1—''Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit'' describes the definition of homebound in that the patient is confined to his/her home, which has two criteria: (1) the patient must either, because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence; or (2) otherwise have a condition such that leaving his or her home is medically contraindicated. The patient must also meet two additional requirements defined in criterion two such that there must exist an inability to leave home; and leaving home must require a considerable and taxing effort.

The Medicare Claims Processing Manual (chapter 16, § 60.1.2) also explains the information that must be included on an independent laboratory claim for specimen drawing. Specifically, the manual states that in addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing ordered by a physician should be appropriately annotated, for example, ''patient confined to home,'' ''patient homebound,'' or ''patient in nursing home, no qualified person on duty to draw specimen.'' The manual states that A/B MACs (B) must assure the validity of the annotation through scientific claims samples, as well as through regular bill review techniques. (This could be done by use of the information in A/B MAC (B) files, and where necessary, contact with the ordering physician.) If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, medical necessity criteria in Medicare Benefit Policy Manual, Chapter 15, the manual provides that an educational contact with the ordering physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met. The manual states that the specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.

The Medicare Claims Processing Manual (chapter 16, § 60.1.3) describes specimen drawing for dialysis patients. It states that, with the implementation of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.[164] Clinical laboratory tests for dialysis patients can be performed individually or in predetermined groups on automated profile equipment. The manual states that a specimen collection fee determined by CMS will be allowed only in the following circumstances:

- Drawing a blood sample through venipuncture (that is, inserting into a vein a needle with a syringe or vacutainer to draw the specimen).
- Collecting a urine sample by catheterization.

The manual provides that special rules apply when such services are furnished to dialysis patients. That is, the specimen collection fee is not separately payable for patients dialyzed in the ESRD facility or for patients dialyzed at home. A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements. Payment for specimen collection is included under the ESRD PPS, regardless of whether the laboratory test itself is designated as payable under the ESRD PPS as a renal dialysis service or is separately billable by the ESRD facility with the AY modifier (*see* Medicare Claims Processing Manual, chapter 16, § 40.6). Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD PPS base rate, may be paid separately.

We stated that we believed that the implementation of the ESRD PPS made the specimen collection provision for ESRD beneficiaries in the ESRD facility setting obsolete. That is, prior to the ESRD PPS, ESRD facilities could be paid for laboratory services furnished to ESRD beneficiaries that were considered to be separately payable. Under the prior composite rate system, ESRD

[163] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[164] The manual refers to the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite rate.

facilities with the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification could bill Medicare Part B directly and be paid based on the CLFS for certain laboratory tests, and when appropriate, for a specimen collection fee.[165] In implementing the ESRD PPS, we also implemented consolidated billing requirements in the CY 2011 ESRD PPS final rule (75 FR 49168 through 49173). In that ESRD PPS final rule, we stated that we established these consolidated billing requirements because the ESRD PPS provides an all-inclusive payment for renal dialysis services and home dialysis items and services and the ESRD facility is responsible for all of the renal dialysis services that its patients receive. We further explained that items and services that were paid separately under the basic case-mix adjusted composite rate (such as laboratory tests), would no longer be billed for by other entities (such as laboratories), and therefore, payment for these services would be made only to the ESRD facility so that duplicate payment is not made by Medicare (75 FR 49168).

Additionally, section 1881(b)(14)(B)(i) and (iv) of the Act provides that items and services included in the prior composite rate and other diagnostic laboratory tests not reflected in the composite rate that are furnished to individuals for the treatment of ESRD are renal dialysis services that must be included as part of the ESRD PPS bundled payment. In the CY 2011 ESRD PPS final rule, we explained that patients with ESRD often have comorbid conditions which would require many of the same laboratory tests as those required to monitor a patient's ESRD (75 FR 49168). In that ESRD PPS final rule, we acknowledged that it may be difficult to differentiate between a renal dialysis service laboratory test and tests ordered for non-renal dialysis service conditions. Therefore, to ensure proper payment in all settings, as part of the consolidated billing approach, we provided ESRD facilities and independent laboratories the ability to identify non-renal dialysis service laboratory tests, by using the AY modifier, which allows for separate payment under Medicare Part B (75 FR 49168 through 49169). We noted that while this longstanding policy permits ESRD facilities to be paid separately for the non-renal dialysis service laboratory tests, the specimen collection fee is no longer available since staff time used to collect specimens is considered to be a composite rate service (§ 413.171), and therefore, payment for specimen collection is made through the ESRD PPS bundled payment to the ESRD facility. Therefore, we stated that we believed this section of the manual guidance describing specimen drawing for dialysis patients is no longer applicable, and we would not reflect this policy in regulation and would remove this section of the manual accordingly. We noted when an ESRD beneficiary goes to an independent laboratory or a hospital setting, the same payment rules would apply for specimen collection as they would for a non-ESRD beneficiary for that setting.

Lastly, the Medicare Claims Processing Manual (chapter 16, § 60.1.4) includes coding requirements for the specimen collection fees. Specifically, the following HCPCS codes and terminology must be used:

- 36415—Collection of venous blood by venipuncture.
- G0471—Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA).
- P9612—Catheterization for collection of specimen, single patient, all places of service.
- P9615—Catheterization for collection of specimen(s) (multiple patients).

c. Codification of the Laboratory Specimen Collection Fee Policy in Regulation

As noted previously, most of our laboratory specimen collection fee policies are not reflected in the CLFS regulations. In the CY 2023 PFS proposed rule, we proposed the laboratory specimen collection fee policies we would include in regulations.

Section 1833(h)(3) of the Act specifies that payment amounts for the specimen collection fee and travel allowance are ''in addition'' to the payment amounts for CDLTs on the CLFS. As § 414.507 pertains to payment for CDLTs, we stated that we believed it would be appropriate to create a separate regulation to more clearly reflect that payment for the specimen collection fee and travel allowance is in addition to payment for CDLTs. We proposed to create § 414.523 titled *Payment for laboratory specimen collection fee and travel allowance.* We proposed to specify in § 414.523(a) that in addition to the payment amounts provided for CDLTs, new CDLTs, and new ADLTs, CMS would pay a specimen collection fee and a travel allowance. In § 414.523(a)(1), we proposed that we would reflect the longstanding specimen collection fee policies described in the manual that continue to be applicable. As noted in the proposed rule, we would not reflect in the regulation the specimen collection fee policies that are no longer applicable—specifically, the policies relating to physician eligibility for specimen collection and specimen drawing for dialysis patients—and would remove those policies from the manual.

First, we proposed that § 414.523(a)(1) would specify that CMS will pay $3 for all specimens collected in one patient encounter. As previously stated, section 1833(h)(3)(A) of the Act requires the Secretary to provide for and establish a nominal fee to cover the appropriate costs in collecting the sample for laboratory testing. We have paid $3 as the nominal specimen collection fee amount for several years and proposed to maintain the $3 amount. We noted that the statute specifies that the amount is ''nominal'' and we believed $3 is an appropriate nominal amount to recognize the costs associated with specimen collection. We also stated that we believed that in enacting section 216(a) of PAMA, Congress recognized CMS's authority to establish the specific nominal fee amount as $3 when it added section 1834A(b)(5) of the Act to increase by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a specimen collected from an individual in a SNF or by a laboratory on behalf of an HHA. We solicited comments on the proposal to maintain the $3 nominal specimen collection fee amount, including how this amount could be updated.

We proposed to move and clarify the provision in our regulations regarding the increased specimen collection fee under section 1834A(b)(5) of the Act, as discussed in the previous paragraph. We explained that we implemented this PAMA requirement in a Medicare Change Request (CR) transmittal effective December 1, 2014 (Transmittal #R3056CP; CR #8837) and ultimately finalized this policy in § 414.507(f).[166] The CR provides that, in the case of a specimen collected from an individual in a SNF or from an individual by a laboratory on behalf of a HHA (billed using new HCPCS code, G0471 (*Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health*

[165] Pub. 100–02, Chapter 11, Section 20.2.E.2 and 3. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[166] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3056CP.pdf.*

agency (HHA))), the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act shall be increased by $2, from $3 to $5, in accordance with section 216(a) of the PAMA. The specimen collection fee is raised from $3 to $5 only when the specimen is being collected by a laboratory technician and when the specimen is from an individual in either a SNF or HHA. We proposed that this requirement, which is currently reflected in § 414.507(f), would be moved to § 414.523(a)(1)(iv) and would be revised to state that beginning April 1, 2014, for a specimen collected from a Medicare beneficiary in a SNF or on behalf of an HHA, the specimen collection fee otherwise paid under paragraph (a)(1) of § 414.523 is increased by $2.

In addition, we proposed to include in regulation that one specimen collection fee would be allowed for each single patient encounter. This means that, if different types or multiple specimens are drawn from one patient, only one specimen collection fee would be allowed. We noted in the proposed rule that we believed this policy is consistent with section 1833(h)(3)(A) of the Act, which provides that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter. We proposed to reflect this policy in § 414.523(a)(1) by indicating that CMS pays $3 for ''all specimens collected in one patient encounter.''

In § 414.523(a)(1)(i) through (iii), we proposed to indicate the specimen collection requirements that must be met for a specimen collection fee to be payable are as follows. The specimen is: used to perform a CDLT paid under the CLFS regulations in 42 CFR part 414, subpart G; collected by a trained technician from a Medicare beneficiary who is homebound as described in 42 CFR 424.22(a)(1)(ii) or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; of the following type—blood specimen collected through venipuncture or a urine sample collected by catheterization.

In § 414.523(a)(1)(ii), we proposed to clarify the requirement that the specimen must be collected by a ''trained technician.'' Section 1833(h)(3) of the Act refers to staff providing specimen collection services as ''trained personnel'' whereas the Medicare Claims Processing Manual, chapter 16, section 60.2, refers to ''the technician.'' The United States Bureau of Labor Statistics (BLS) defines clinical laboratory technologists and technicians as workers who collect samples and perform tests to analyze body fluids, tissue, and other substances.[167] The term ''laboratory technician'' may not apply to those staff that would generally be providing specimen collection services, as the staff collecting specimens may not also be involved in analyzing the specimens. Therefore, for the purposes of our Medicare payment policies for specimen collection and travel allowance, we proposed to use the phrase ''trained technician'' to refer to those staff providing specimen collection services. We noted that we believed this clarification would more closely align the regulatory text pertaining to specimen collection and travel allowance with the statute.

As discussed in the proposed rule, Medicare allows payment of a specimen collection fee when it is medically necessary for a trained technician to draw a specimen from either a nursing home patient or homebound patient. Medicare does not allow a specimen collection fee for the technician if a patient in a facility is: (1) not confined to the facility; or (2) the facility has qualified personnel available to perform the specimen collection. We proposed to reflect in regulation that the specimen must be collected either from a Medicare beneficiary who is homebound as described in § 424.22(a)(1)(ii), or from a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen. We noted that we believed the proposed requirement regarding homebound beneficiaries would be consistent with Medicare policy, which describes home health services requirements. We proposed to clarify that payment for specimen collection would only be made to the laboratory when no qualified personnel are available at the inpatient facility to collect the specimen. We also noted that we believed the proposed clarification would reflect the justification for ''medical necessity'' for purposes of section 1862(a)(1) of the Act. We proposed to codify the requirement in § 414.523(a)(1)(ii)(B) but would not explicitly state the term ''medically necessary''.

We proposed to clarify that a specimen collected by a trained technician would have to be either blood collected through venipuncture or a urine sample collected by catheterization. We proposed to codify the requirement in § 414.523(a)(1)(iii), which would state that the specimen collection fees are permitted for only these two types of specimens: (1) blood collected through venipuncture or (2) a urine sample collected by catheterization. We acknowledged that the manual guidance (described above) uses the terms ''such as'' and ''example'' to describe the types of specimens for which specimen collection fees are paid, which suggests that specimen collections of samples other than blood and urine are eligible for specimen collection fees. We noted, however, that there are only two HCPCS codes for the two types of specimen collections, which means we do not pay, and have not been paying, specimen collection fees for any other types of specimens. Therefore, as discussed in the proposed rule, under our current policy a specimen collection fee would not be payable for any other specimen types, for example, a throat culture or a routine capillary puncture for clotting or bleeding time.

We welcomed public comment on the proposed codification and modification of the laboratory specimen collection fee policies. We noted that if finalized, we would make conforming changes to the Medicare Claims Processing Manual, Chapter 16, section 60, to reflect changes or clarifications and remove sections that are no longer applicable.

Lastly, we solicited comments on specimen collections performed by physician office laboratories (POLs). As discussed in the CY 2023 PFS proposed rule, we proposed to delete the section in the manual regarding physician specimen collection, as codes exist to describe these services when performed by physicians under the PFS. However, we noted in the proposed rule that we understand that specimens may be collected in the physician's office by POL personnel. As stated in 42 CFR 410.32(d)(1)(iii), Medicare Part B pays for covered diagnostic laboratory tests that are furnished by the office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine. When the physician's office is furnishing CDLTs for its own patients and collecting specimens for those tests, we do not believe this would include specimen collection for homebound or non-hospital inpatients or involve travel for specimen collection, since a POL is not an independent laboratory. However, we sought comments on any possible considerations for the removal of the manual section related to POL specimen collection.

The following is a summary of the public comments received on the laboratory specimen collection fee proposals and our responses:

[167] *https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.*

Comment: Several commenters supported our proposal to codify longstanding specimen collection fee policies at § 414.523(a)(1), as well as our proposal to make certain changes to modify or clarify those policies. Other commenters appreciated the ability to be paid for laboratory specimen collection.

Response: We appreciate the commenters' support to codify longstanding specimen collection fee policies and make certain changes to modify or clarify those policies, as well as commenters' support for the payment of laboratory specimen collection required by section 1833(h)(3)(A) of the Act.

Comment: We received several comments on our proposal to maintain the $3 fee for specimen collection for venous blood by venipuncture (CPT® code 36415) and the $5 fee for specimen collection from a beneficiary in a SNF or by a laboratory on behalf of a home health agency (HCPCS code G0471). Some commenters requested that we increase the $3 specimen collection fees, with requested amounts ranging from $8.28 to $12, to account for labor shortages, wage increases, supplies cost increases, and inflation. Several commenters also recommended that CMS update the specimen collection fee for inflation by utilizing the CPI–U for the years since the establishment of the specimen collection fee and that CMS continue utilizing such an update for future years in order to account for the changes in costs for resources related to specimen collection.

One commenter that requested an increase in the specimen collection fee amount to $8.28 supported their suggestion with an analysis of the costs associated with collecting a blood specimen using cost data, including supplies, wages, and benefits from three laboratories—one that services a variety of clients, one that services physician offices and SNFs, and one that services only SNFs—and selected the least expensive cost provided by the three laboratories for each line item in the cost analysis.

Several commenters requested that we increase the $3 and $5 specimen collection fee amounts to $12 and $14, respectively. The commenters noted that the $3 amount was inadequate when it was first implemented and the costs to provide specimen collection services have increased exponentially since the implementation of the fee. These commenters opined that a $12 collection fee amount is a ''nominal'' amount and is approximately one-half of the 2020 Medicare reimbursement for CPT® code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional), which, though less complex than specimen collection, is comparable in that the presenting problems are minimal, the service does not require the presence of a physician or other health care professional, and the service typically takes less than 5 minutes to complete. Commenters also noted that we drew this same comparison to CPT® code 99211 when determining a ''nominal'' fee for COVID–19 specimen collection.

One commenter stated that, in contrast to specimen collections for venous draws billed under CPT® code 99211 for Level 1 office visits, venous draws from patients in nursing homes are far more challenging because nursing home patients are often being treated with medications that affect their cognition, specimen collections may occur in the pre-dawn hours, and many patients suffer from multiple complex co-morbidities, which can complicate a venous draw. Additionally, the commenter noted that technicians collecting samples from Medicare beneficiaries in SNFs are also faced with numerous operational barriers and that the $5 reimbursement for specimen collection from SNF patients is approximately 80 percent less than reimbursement for a Level I office visit billed under CPT® code 99211.

Response: We appreciate the thoughtful and detailed recommendations and comments on our proposal to maintain the $3 nominal specimen collection fee amount, and we recognize that some commenters believe this longstanding nominal fee amount does not cover the costs of specimen collection. As previously discussed, section 1833(h)(3)(A) of the Act requires the specimen collection fee to be ''nominal,'' which suggests that Congress did not intend it to be reimbursement for actual or specific costs. In fact, in 2014, Congress established a requirement in PAMA under section 1834A(b)(5) of the Act that specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA be paid an additional $2. We believe that specification of an additional $2 amount for those types of specimen collection was some indication Congress considered the $3 specimen collection fee at the time to be an appropriate amount and consistent with what Congress considered to be a ''nominal'' amount; Congress could have changed the $3 amount when it required the additional $2 for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA. The statute also specifies that the nominal fee must ''cover the appropriate costs in collecting the sample.'' The history of the laboratory specimen collection fee policy indicates that drawing, collecting, or handling a specimen were the costs the policy was intended to cover.[168] [169] [170] We believe these activities continue to be appropriate costs to be covered by the nominal specimen collection fee. While we have long considered the $3 fee amount to be an appropriate nominal fee to reflect those costs, based on the comments received and our further analysis, we believe that it is appropriate to now update the specimen collection fee amount for CY 2023, and continue to update it in subsequent years.

As commenters have stated, costs related to collecting, drawing, and handling specimens have increased over the years, with the PHE for COVID–19 starkly highlighting those increased costs and the ongoing need for specimen collection services. Commenters noted that the costs of drawing, collecting, or handling specimens have also increased due to typical inflation, among other factors, and these factors are expected to persist even once the PHE for COVID–19 ends. We recognize there are costs associate with the types of items and services necessary for drawing, collecting, or handling a specimen, and we understand there are an array of financial pressures associated with the maintenance of supplies and retaining staff, such as supply shortages, labor shortages, or wage increases. While the specimen collection fee is not intended to reimburse laboratories for actual costs incurred for drawing, collecting, or handling a specimen, we believe updating the $3 amount for inflation is an appropriate way for CMS to recognize that specimen collection costs do increase, and that increasing the nominal fee by the CPI–U will address those growing pressures.

We appreciate commenters' analysis of specimen collection costs to justify updating the $3 amount. However, as we explained above, we do not believe the nominal fee for specimen collection is intended to reimburse for specific

[168] See Omnibus Reconciliation Act of 1980 (OBRA), (Pub. L. 96–499), *https://www.congress.gov/96/statute/STATUTE-94/STATUTE-94-Pg2599.pdf*.

[169] See section 2023 of the Deficit Reduction Act of 1984, July 18, 1984, *https://www.congress.gov/98/statute/STATUTE-98/STATUTE-98-Pg494.pdf*.

[170] *https://www.ncbi.nlm.nih.gov/books/NBK223053/*.

costs. Therefore, we did not consider the data analysis provided by the commenter as a source for establishing an amount. We note, however, that the specimen collection fee amount resulting from the approach we are finalizing, $8.57, is very close to the amount suggested by the commenter, $8.28. We are also not accepting commenters' suggestion that we increase the specimen collection fee to $12 because it is approximately one-half of the 2020 Medicare reimbursement for CPT® code 99211. Although in the April 6, 2020 IFC, we did use CPT® code 99211 as a benchmark to establish a nominal fee for COVID–19 specimen collection, we believe the circumstances involved for routine specimen collection are vastly different from those involving collecting a sample to diagnosis a novel communicable infectious disease. As we discussed in the April 6, 2020 IFC (85 FR 19256), we had to look to similar services in other settings of care as a potential benchmark absent concrete information regarding the costs associated with independent laboratories collecting such specimens for COVID–19 tests in the context of the PHE. We believe the $3.00 nominal fee is our benchmark for recognizing the costs associated with routine specimen collection, and deriving a fee amount based on a PFS service of CPT® code 99211 is not applicable outside of the PHE.

As we noted above, we believe that it is appropriate to now update the specimen collection fee amount for CY 2023, and continue to update it in subsequent years, and we believe using the CPI–U is an appropriate way to do both. To establish the nominal specimen collection fee for CY 2023, we first calculated the inflation factor to be applied to the $3.00. To derive this inflation factor, we used the historical CPI–U from June of 2022 and divided it by the historical CPI–U for June 1984. We selected June of 1984 as the comparison date (that is, the date we are comparing past $3 value with present-day value) because that is the year Congress established the CLFS and the related laboratory specimen collection fees under section 1833(h)(3)(A) of the Act. We selected June 2022 as the date that reflects the present day because this will allow us to update the specimen collection fee amount for future years to reflect historical growth for a 12-month period in a consistent manner. This methodology, June 2022 CPI–U/June 1984 CPI–U, yielded an inflation factor of 2.857. We multiplied the inflation factor of 2.857 by $3, which resulted in a payment rate of $8.57 ($3 × 2.857=$8.57). Accordingly, we are finalizing $8.57 as the nominal specimen collection fee for CY 2023. In addition, as required by PAMA, we are increasing this amount by $2 for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA, which results in $10.57 as the specimen collection fee amount for specimens collected from those beneficiaries.

Comment: Several commenters requested that we utilize the CPI–U to update the specimen collection fee amounts on an annual basis moving forward in order to account for the impact of inflation.

Response: We appreciate the commenters' recommendations on how we might update the specimen collection fee amounts in future years. As we stated above, we are finalizing an increase to the specimen collection fee amount from $3 to $8.57 for CY 2023. As we also noted above, after considering the comments and conducting further analysis, we believe that it is appropriate to update the nominal specimen fee to account for inflation in subsequent years and we believe using CPI–U is an appropriate way to account for the annual impact of inflation on costs of drawing, collecting, or handling specimens.

Thus, we are finalizing that, beginning January 1, 2024, we will update the specimen collection fee amount of $8.57 for each calendar year using the 12-month percentage increase in the CPI–U of the most recent year of data published by BLS, that is for the 12-month period ending June 30th of the year preceding the update year. We believe that updating the fee based on the 12-month percentage increase in the CPI–U is consistent with other CLFS authorities such as section 1833(h)(7) of the Act, which requires us to update the payment amount for a diagnostic or screening pap smear laboratory test annually by a percentage increase or decrease equal to the percentage increase or decrease in the CPI–U, as well as other Medicare payment systems (for example, the CLFS prior to 2018, the Ambulance Fee Schedule, and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Fee Schedule (DMEPOS)). In addition, we selected the updated period as the 12-month period ending June 30th of the year preceding the update year, to maintain consistency with Medicare payment systems that are updated on annual basis.

Comment: One commenter requested we establish a nominal fee to cover the packaging and shipping of definitive drug testing collection kits to and from patients who are being treated remotely.

Response: Section 1833(h)(3)(A) of the Act requires the specimen collection fee to cover the appropriate costs of collecting the sample on which a CDLT is performed. The statute does not specify the establishment of a fee to cover packaging and shipping of definitive drug testing collection kits to and from patients who are being treated remotely.

Comment: Several commenters requested that the HCPCS codes and nominal fees established for COVID–19 testing specimen collection in the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC (85 FR 19230), should be maintained past the end of the PHE because: expenses associated with specimen collection during the PHE (for example, increased use of PPE due to more stringent infection control requirements) have become permanent; COVID–19 and variants will continue to circulate in congregate living facilities such as SNFs and assisted living facilities for the elderly and in the community; the need for diagnostic and screening tests for COVID–19 will not terminate automatically when the PHE is terminated; the duration of a COVID–19 vaccine's protective immunity is not known; and after the end of the PHE, the risks to those collecting specimens for COVID–19 testing will remain, as will the costs associated with mitigating those risks (for example, PPE and testing for specimen collectors themselves).

Response: We appreciate commenters' recommendations on continuing the increased specimen collection fees in place for COVID–19 testing beyond the PHE. We recognize that the PHE may have changed the specimen collection landscape in that some COVID–19 protocols have become the standard for the types of resources utilized and supplies needed for other types of specimen collection. We have indicated that the increased specimen collection fees during the PHE will end with the end of the COVID–19 PHE (85 FR 19256; 86 FR 39309; 86 FR 65327).

Comment: One commenter requested that we remove the proposal to only pay for specimens collected by ''trained technicians.'' The commenter asserted that the ''trained technician'' title is vague and does not properly distinguish between laboratory technicians with varying degrees of education and experience. Furthermore, the commenter expressed concern that the term ''trained technicians'' did not include phlebotomists, and therefore, would seemingly disincentivize the

employment of phlebotomists, create issues in workforce demand, and result in higher costs in acquiring personnel who were sufficiently qualified.

Response: As previously noted, section 1833(h)(3) of the Act refers to staff providing specimen collection services as ''trained personnel,'' whereas the Medicare Claims Processing Manual, chapter 16, section 60.2, refers to ''the technician.'' The BLS defines clinical laboratory technologists and technicians as workers who collect samples and also perform tests to analyze body fluids, tissue, and other substances, and it defines a phlebotomist as a professional who draws blood for tests, transfusions, research, or blood donations. The term ''laboratory technician'' may not apply to those staff that would generally be providing specimen collection services, as the staff collecting specimens may not also be involved in analyzing the specimens. Therefore, for the purposes of our Medicare payment policies for specimen collection and travel allowance, we proposed to use the phrase ''trained technician'' to refer to those staff providing specimen collection services. In our proposal, we noted that we believed this clarification would more closely align the regulatory text pertaining to specimen collection and travel allowance with the statute. We note that the term ''trained technician'' does not mandate certain educational requirements and, for the purposes of the specimen collection provisions, the term includes a phlebotomist. Therefore, we do not believe using the term trained technician will disincentivize laboratories from employing phlebotomists. In fact, in the proposed rule where we discussed our proposed codification and modifications of the CLFS specimen collection travel allowance policy, we indicated that we believed the BLS definition of phlebotomist more closely aligns with the trained technicians that we believed are providing the types of specimen collection services for which CMS provides a specimen collection fee. Therefore, we proposed that a component of the travel allowance mileage rate—the amount to cover expenses for a trained technician—would be based on the most recent median hourly wage for phlebotomists, as published in the BLS.

After consideration of comments and further analysis, we are finalizing our specimen collection fee policies at § 414.523(a)(1) with certain modifications. Beginning January 1, 2023, CMS will pay a general specimen collection fee of $8.57 for all specimens collected in one patient encounter. This fee will be increased by $2 ($10.57) for specimen collection from a Medicare beneficiary in a SNF or on behalf of an HHA for all specimens collected in one patient encounter. Additionally, we are finalizing that beginning January 1, 2024, we will update the specimen collection fee amount for each CY by the percent change in the CPI–U for the 12-month period ending June 30th of the year preceding the update year. We will issue these updates to the specimen collection fee amounts through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. To be eligible for a specimen collection fee, the specimen must be: used to perform a CDLT paid under the CLFS regulations at 42 CFR part 414, subpart G; collected by a trained technician from a Medicare beneficiary who is homebound, as described in § 424.22(a)(1)(ii), or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; and of the following type—a blood specimen collected through venipuncture or a urine sample collected by catheterization.

d. Background on the Laboratory Specimen Collection Travel Allowance Policy

Section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample on which a CDLT was performed, except that such a fee may be provided only to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). Like the laboratory specimen collection fee policy discussed previously, our longstanding policies and instructions regarding the statutory requirements for the CLFS specimen collection travel allowance are described in the Medicare Claims Processing Manual guidance and CRs, currently with no corresponding regulations text. In an August 18, 1993 proposed rule titled ''Medicare and Medicaid: Programs; Payment for Clinical Diagnostic Laboratory Tests,'' we proposed to reflect both the CLFS specimen collection and travel allowance payment policies in regulation (58 FR 43838), however, the proposals therein were not finalized.

As discussed in that proposed rule, due to the variability in time, distance, and wage circumstances in different localities, we implemented the travel allowance under section 1833(h)(3)(B) of the Act by allowing the MACs discretion in calculating travel allowances. We provided general guidance through our manuals, specifically in the Medicare Claims Processing Manual, chapter 16, section 60.2.[171]

The Medicare Claims Processing Manual guidance at chapter 16, section 60.2 describes two methods for calculating and billing travel allowance for specimen collection. HCPCS code P9603 is used when the average round trip to a beneficiary's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. HCPCS code P9604 is used when the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis. The manual further states that the travel allowance is intended to cover the estimated travel costs for a laboratory technician to travel to collect the specimen and to reflect the technician's salary and travel costs. The travel allowance can be made only where a specimen collection fee is also payable; that is, no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The manual also states that the travel allowance may not be paid to a physician unless the trip to the beneficiary's home, or to the nursing home where the beneficiary resides, was solely for the purpose of drawing a specimen. Otherwise, the travel costs are considered to be associated with the other purposes of the trip. Furthermore, the manual states that the travel allowance is not distributed by CMS. Instead, the MACs (that is, within the claims processing system) calculate the travel allowance for each claim using the rules for the HCPCS codes used for travel allowances, which are P9603—Per Mile Travel Allowance and P9604—Flat Rate.

As described in the manual, the conditions for usage of HCPCS code P9603 are that the minimum ''per mile travel allowance'' is $1.04 (based on CY 2022 instructions). The per mile travel allowance is to be used in situations where the average trip to beneficiaries' homes is farther than 20 miles, and is to be prorated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.

The manual further states that the per mile allowance is computed using the Federal mileage rate (as determined by the Internal Revenue Service (IRS)), plus an additional 45 cents a mile to cover the technician's time and travel costs.

[171] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf.*

For 2022, the Federal mileage rate is 58.5 cents;[172] that amount plus 45 cents equals $1.035, rounded up to $1.04. The manual currently indicates that contractors have the option of establishing a higher per mile rate in excess of the minimum ($1.04 a mile in CY 2022) if local conditions warrant it. The manual also states that the minimum mileage rate will be reviewed and updated in conjunction with the CLFS as needed, and that at no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.[173]

For the flat-rate HCPCS code, P9604, the manual provides the following conditions of usage: CMS will pay a minimum of $10.40 for the flat rate code (HCPCS code P9604, based on CY 2022 instructions), which is the one-way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles. The flat rate travel allowance is to be prorated for more than one blood draw at the same address, and for stops at the homes of Medicare beneficiaries and non-Medicare patients. The laboratory performs the proration calculation when the claim is submitted based on the number of beneficiaries seen on that trip, and the specimen collection fee will be paid for each beneficiary encounter.

The manual states that this rate is based on the assumption that a trip is an average of 15 minutes and up to 10 miles one way and uses the Federal mileage rate (as determined by the IRS) and a laboratory technician's time of $17.66 an hour, including overhead. The manual states that contractors have the option of establishing a flat rate in excess of the minimum of $10.00, if local conditions warrant it, and that the minimum national flat rate will be reviewed and updated in conjunction with the CLFS, as necessitated by adjustments in the Federal travel allowance and salaries. The manual provides examples of the flat rate calculation and describes further MAC flexibilities regarding payment for the CLFS specimen collection travel allowance. The manual also indicates that MACs may use their discretion for the payment of travel allowance in circumstances where the CDLTs are needed on an emergency basis outside the general business hours of the laboratory making the collection. The manual also states that updates to the travel allowance amounts will be issued by CMS via Recurring Update Notification (RUN) on an annual basis.

In summary, the Medicare Claims Processing Manual, chapter 16, section 60.2, indicates that HCPCS code P9603 is used when the average round trip to a beneficiary's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. HCPCS code P9604 is used when the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis. In instances where one trip is made in order to execute specimen draws or pickups from multiple patients, the travel payment component is prorated based on the number of Medicare beneficiaries and non-Medicare patients (not the number of specimens collected) on that trip. All instances of specimen collection and pickups are included in the proration, and the prorated specimen collection travel allowance is billed on behalf of each Medicare patient.

Furthermore, we have provided additional payment instructions through RUN CLFS—Medicare Travel Allowance Fees for Collection of Specimens CRs; the latest being CR 12593,[174] which was issued on January 14, 2022. Consistent with the manual, CR 12593 states that the travel allowance HCPCS codes allow for payment either on a per-mileage basis (P9603) or on a flat-rate per-trip basis (P9604). The CR states that under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), the travel payment component is prorated based on the number of specimens collected on that trip, for both Medicare and non-Medicare patients, either at the time the claim is submitted by the laboratory or when the flat rate is set by the contractor.

CR 12593 states that the Per Mile Travel Allowance (P9603) is to be used in situations where the average trip to the patients' homes is longer than 20 miles round trip and is to be prorated in situations where specimens are drawn from non-Medicare patients in the same trip. For CY 2022, the allowance per mile was computed using the Federal mileage rate of $0.585 per mile plus an additional $0.45 per mile to cover the technician's time and travel costs. The IRS determines the standard mileage rate for businesses based on periodic studies of the fixed and variable costs of operating an automobile, and CMS utilizes this amount for P9604. The CR also states that the Per Flat-Rate Trip Basis Travel Allowance (P9604) is a set fee amount, which is $10.40 for CY 2022.

In summary, CR 12593 states that the travel payment component is prorated based on the number of specimens collected on the trip (and not the number of Medicare and non-Medicare patients), for both Medicare and non-Medicare patients, which differs from the manual instruction which states that the travel allowance should be prorated based on the number of Medicare beneficiaries and non-Medicare patients (not the number of specimens collected) on that trip.

e. Policy Concerns and Recommendations on the CLFS Specimen Collection Travel Allowance

Laboratories, members of the laboratory industry, and other interested parties have expressed concerns regarding our current CLFS travel allowance payment policy, suggesting that the travel proration methodology is unclear and that guidance in the Medicare Claims Processing Manual, payment CRs and guidance provided by the MACs are conflicting. Additionally, members of the public have asserted that the travel allowance requirements are administratively complex.

In the CY 2022 PFS proposed rule (86 FR 39310), we requested broad comments on our policies for specimen collection fees and the travel allowance for consideration for possible updates to policies in the future through notice and comment rulemaking. As discussed in the CY 2022 PFS final rule (86 FR 65328), commenters supported clarification to the existing travel allowance policy and also made suggestions regarding possible refinements.

Several commenters described their concerns regarding the current travel allowance policy, stating that the current system requires the individual tracking of miles and paperwork documenting those miles, as well as the calculation of billable charges. Commenters stated that this system creates inconsistencies across facilities providing specimen collection services and creates confusion and burden for health care providers and MACs. One commenter also noted that because of the complex logistics involved in obtaining specimens from homebound patients and non-hospital inpatients and transporting the specimens for prompt processing, a disincentive is created for serving this potentially underserved patient population, leading to potential access issues for Medicare beneficiaries.

[172] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2022.*

[173] The Medicare Claims Processing Manual is available on the CMS website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf.* The manual provides examples of the per-mile travel allowance in section 60.2—Travel Allowance.

[174] *https://www.cms.gov/files/document/r11184cp.pdf.*

Several commenters requested that CMS simplify the travel allowance by creating a single per-encounter flat-rate payment for travel, which would simplify personnel and transportation expenses by eliminating the individual tracking of miles and paper documenting of those miles as well as the calculation of billable charges. The commenters stated that a flat-rate approach would also provide greater consistency across facilities served and reduce the burden on health care providers and MACs, and therefore, further support continued patient access to these laboratory services. A few commenters suggested the creation of a rural add-on payment to provide payment to those laboratories serving Medicare beneficiaries residing in remote areas. Several commenters also stated that the current travel allowance is prone to billing inconsistencies, so simplifying the calculation of the travel allowance would increase the overall understanding of the policy among impacted parties, decrease the instances of health care providers inadvertently overbilling for mileage, reduce program integrity concerns, and improve clarity for all parties involved.

Several commenters also recommended that business requirements outlined in the annual Medicare travel allowance CR be updated to require the contractor to search their files to adjust claims already paid at the prior year travel allowance rather than require action by laboratories. The commenter requested that contractors be instructed to review claims and reprocess at the updated rates rather than require laboratories to initiate the revisions.

Additionally, the OIG issued an August 25, 2021 report, *CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances* (A–06–20–04000),[175] in which the OIG discussed ongoing concerns regarding the Medicare CLFS travel allowance policy and summarized findings from previous audits of MACs in which claims for phlebotomy travel allowances were paid using incorrect prorated mileage and claims for phlebotomy travel allowances were paid using incorrect payment rates. The OIG also described instances in which health care provider documentation was insufficient to warrant payment of the phlebotomy travel allowances.

The 2021 OIG report presented recommendations to CMS regarding the CLFS travel allowance policy, including working with the MACs to educate health care providers about the documentation requirements for specimen collection travel allowances, instructing the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate, and issuing regulations related to phlebotomy travel to clarify various aspects of the travel allowance payment policy.

In the CY 2022 PFS proposed rule (86 FR 39310 through 39311) and CY 2022 PFS final rule (86 FR 65328), we discussed the travel allowance policy and stated that we made permanent the option for laboratories to maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic documentation applies to specimen collection for any CDLT. We noted that laboratories will need to be able to produce electronic documentation in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for submission of this information if necessary. We stated that we believed this flexibility to maintain electronic documentation of miles traveled provides clarity to laboratories about documentation requirements for the Medicare CLFS travel allowance for specimen collection payment policy.

Additionally, we have instructed the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate, thereby addressing the OIG's and commenters' suggestions regarding reprocessing using the updated rates through the revision of business requirements in the January 14, 2022 RUN CLFS—Medicare Travel Allowance Fees for Collection of Specimens CR 12593.[176] The OIG and commenters alike recommended that we update the business requirements outlined in the annual Medicare travel allowance CR to require the MACs to search their files to adjust claims already paid at the prior year's travel allowance amount rather than require action by laboratories. Specifically, in the CR, we included the Business Requirement 12593.5, which states that ''Contractors shall adjust previously paid travel allowance claims with dates of service on or after January 1, 2022, in order to apply the updated payment rate and initiate those adjustments within 60 days, if claims are paid at the prior year's rates before the new rate is entered into the MACs' systems.'' We stated that we believed this modification to the business requirements will eliminate the need for action by laboratories for adjustments to claims and instead provide instruction to contractors to review claims and reprocess at the updated rates as appropriate.

f. Codification and Modifications of the CLFS Specimen Collection Travel Allowance Policy

As described in detail in the CY 2023 PFS proposed rule (87 FR 46070 through 46081), in light of the concerns from the public, and in an effort to respond to the OIG's recommendation that CMS issue regulations regarding certain aspects of the travel allowance for specimen collection payment policy, we proposed to codify in our regulations, and make certain modifications and clarifications to, the Medicare CLFS travel allowance policies. As discussed in the proposed rule, we believed the proposals would achieve CMS' aims of simplifying and clarifying our travel allowance policies. We proposed to add § 414.523(a)(2), ''Payment for travel allowance,'' to reflect the requirements for the travel allowance for specimen collection. Specifically, in accordance with section 1833(h)(3)(B) of the Act, we proposed to include in our regulations the following: (1) general requirement; (2) travel allowance basis; and (3) travel allowance amount.

Section 1833(h)(3)(B) of the Act states that the Secretary shall provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample. We noted in the proposed rule that we believe this language indicates that only instances of specimen collection requiring trained technicians [177] for the purposes of collecting the sample are to be included in the travel allowance calculation. Therefore, travel for simple pickup of specimens or for specimen collection that does not require the services of trained technicians should not be considered in the calculation of the travel allowance. This means, the travel allowance may be paid only if a specimen collection fee is also payable; for example, no travel allowance would be paid if a trained technician merely performs a messenger service to pick up a specimen drawn by other technicians.

[175] *https://oig.hhs.gov/oas/reports/region6/62004000.asp.*

[176] *https://www.cms.gov/files/document/r11184cp.pdf.*

[177] As noted previously in this section of the proposed rule, we are proposing to use the term ''trained technician'' for purposes of our specimen collection fee and travel allowance policies.

The Medicare Claims Processing Manual, chapter 16, section 60.2 states, ''The additional allowance can be made only where a specimen collection fee is also payable, that is, no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel.'' We proposed to codify this general requirement at § 414.523(a)(2)(i), indicating that the provision would state that CMS pays a travel allowance where the specimen is one for which a specimen collection fee is paid and would make clear that all of the requirements for the specimen collection fee to be paid (which are specified in § 414.523(a)(1)) would need to be met for the travel allowance to be payable.

Additionally, section 1833(h)(3)(B) of the Act states that the travel allowance may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). We explained that we interpreted this statutory language to mean that the fee only applies when a trained technician draws a specimen from a patient who either is in an inpatient facility that is not a hospital or is a homebound patient. (A discussion regarding the definition of a homebound patient is provided in section III.B.6.b. of the proposed rule and III.C.6.b of this final rule.) The Medicare Claims Processing Manual, chapter 16, section 60.2 states that ''Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient.'' We noted that we believed it is appropriate to codify that the travel allowance is permitted only where the individual from whom the specimen is collected is homebound or is an inpatient in an inpatient facility (other than a hospital). We proposed to codify this requirement at § 414.523(a)(2), which as we noted would therefore require all of the specimen collection fee requirements at § 414.523(a)(1) to be met, and which would include the proposed requirement at § 414.523(a)(1)(ii) that the specimen is collected from a Medicare beneficiary who is homebound as described in § 424.22(a)(1)(ii) or a non-hospital inpatient.

In § 414.523(a)(2)(ii), we proposed to codify and clarify that CMS pays a travel allowance on the following bases: (A) flat-rate travel allowance; and (B) per-mile travel allowance. We explained that we interpreted the statutory language in section 1833(h)(3)(B) of the Act that requires us to pay a fee for trained personnel to travel to the location of an individual to collect the sample to mean that the travel allowance fee is only applicable to travel that is for the purpose of collecting the specimen from a Medicare beneficiary. To that end, we noted that we believed only one travel allowance payment may be made for specimen collection for a Medicare beneficiary based on the beneficiary's location, and only when a Medicare beneficiary requires the collection of a specimen necessary for performance of CDLTs. We also noted that we believed that non-Medicare patients should not be included in any portion of the calculation of the travel allowance. This interpretation would be a modification to existing guidance in the Medicare Claims Processing Manual, chapter 16, section 60.2, which states that the travel allowance ''is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.'' As explained in the proposed rule, this modification would reflect our position that only Medicare patients should be considered in the calculation and payment of the travel allowance, which would more closely align with the statutory language regarding ''the location of an individual,'' that is, the location of a Medicare beneficiary receiving specimen collection services. We also noted that we believed this modification would address concerns from laboratories, the OIG, and other interested parties who requested clarification regarding the inclusion of Medicare and non-Medicare beneficiaries in the travel allocation calculation.

We proposed that, whether a laboratory bills the flat-rate travel allowance basis or the per-mile travel allowance basis would depend upon the total miles traveled and number of locations. Section 1833(h)(3)(B) of the Act states, in establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample. Therefore, we noted that we believed a key component of the travel allowance payment for specimen collection is the number of miles traveled for the specimen collection.

In considering potential methodologies for calculating a travel allowance for specimen collection, we discussed in the proposed rule that we conducted an analysis of the usage of the existing Per Mile Travel Allowance HCPCS code (P9603) to understand the usage of P9603 and analyze the billing of miles related to travel allowance for specimen collection. In CY 2019, among professional and institutional Medicare claims, there were approximately 3.2 million total claim lines billed for HCPCS code P9603 (per-mile travel allowance). Among the P9603 claim lines, the average mileage billed per claim line was 18.8 with a standard deviation of 33.4. However, the median distance traveled per line was 7 miles. Of all P9603 claim lines, 76.3 percent were billed with less than 20 miles, and 37.9 percent of all P9603 claim lines were billed with less than five miles. The average payment per line for P9603 in CY 2019 was $18.13; however, the median payment per line was $6.09. Additionally, our analysis also showed that 23.7 percent of miles traveled were greater than 20 miles, with 150,442 claim lines of the approximately 3.2 million total claim lines, or 4.7 percent, logging more than 85 miles per trip. As discussed in the proposed rule, we believed that these long-distance trips likely reflect specimen collection from beneficiaries in rural areas (which are generally underserved zones). Given that the majority of P9603 claim lines (76.3 percent) are billed with less than 20 miles, we also noted that we believed that 20 miles would be an appropriate threshold for use in the travel allowance bases for specimen collection. In addition, to address concerns about administrative complexity, we proposed that the flat-rate travel allowance basis only would be available for trips involving one location.

Specifically, we proposed in § 414.523(a)(2)(ii)(A) that the flat-rate travel allowance basis would apply when the trained technician travels 20 eligible miles or less to and from one location for specimen collection from one or more Medicare beneficiaries. We stated that we believed that section 1833(h)(3) of the Act supports payment for specimen collection and travel allowance for only Medicare beneficiaries and should not include non-Medicare beneficiaries. As proposed, laboratories would bill Medicare using existing HCPCS code P9604 to receive payment for the flat-rate travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid. As discussed in the proposed rule, we believed that providing payment for the proposed flat-rate travel allowance basis would serve to simplify the administrative requirements for laboratories in terms of billing and

record-keeping activities. Additionally, we discussed in the proposed rule that the clarification regarding requirements for proration would address issues raised by interested parties, including the OIG, who expressed concerns regarding inconsistencies in current guidance. We sought comment on considerations related to the flat-rate travel allowance basis, including considerations for proposed distance, alternatives for a possible flat-rate travel allowance basis, as well as the utility of this basis or the potential exclusion of this basis for the purposes of the travel allowance for specimen collection.

In addition to the flat-rate travel allowance basis, we proposed in § 414.523(a)(2)(ii)(B) the per-mile travel allowance basis, which we explained would apply when the trained technician travels more than 20 eligible miles to and from one location for specimen collection from one or more beneficiaries or when the trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary. We clarified that this proposed basis would apply in two circumstances—where round-trip travel to one location is greater than 20 eligible miles and where travel is to more than one location, regardless of the number of miles traveled. We proposed to modify the per-mile travel allowance policy in this way for greater clarity, administrative simplification, and consistency with statute. As proposed, the laboratory would receive payment under the per-mile travel allowance basis for the total number of miles traveled for specimen collection, which would be allocated to each Medicare beneficiary for whom a specimen collection fee is paid. We discussed that we believed the proposal would serve to address the OIG's recommendations that CMS clarify various aspects of the travel allowance payment policy, including requirements for proration, which we discussed more fully in the travel allowance amount calculation proposal in the proposed rule. We sought comment on all aspects of the proposed per-mile travel allowance basis.

Additionally, we proposed to specify travel allowance amount requirements pertaining to eligible miles, the travel allowance mileage rate, and the travel allowance amount calculation at § 414.523(a)(2)(iii). At § 414.523(a)(2)(iii)(A), we proposed that eligible miles would begin at the laboratory and end at the laboratory where the trained technician returns the specimen(s) for testing. We noted that we believed the laboratory is the most likely place where the trained technician would become aware of the laboratory order and acquire the necessary supplies to perform the specimen collection. We explained that although we do not believe the trained technician would commence travel related to specimen collection from a location other than the laboratory, we sought comment as to whether there are alternative starting locations we should consider. We noted that the provision requiring that the mileage calculation begins at a laboratory, as proposed, would codify existing policy in the Medicare Claims Processing Manual, chapter 16, section 60.2, which provides several examples of travel allowance scenarios that reference the start of a travel allowance route as beginning at a laboratory, and would be consistent with section 1833(h)(3)(B) of the Act.

We further proposed in § 414.523(a)(2)(iii)(A) that eligible miles would not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons. We noted that we believed the statutory language in section 1833(h)(3)(B) of the Act supported the proposal to exclude from the calculation of eligible miles any miles traveled to a location where no specimens are collected, to the location of a non-Medicare beneficiary for specimen collection, to a Medicare beneficiary where no specimen collection occurs, or for personal purposes. We explained that the proposed provision would codify the Medicare Claims Processing Manual, chapter 16, section 60.2, which states that ''the travel allowance is intended to cover the estimated travel costs of collecting a specimen.''

In § 414.523(a)(2)(iii)(B), we proposed to set forth the travel allowance mileage rate, to be used in the travel allowance amount calculations. Section 1833(h)(3)(B) of the Act requires the travel allowance to cover both the ''transportation'' and ''personnel expenses'' for trained personnel to travel to the location of an individual to collect a sample. As proposed, the travel allowance mileage rate would reflect both of these components.

As described in the proposed rule, we issue annual travel allowance amounts through CR publications, such as CR 12593.[178] Currently, CMS adds the IRS standard mileage rate to an additional $0.45 per mile, which is intended to pay for the trained personnel's time, as described in CR 12593, where the additional $0.45 per mile addresses time and travel costs required by the technician for approximately 15 minutes of labor. The manual states that this rate is based on the assumption that a trip is an average of 15 minutes and up to 10 miles one way and uses the Federal mileage rate (as determined by the IRS) and a technician's time of $17.66 an hour, including overhead. For CY 2022, the IRS standard mileage rate is $0.585. That amount plus $0.45 for the trained personnel's labor yields a travel allowance mileage rate of $1.035, which is rounded up to $1.04 for CY 2022. We proposed to codify the travel allowance mileage rate in regulation, as well as modify and clarify certain aspects of it.

The IRS updates and issues standard mileage rates on a periodic basis, generally annually.[179] These rates are used to calculate the deductible costs of operating an automobile for business, charitable, medical, or moving for the purpose of calculating Federal taxes. We proposed that the ''transportation'' component of the travel allowance mileage rate would equal the IRS standard mileage rate, which would be consistent with our current policy. We noted that we believed using the IRS standard mileage rate would continue to be an appropriate way to cover transportation as the IRS rate accounts for the costs associated with transportation per mile traveled. We sought comment on the proposal to use the IRS standard mileage rate to cover the transportation component of the travel allowance mileage rate.

In addition, we proposed to include an amount to cover the ''personnel expenses'' component of the travel allowance mileage rate where the trained technician's personnel expenses would be based on a wages-per-mile amount. First, we proposed that personnel expenses are wages in this context, where wages would represent the cost of the trained technician's time for traveling to collect the sample. We also proposed to base the specific wage amount on data from the BLS, which publishes salary statistics for occupations in the United States. The BLS defines a phlebotomist as a professional who draws blood for tests, transfusions, research, or blood donations.[180] The BLS separately defines clinical laboratory technologists and technicians as workers who collect samples and perform tests to analyze body fluids, tissue, and other

[178] *https://www.cms.gov/files/document/r11184cp.pdf.*

[179] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2022.*

[180] *https://www.bls.gov/ooh/healthcare/phlebotomists.htm.*

substances.[181] For purposes of the travel allowance, we stated that we believed the BLS definition of phlebotomist more closely aligns with the trained technicians that we believed are providing the types of specimen collection services described earlier in this section, as a phlebotomist typically draws blood or other specimens, while a laboratory technologist may both collect the specimen as well as analyze the specimen. We noted that we did not believe that trained technicians collecting the specimen for the purposes of our specimen collection policies are also analyzing the specimens. Therefore, we proposed to use wage data in the BLS-defined category of phlebotomist to establish the personnel expense component of the travel allowance mileage rate.

For CY 2021 (the latest available information), the BLS states that the median pay (or the wage at which half of the workers in the occupation earned more than that amount and half earned less) for phlebotomists is $17.97 per hour.[182] To account for the personnel expenses associated with travel for specimen collection, we proposed to use the latest available published figure for the median hourly wage amount for phlebotomists, which is published by the BLS, for the purposes of annually updating the travel allowance amount for specimen collection. We proposed to codify this aspect of the travel allowance mileage rate at § 414.523(a)(2)(iii)(B) by describing that the travel allowance mileage rate includes an amount to cover expenses for a trained technician equal to the most recent median hourly rate for phlebotomists, as published by the BLS. As discussed in the proposed rule, this approach would be a clarification of and modification to current guidance, as CR 12593 describes that the $0.45 per mile added to the IRS rate is meant to address the trained personnel's time and travel costs based on approximately 15 minutes of labor.

Next, we discussed that we would calculate a per-mile amount to derive the approximate number of miles traveled by the trained technician each hour. To do so, we proposed to use an average driving speed. The average miles-per-hour driving speed would be multiplied by the trained technician's estimated wages, as described above, and the result would be an amount that represents wages per mile, which would be the personnel expenses associated with travel for specimen collection. We proposed to use an average driving speed of 40 miles per hour, as we believed most of the travel related to specimen collection would be performed in local and residential areas, as our data show that the median number of miles traveled for specimen collection is approximately 7 miles.

Therefore, to establish the personnel expenses component of the travel allowance mileage rate, which would be a per-mile amount, we proposed that we would divide the most recent median hourly wage for phlebotomists, as published by the BLS, by 40 to represent an average miles-per-hour. We proposed to codify this aspect of the travel allowance mileage rate at § 414.523(a)(2)(iii)(B). For CY 2023, the amount would be equal to the most recent BLS median hourly wage for a phlebotomist of $17.97 per hour (which is currently the BLS CY 2021 rate) divided by 40, which is $0.45 per mile. We noted that this amount is consistent with the amount that we add to the IRS rate under our current travel allowance policy.

In summary, we proposed to establish in § 414.523(a)(2)(iii)(B) that the travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the BLS, divided by 40 to represent an average miles-per-hour driving speed. We indicated in the proposed rule that the travel allowance mileage rate would be updated annually using the most recent IRS and BLS information, which we would issue in subregulatory guidance annually through CRs.

We sought comment on all aspects of the proposed travel allowance mileage rate, including the use of the IRS standard mileage rate to cover transportation, the proposed use of estimated wages and average driving speed to cover personnel expenses, and other specific considerations or alternatives for establishing the rate.

Finally, we proposed to include in § 414.523(a)(2)(iii)(C) the travel allowance amount calculations for the flat-rate travel allowance basis and the per-mile travel allowance basis discussed previously in this section of the final rule. We stated that we believed that these proposed calculations would be a modification to existing guidance, which we noted would clarify and revise the travel allowance amount calculations in several respects.

As explained in the proposed rule, in our analysis of mileage traveled for the purposes of specimen collection, described above, the results indicate that the median mileage per trip for specimen collection per Medicare beneficiary is approximately 7 miles; therefore, we noted that we believed that a reasonable approximation of the typical mileage required for specimen collection per beneficiary is about 10 miles. As such, for the flat-rate travel allowance basis, we proposed in § 414.523(a)(2)(iii)(C)(*1*) that the travel allowance amount calculation is the travel allowance mileage rate multiplied by ten (10) (for CY 2023 example purposes, this amount would be $10.40) and divided by the number of beneficiaries for whom a specimen collection fee is paid. We explained that dividing by the number of beneficiaries for whom a specimen collection fee is paid would ensure that the flat-rate travel allowance amount is apportioned to each beneficiary receiving specimen collection services and that payment is calculated in an operationally feasible manner, as a laboratory must submit a claim for each beneficiary to receive payment for travel allowance; this would allow for a fixed payment amount to be straightforwardly apportioned to the number of beneficiaries for whom a specimen collection fee is paid in a single location. We noted that we believed this proposed flat-rate travel allowance calculation would simplify payment for travel to one location for specimen collection services requiring travel of 20 miles or less, which would ease administrative burden. Additionally, we stated, the proposed methodology would be consistent with the existing flat-rate travel allowance payment policy described in CR 12593 and would clarify the proration methodology.

For an example of the proposed flat-rate travel allowance calculation, consider a situation in which a trained technician travels 7 miles from the laboratory to a nursing home to collect blood specimens collected through venipuncture from five patients, four of whom are Medicare beneficiaries. The trained technician collects three specimens from Medicare beneficiaries, collects one specimen from the non-Medicare patient, and simply picks up a previously collected specimen from one Medicare beneficiary. The trained technician then drives 7 miles back to the laboratory to deliver the specimens without making any other stops. The trained technician has provided specimen collection services to three Medicare beneficiaries. One Medicare beneficiary did not require specimen

[181] *https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.*

[182] *https://www.bls.gov/ooh/healthcare/phlebotomists.htm.*

collection services, and therefore, a specimen collection fee would not be payable. In this example, the laboratory would use the flat-rate travel allowance basis because the trained technician traveled a total of 14 miles. To calculate the travel allowance mileage rate, the laboratory would divide flat-rate travel allowance amount of $10.40 by the number of beneficiaries for whom a specimen collection fee is paid (three beneficiaries), which equals $3.47. To bill for the travel allowance, the laboratory would submit one claim for each beneficiary for whom a specimen collection fee is paid by billing HCPCS code P9604.

We proposed that updates to travel allowance mileage rates would be issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. We sought comment on all aspects of the proposed calculation of the flat-rate travel allowance amount, including considerations for the proposed mileage factor of ten (10) and the proposed proration by the number of beneficiaries for whom a specimen collection fee is paid.

We also proposed to clarify, modify, and codify in regulation the calculation for the per-mile travel allowance amount. Under proposed § 414.523(a)(2)(iii)(C)(*2*), the per-mile travel allowance amount would equal the number of eligible miles multiplied by the travel allowance mileage rate, divided by the number of beneficiaries for whom a specimen collection fee is paid.

As discussed previously, we believe that section 1833(h)(3) of the Act supports payment for specimen collection and travel allowance only for Medicare beneficiaries, and we proposed that the per-mile travel allowance amount calculation would only consider the number of Medicare beneficiaries from whom specimens are collected in the proration of the per-mile travel allowance. As the current policy in manual guidance and the CR factor are inconsistent in referring to the number of specimens or number of patients, we noted that the proposal would be a policy change to clarify that only the number of Medicare beneficiaries for whom a specimen collection fee is paid should be included in the calculation.

We explained that, to calculate the per-mile travel allowance amount, the laboratory would first calculate the total number of eligible miles, as set forth in proposed § 414.523(a)(2)(iii)(A), the trained technician traveled—this would be the total number of miles traveled by the trained technician to locations where one or more Medicare beneficiaries received specimen collection services and back to the laboratory where the technician returns the specimen(s) for testing. The eligible miles would be multiplied by the travel allowance mileage rate as set forth in proposed § 414.523(a)(2)(iii)(B), then divided by the number of beneficiaries for whom a specimen collection fee is paid, which would yield a prorated travel allowance amount. Under this approach, the laboratory would receive payment for the total number of eligible miles traveled for specimen collection, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid. The laboratory would then submit a claim billing HCPCS code P9603 for payment of the per-mile travel allowance amount for each beneficiary for whom a specimen collection fee is paid. We stated that we believed this calculation for the per-mile travel allowance basis would resolve concerns raised by the public about inconsistent guidance.

For an example of the per-mile travel allowance amount calculation, consider a trained technician traveling 45 miles from a laboratory in a city to a rural SNF, collecting blood specimens through venipuncture from 6 Medicare beneficiaries, and then driving 45 miles to return to the laboratory. In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled more than 20 eligible miles to one location for specimen collection. To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles traveled to the location of Medicare beneficiaries receiving specimen collection services, which, in this case is 45 miles from the laboratory to the SNF and 45 miles from the SNF returning to the laboratory, for a total of 90 eligible miles. The eligible miles would then be multiplied by the travel allowance mileage rate of $1.04, yielding a total of $93.60. This total amount would then be prorated by dividing by the number of Medicare beneficiaries for whom a specimen collection fee is paid (6), yielding a per-beneficiary amount of $15.60 ($93.60/6 = $15.60). To bill for the travel allowance, the laboratory would submit one claim for each beneficiary in the amount of $15.60 HCPCS code P9603.

In another example, a trained technician travels 40 miles from a laboratory to the location of a Medicare beneficiary to collect a blood specimen through venipuncture, then travels 10 miles to the location of a non-Medicare patient to collect a blood specimen through venipuncture, then travels 20 miles to the location of two Medicare beneficiaries to collect urine specimens by catheterization, and then travels 20 miles to return to the laboratory. In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled to more than one location for specimen collection. To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles, which would include the miles traveled from the laboratory to the locations of Medicare beneficiaries to collect specimens plus the miles back to the laboratory for specimen drop-off. Eligible miles would not include the 10 miles traveled to the location of the non-Medicare patient to collect a specimen, but would include the 40 miles traveled from the laboratory to the location of the first Medicare beneficiary, the 20 miles to the location of the two Medicare beneficiaries, and the return trip to the laboratory of 20 miles, for a total of 80 eligible miles. The eligible miles would then be multiplied by the travel allowance mileage rate of $1.04, yielding a total of $83.20. This total would then be prorated by dividing by three (3) Medicare beneficiaries for whom a specimen collection fee is paid, yielding an amount of $27.73. The laboratory would then submit a claim using HCPCS code P9603 for travel allowance for each of the Medicare beneficiaries in the amount of $27.73. Again, the laboratory would receive payment for the eligible miles traveled by the trained technician, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid.

We stated that the proposed travel allowance payment policies would represent both modifications to and clarifications of the specimen collection travel allowance payment methodologies currently described in guidance. We noted that we believed the proposed changes and clarifications, if finalized, would improve and simplify the administration of the travel allowance payment policy. Laboratories would use HCPCS code P9604 to bill for the flat-rate travel allowance basis for shorter trips to one location, and HCPCS code P9603 to bill for the per-mile travel allowance basis for longer trips to one location and trips to multiple locations, which we believed would ensure payment for specimen collection services based upon eligible miles required for such travel and address concerns of interested parties about the provision of specimen collection services for individuals residing in remote locations.

We sought comment on all aspects of this travel allowance proposal,

including the proposed general requirement, the proposed provisions regarding the flat-rate and the per-mile travel allowance bases and the utility of having both approaches, the proposed provisions regarding eligible miles and the travel allowance mileage rate, as well as considerations for the methodologies to calculate the travel allowance amounts. We also sought comments on possible alternative considerations for the CLFS travel allowance, including suggestions based on private-payor and/or other approaches for tracking mileage and paying for travel allowance, including per-beneficiary per-encounter bases, or other approaches for providing payment for travel for specimen collection. We noted that our proposed regulations would not require MACs to calculate travel allowance payments, nor would they reflect the MAC flexibilities with respect to travel allowance payment that are currently in guidance, such as their discretion to pay the travel allowance in circumstances where CDLTs are needed on an emergency basis; we sought comment on this issue as well.

We noted that we would make conforming changes to the Claims Processing Manual, Chapter 16, section 60 to reflect the proposed travel allowance policies, if finalized, including any changes or clarifications. We also stated in the proposed rule that we would remove sections of the manual containing policies that are no longer applicable.

The following is a summary of the public comments received on the proposed provisions related to the travel allowance for specimen collection policies and our responses:

Comment: Many commenters expressed support for the proposals to codify and clarify the CLFS travel allowance policies. Commenters appreciated the clarifications regarding all aspects of the payment policies related to the CLFS travel allowance, including the proposed general requirements, travel allowance bases, travel allowance amount, and travel allowance amount calculations. Several commenters specifically supported the general requirements including the requirement that travel allowance amount may be paid only when a specimen collection fee is also paid.

Several commenters also expressed support for the proposed travel allowance bases. Commenters supported the flat-rate travel allowance basis as applying to travel to and from one location of 20 miles or less (P9604), and likewise supported the per-mile travel allowance in instances when the technician travels more than 20 miles to and from one location for specimen collection from one or more Medicare beneficiaries or the technician travels to more than one location for specimen collection from more than one Medicare beneficiary (P9603). One commenter appreciated that the travel allowance proposal would reimburse for travel of longer distances on a per-mile basis, which the commenter believed would help promote access to services in more remote or rural areas. Some commenters noted that codification and clarification of CLFS travel allowance policies would help promote continued access to CDLT services.

Response: We believe that the modifications and clarifications to the travel allowance payment policies will improve and simplify the administration of the travel allowance payment policy. We appreciate the commenters' support for the proposed travel allowances bases, and we believe the descriptions of the two travel allowance bases will help clarify which travel allowance basis laboratories should use, which will increase the accuracy of billing the travel allowance for specimen collection. We are finalizing as proposed the general requirement at § 414.523(a)(2)(i) and the travel allowance bases at § 414.523(a)(2)(ii).

Comment: Several commenters supported the proposed description of eligible miles, noting specific support for excluding miles traveled for any purpose unrelated to specimen collection. However, several commenters did not agree with the proposal that eligible miles would begin and end at the laboratory, and suggested that eligible miles could instead begin at the home of the trained technician or elsewhere when the trained technician begins their shift at a location other than the laboratory. Some commenters specified that some laboratories strategically recruit technicians based on the location of their home residence to efficiently staff technicians on routes closer to the facilities and/or patients served to limit travel time and maximize the number of patients served per day. Others also mentioned that laboratories may ship specimen collection supplies to the technician or locations closer to their residence for efficiency. Additionally, several commenters noted that electronic ordering procedures may negate the necessity for technicians to begin at the laboratory because orders for laboratory services may now be conveyed electronically through an electronic medical records system to the technician before they begin their route, or the technician may receive the details of specific laboratory orders on paper requisitions when the technician arrives at the location of the Medicare beneficiary, like a SNF, thereby negating the need for the technician to travel to the physical location of the laboratory in order to obtain the order for laboratory services. Commenters further stated that the end point could include the laboratory itself but may also include parcel drop-off points, courier sites, or other locations where the specimen is transferred to the next entity.

Response: We agree with the commenters that a trained technician's travel for specimen collection from Medicare beneficiaries may begin at a location other than the technician's home and therefore we are modifying our proposed description of eligible to miles to reflect that eligible miles do not necessarily have to begin at the laboratory. We will now specify that eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection. We believe that broadening the description of eligible miles this way will provide flexibility for the types of locations that could serve as the starting point for travel related to specimen collection.

Additionally, as described above, commenters noted that travel for specimen collection could end at a location other than the laboratory and asserted that technicians often deliver the collected specimens to a drop-off location for courier or shipping services. Therefore, we are also modifying our proposed description of eligible miles do not necessarily have to end at the laboratory. We will now specify that eligible miles end at the laboratory or the ending point of the technician's travel for specimen collection. We believe that broadening the description of eligible miles this way will provide flexibility for the types of locations that could serve as the ending point for travel related to specimen collection.

We reiterate that only those miles that are related to the technician's travel for specimen collection from a Medicare beneficiary will meet the requirements eligible miles for the purposes of the travel allowance. Miles that are not related to specimen collection, as described above, may not be included as eligible miles for the purposes of Medicare payment for travel allowance for specimen collection. As we discuss above, this aspect of the policy will also be codified in regulation at § 414.523(a)(2)(iii)(A), where we describe that eligible miles do not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

In summary, we are revising the description of eligible miles at § 414.523(a)(2)(iii)(A) such that eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection and end at the laboratory or the ending point of the technician's travel for specimen collection.

Furthermore, as described in section III.C.6.e. of this rule, as well as in the CY 2022 PFS proposed rule (86 FR 39310 through 39311) and CY 2022 PFS final rule (86 FR 65328), we have made permanent the option for laboratories to maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained technicians to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic documentation applies to specimen collection for any CDLT. Laboratories should continue to utilize electronic and/or other documentation in order to demonstrate miles traveled for the purposes of specimen collection. We reiterate that laboratories will need to be able to produce electronic documentation in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for submission of this information if necessary. We believe that the electronic documentation of miles traveled will continue to reduce administrative burden for laboratories for the Medicare CLFS travel allowance for specimen collection payment policy while also serving as evidence of the miles traveled.

Comment: One commenter was concerned that having to track mileage for travel and account for the number of Medicare beneficiaries from whom specimens are collected would impose administrative burden on laboratories seeking payment for the travel allowance.

Response: The commenter is correct that laboratories will be required to track eligible miles for the travel allowance, as well account for the Medicare beneficiaries from whom specimen are collected. However, we believe that these activities are consistent with typical administrative activities necessary to conduct business and will not impose an undue burden upon laboratories. Furthermore, we believe laboratories that currently provide these services are already tracking this information. As described in above and in section III.C.6.e. of this final rule, laboratories may now maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of a Medicare beneficiary to collect a specimen sample.

Comment: We received several comments regarding our proposed travel allowance mileage rate. Several commenters supported the usage of the IRS standard mileage rate and the usage of the median hourly wage rate for phlebotomists as published by the BLS. Several commenters also supported using the factor of 40 to represent average miles-per-hour driving speed.

Response: We believe that these components of the travel allowance mileage rate appropriately align with the statutory requirement at section 1833(h)(3)(B) of the Act that the travel allowance cover both the ''transportation'' and ''personnel expenses'' for trained personnel to travel to the location of an individual to collect a sample.

Comment: Several commenters stated that the travel allowance mileage rate should incorporate more expenses than wages. The commenters noted that the BLS wage rate definition indicates that the wage rate is based on total earnings before payroll deductions, excluding premium pay for overtime and for work on weekends and holidays, shift differentials, and nonproduction bonuses such as lump-sum payments provided in lieu of wage increases. Therefore, commenters stated that CMS should consider including a component in the travel allowance mileage rate that accounts for overhead and other associated costs, such as taxes, contributions, and registration fees.

Response: We recognize that utilizing the BLS median wage rate for a phlebotomist accounts for wages specifically related to the phlebotomist and would not expressly account for overhead costs for employing a phlebotomist. However, as we stated in the proposed rule, we believe that utilizing the median wages for phlebotomists is a reasonable proxy for estimating the personnel expenses related to CLFS travel allowance for the range of professionals that could be employed as the trained technician. As described above, we note that the term ''trained technician'' does not specify certain educational requirements, and we believe that the types of professionals serving as ''trained technicians'' for the purposes of specimen collection could include a variety of types of specialists with varying levels of training, including a phlebotomist.

We believe that utilizing the wage amounts for a phlebotomist provides a reasonable proxy for accounting for the personnel expenses for the range of types of trained professionals traveling to the location of a Medicare beneficiary to collect the sample. We continue to believe that in this context, wages for a phlebotomist broadly represent the general personnel costs for the types of professionals serving as a trained technician and generally account for the trained technician's time for traveling to collect the sample and serve as a reasonable proxy for the personnel expense's component described in the statute. Therefore, we are finalizing as proposed the travel allowance mileage rate at § 414.523(a)(2)(iii)(B) and we will update the Medicare Claims Processing Manual, Chapter 16, section 60 guidance accordingly.

Comment: One commenter requested that we further explain what we mean by ''trained technician'' and that the wage rate we apply in the travel allowance amount methodology reflect such description.

Response: As described above, section 1833(h)(3) of the Act refers to staff providing specimen collection services as ''trained personnel'' whereas the Medicare Claims Processing Manual, chapter 16, section 60.2, refers to ''the technician.'' We note that the BLS defines clinical laboratory technologists and technicians as workers who collect samples and also perform tests to analyze body fluids, tissue, and other substances, and, therefore, we believe that the category of ''laboratory technician'' may not apply to those staff that would generally be providing specimen collection services requiring travel, as the staff collecting and transporting specimens may not also be involved in analyzing the specimens. Therefore, for the purposes of our Medicare payment policies for specimen collection and travel allowance, we proposed to use the phrase ''trained technician'' to refer to those staff providing specimen collection services and related travel. We continue to believe this clarification would more closely align the regulatory text concerning specimen collection and travel allowance with the statute. We noted that the BLS defines a phlebotomist as a professional who draws blood for tests, transfusions, research, or blood donations.

Additionally, we clarify that the term ''trained technician'' does not specify certain educational requirements, and we are not creating qualification requirements for those individuals providing specimen collection services to Medicare beneficiaries.

Comment: Several commenters expressed support for the proposed travel allowance amount calculation. Commenters specifically appreciated the clarification regarding the proration by the number of beneficiaries for whom a specimen collection fee is paid.

Response: We continue to believe these changes and clarifications will improve and simplify the administration of both the specimen collection and travel allowance payment policies.

In consideration of public comments, we are finalizing the proposed provisions for the laboratory specimen collection fee and travel allowance at 42 CFR part 414, subpart G with refinements to the description of eligible miles such that eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection and end at the laboratory or the ending point of the technician's travel for specimen collection where the trained technician returns the specimen(s) for testing.

We note that updates to the travel allowance mileage rate will be issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. Updates will be made to the travel allowance mileage rate based upon the most recently published IRS standard mileage rate,[183] as well as the most recently published wage rate for phlebotomist as published by the BLS.[184] The revised travel allowance mileage rate will be effective for the January update of the clinical laboratory fee schedule file. Additionally, we note that we will make conforming changes to the Claims Processing Manual, Chapter 16, section 60 to reflect the changes to the travel allowance policies, including any changes and/or clarifications and will remove sections of the manual containing policies that are no longer applicable, consistent with the policies established in this final rule.

D. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Act), regulation (42 CFR 410.37), and National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). The statute and regulations expressly authorize the Secretary to add other tests and procedures (and modifications to tests and procedures) for colorectal cancer screening with such frequency and payment limits as the Secretary finds appropriate based on consultation with appropriate organizations. (Section 1861(pp)(1)(D) of the Act; § 410.37(a)(1)(v)). For a number of CRC screening tests, the statute at section 1834(d) of the Act established frequency and payment limits restricting coverage to individuals at least 50 years of age. In the CY 2023 PFS proposed rule (87 FR 45860), we proposed to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation to 45 years in our regulations at § 410.37 and in NCD 210.3. As proposed, the provision would align our coverage with a recently revised recommendation by the United States Preventive Services Task Force (USPSTF) for certain CRC tests as permitted by section 1834(n) of the Act. Moreover, after consulting with appropriate organizations, we proposed to modify the payment limitation for other CRC screening tests identified in § 410.37 and in NCD 210.3 to permit coverage for individuals to begin at age 45.

In addition, we proposed to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. We explained that historically, CMS has viewed a colonoscopy after a positive non-invasive stool-based CRC screening test to be a diagnostic colonoscopy. In recent years, the clinical recommendations and guidance of medical professional societies and screening experts have evolved for stool-based colorectal cancer screening due to a number of factors including the relative number of false positive results, low follow-up colonoscopy rates and patient access barriers. For example, the positive predictive value of a FIT (fecal immunochemical test) (the likelihood that an individual with a positive FIT test result actually has colorectal cancer) reportedly varies widely from 8 to 21 percent depending on the test and testing center.[185] Importantly, recent published evidence has again highlighted that individuals who did not get a follow-up colonoscopy were about twice as likely to die of colorectal cancer compared to individuals who did have one.[186] Since the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allow for early detection and treatment and reduce cancer mortality, the follow-up colonoscopy is integral with non-invasive stool-based CRC screening, since improvements in health outcomes would not be possible without the follow-up. Medical professional organizations and clinical experts have reached consensus based on the evidence on this recommendation. In May 2021, USPSTF revised their evidence-based recommendation to include the statement ''Positive results on stool-based screening tests require follow-up colonoscopy for the screening benefits to be achieved.'' [187] Accordingly, we proposed to modify CRC screening tests within our authority in consultation with appropriate organizations. The outcome of our more appropriate and complete approach to CRC screening will be that, in many cases, beneficiary cost sharing for both the initial screening stool-based test and the follow-on screening colonoscopy test will not apply because both tests will be paid at 100 percent (no applicable copayment percentage) as specified preventive screening services under the statute. The issue of when the follow-on screening colonoscopy involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test will not change from current policy. We noted in the proposed rule that we believe the new understanding will encourage the wider utilization of non-invasive CRC screening tests and reduce barriers to screening, prevention and early detection of CRC.

As proposed, our policies would update Medicare coverage and payment policies to align with our new understanding of CRC screening. We noted that we believe the proposals would expand access to quality care and improve health outcomes through prevention, early detection, more effective treatment and reduced mortality. Moreover, we noted that we believe they would directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and

[183] *https://www.irs.gov/tax-professionals/standard-mileage-rates.*

[184] *https://www.bls.gov/ooh/healthcare/phlebotomists.htm.*

[185] Nielson CM, Petrik AF, Jacob L, et al. Positive predictive values of fecal immunochemical tests used in the STOP CRC pragmatic trial. Cancer Med. 2018;7(9):4781–4790. doi:10.1002/cam4.1727.

[186] Zorzi M, Battagello J, Selby K, et al. Non-compliance with colonoscopy after a positive faecal immunochemical test doubles the risk of dying from colorectal cancer. Gut. 2022;71(3):561–567. doi:10.1136/gutjnl–2020–322192.

[187] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

communities of color that are especially impacted by the incidence of CRC.

We also discussed that the proposals directly supported President Biden's Cancer Moonshot Goal to cut age-adjusted death rate from cancer by at least 50 percent and addressed his recent Proclamation of March as National Colorectal Cancer Awareness Month. As noted in the proposed rule, the proclamation stated that ''early stages of colorectal cancer often emerge without symptoms, and it is important to begin regular screenings starting at the age of 45.'' It continued with ''Thanks to the Affordable Care Act, most health insurance plans must cover certain preventive services with no out-of-pocket costs. This coverage now includes colorectal cancer screenings for adults over the age of 45, making it easier to get colorectal cancer screenings and helping improve access to earlier treatment.'' [188]

1. Background

In CY 2019, the last year for which incidence data are available, CRC accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[189] The National Cancer Institute estimates that in 2021, 149,500 individuals will be newly diagnosed with CRC and 52,980 individuals will die from CRC in the United States.[190] The Center for Disease Control and Prevention (CDC) advises, ''Colorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best . . . Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [191]

Rural communities and communities of color are especially impacted by the incidence of CRC. A CDC study found the death rate of CRC (per 100,000) to be 17.1 in rural nonmetropolitan counties verses 14.0 in metropolitan counties with populations greater than 1 million.[192] African Americans experience both new cases and deaths from colorectal cancer at rates significantly above those of all races.[193] An article in the American Journal of Pathology states African Americans also are often diagnosed at a younger age (median ages, 66 and 70 years for African American men and women compared with 72 and 77 years for white men and women, respectively). Moreover, African Americans are two times more likely to be diagnosed with CRC before the age of 50 years, which justified the recommendation to begin endoscopic screening at the age of 45 years instead of 50 years.[194]

In May 2021, the USPSTF issued a revised Final Recommendation Statement on CRC Screening. This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC Screening. In terms of health disparities in CRC and CRC screening, the May 2021 revised USPSTF statement reads, ''The causes for these health disparities are complex; recent evidence points to inequities in the access to and utilization and quality of colorectal cancer screening and treatment as the primary driver for this health disparity rather than genetic differences . . . Black adults across all age groups, including those younger than 50 years, continue to have higher incidence of and mortality from colorectal cancer than White adults.'' [195]

In addition to reducing the minimum age for Medicare payment for CRC screening test payment, we proposed to address a longstanding barrier and disincentive to CRC screening using a non-invasive stool-based test as a first step of a complete screening. Examples of Medicare covered non-invasive stool-based CRC screening tests include a guaiac-based fecal-occult blood test (gFOBT) described in regulation at § 410.37(a)(2)(i) and in National Coverage Determination 210.3 Colorectal Cancer Screening Tests, as well as immunoassay-based fecal-occult blood test (iFOBT) and the Cologuard™—Multitarget Stool DNA (sDNA) test described in NCD 210.3. For the best health outcomes from CRC prevention and early detection, it is important that patients receive a complete CRC screening.

In recent years, government bodies and professional societies have reconsidered their understanding of a complete CRC screening and now consider CRC screening incomplete for individuals with a positive result on a stool-based test until a follow-on screening colonoscopy is also completed. The National Colorectal Cancer Roundtable recommends that the patient should only be counted as having completed the CRC screening process after a colonoscopy is performed.[196] Under current Medicare policies, if a Medicare patient initially receives a positive result from a non-invasive and less burdensome screening stool-based CRC test, the test would be viewed as showing signs or symptoms of colorectal cancer. If a beneficiary received a subsequent colonoscopy, we viewed the test as a diagnostic procedure and normal beneficiary cost sharing rules for diagnostic test would apply. Our current policy, however, may discourage patients from seeking a follow-on colonoscopy because of the Medicare cost-sharing. A 2018 guideline update from the American Cancer Society on CRC screening for average-risk adults reads ''Trials offering a choice between a stool test and a structural examination compared with either test alone have generally demonstrated greater uptake when a choice is offered. The best evidence in the United States derives from a randomized trial in a safety-net population comparing annual gFOBT versus colonoscopy versus choice between the 2 in which it was demonstrated that choice was more effective than offering colonoscopy alone. In the first year of the study, which included patient navigation (year 1 only), the screening completion rate was 38% for patients offered colonoscopy, 66 percent for those offered gFOBT, and 68 percent for those offered a choice. While uptake overall was similar in the gFOBT group versus the choice group, it is clear that a ''colonoscopy-only'' referral resulted in substantially lower adherence.'' [197]

One of the goals of CRC screening is to enable the healthcare system to identify patients who need treatment early enough to prevent or treat the condition most effectively. In order to encourage patients to obtain a follow-on

[188] *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/02/28/a-proclamation-on-national-colorectal-cancer-awareness-month-2022/.*

[189] *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[190] *https://seer.cancer.gov/statfacts/html/colorect.html.*

[191] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

[192] Henley SJ, Anderson RN, Thomas CC, Massetti GM, Peaker B, Richardson LC. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties—United States. MMWR Surveill Summ 2017;66(No. SS–14):1–13. DOI: *http://dx.doi.org/10.15585/mmwr.ss6614a1.*

[193] *https://seer.cancer.gov/statfacts/html/colorect.html.*

[194] Augustus GJ, Ellis NA. Colorectal Cancer Disparity in African Americans: Risk Factors and Carcinogenic Mechanisms. Am J Pathol. 2018;188(2):291–303. doi:10.1016/j.ajpath.2017.07.023.

[195] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[196] *http://nccrt.org/wp-content/uploads/0305.60-Colorectal-Cancer-Manual_FULFILL.pdf.*

[197] *https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21457.*

colonoscopy, a number of appropriate organizations have suggested that we adopt a new approach that looks at colorectal cancer screening as a continuum in the scenario where an initial stool-based test returns a positive result and includes a follow-on screening colonoscopy, when determined appropriate by the patient and the healthcare provider. There currently exists a misalignment of applicable patient cost sharing for a follow-on screening colonoscopy after a positive non-invasive stool-based test as Medicare coverage policies have not yet been updated to align to this new understanding of a complete CRC screening described earlier. If the patient had chosen the more expensive, invasive and burdensome screening colonoscopy as the first step in their CRC screening, there would be no applicable beneficiary cost sharing for the screening colonoscopy. However, under current policy, if the patient initially receives a positive result from a non-invasive, less burdensome and less expensive stool-based test as the first step in their CRC screening, beneficiary cost sharing would not be applicable for the initial stool-based test, but would be applicable for the subsequent colonoscopy (because it would be considered a diagnostic testing service given the presence of signs and symptoms of disease based on the result of the initial stool-based test).

2. Statutory Authority

Section 1861(s)(2)(R) of the Act includes CRC screening tests in the definition of medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and specifically names the following tests:

- Screening fecal-occult blood test;
- Screening flexible sigmoidoscopy; and
- Screening colonoscopy.

Section 1861(pp)(1)(D) of the Act also authorizes the Secretary to include in the definition of CRC screening tests other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1834(d) of the Act describes limitations for payment of CRC screening tests, including that no payment may be made for CRC screening tests of screening fecal-occult blood test at section 1834(d)(1)(B)(i) of the Act and screening flexible sigmoidoscopy at section 1834(d)(2)(E)(i) of the Act for patients under the age of 50. Section 1834(d) of the Act does not describe a minimum age limit for screening colonoscopy.

Section 1834(n) of the Act, added by section 4105 of the Affordable Care Act, grants the Secretary the authority to modify coverage of certain preventive services identified in section 1861(ddd)(3) of the Act, which in turn cross-references section 1861(ww)(2) of the Act (including CRC screening tests at section 1861(ww)(2)(E) of the Act). The Secretary may modify coverage to the extent that such modification is consistent with the recommendations of the USPSTF, per section 1834(n)(1)(A) of the Act.

3. Regulatory Authority

Our implementing regulations for CRC screening are codified at § 410.37. Similar to section 1834(d) of the Act, § 410.37 describes limitations on coverage and provide that payment may not be made for screening fecal-occult blood tests at § 410.37(c) or screening flexible sigmoidoscopies at § 410.37(e) for individuals under the age of 50. Also similar to section 1834(d) of the Act, § 410.37(g) does not describe a minimum age requirement for screening colonoscopies. Section 410.37 also establishes coverage for screening barium enemas at paragraph (h) and limits coverage to and individual 50 years of age or greater for an individual who is not at high risk of CRC at paragraph (h). Section 410.37(h) does not describe a minimum age limit for coverage of screening barium enemas for individuals who are at high risk of CRC.

4. National Coverage Determination

NCD 210.3 CRC Screening Tests was last revised effective January 19, 2021, when coverage was expanded to include Blood-based Biomarker Tests. NCD 210.3 was previously revised effective October 9, 2014, when coverage was expanded to include The Cologuard™—Multi-target Stool DNA (sDNA) Test. Prior to that, NCD 210.3 was revised effective January 1, 2004, when coverage was expanded to include immunoassay-based fecal occult blood test (iFOBT), which can be used as alternative to existing guaiac-based fecal occult blood test (gFOBT). Under NCD 210.3, the Blood-based Biomarker Tests, sDNA test, iFOBT and gFOBT tests all include a limitation of coverage that the patient be at least 50 years of age.

In the NCD 210.3 Final Decision Memo dated January 19, 2021, we noted that multiple commenters provided an alert that a draft USPSTF revised CRC recommendation was circulating and which included a recommendation that CRC screening begin at age 45 instead of 50. The commenters on the draft NCD Decision Memo, in the course of the NCD process, also encouraged CMS to align screening age limitations for all CRC screening tests. At that time, the draft USPSTF recommendation had not been finalized. Therefore, we responded that we are finalizing NCD 210.3 coverage of CRC screening tests with an age range of 50 to 85 years of age. That said, if the draft USPSTF recommendation is finalized and/or other society guidelines are revised, we may reconsider, in consultation with appropriate professional organizations, the appropriate CRC screening tests limitations and address appropriately in an efficient manner.

5. Revisions

In May 2021, the USPSTF issued a revised recommendation (with a Grade B) that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[198] Accordingly, we proposed to exercise our authority under section 1834(n) of the Act to modify coverage of certain CRC screening tests to begin when the individual is age 45 or older. The tests included in the May 2021 USPSTF revised recommendation, including stool-based tests of gFOBT, iFOBT and sDNA, and direct visualization test of flexible sigmoidoscopy. Screening colonoscopy does not have a minimum age requirement under Medicare coverage. We invited public comment on this proposal.

The following is a summary of the comments we received and our responses.

Comment: Overall, commenters expressed support for our proposal to exercise our authority under section 1834(n) of the Act modify coverage of certain CRC screening tests described above and recommended by the USPSTF to begin when the individual is age 45 instead of 50.

Response: We thank commenters for their support for our proposal to exercise our authority under section 1834(n) of the Act modify coverage of certain CRC screening tests described above and recommended by the USPSTF to begin when the individual is age 45 instead of 50.

Comment: One commenter recommended that all CRC screening tests should have no minimum age as a condition of coverage or payment,

[198] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

similar to screening colonoscopy described earlier in our provision.

Response: We disagree with the commenter's recommendation that all CRC screening tests should have no minimum age as a condition of coverage or payment. Age limitations as conditions of coverage and payment are a common and long-established safeguard in statute, regulation and NCD, which protect beneficiaries from clinically inappropriate services and protect beneficiaries and the Medicare program from fraud, waste and abuse. The age limitations described in our provision are in alignment with clinical evidence-based recommendations by the USPSTF, American Cancer Society, and other medical specialty societies.

After consideration of public comments, we are finalizing our proposal made in the CY 2023 PFS proposed rule to exercise our authority under section 1834(n) of the Act to modify coverage of certain CRC screening tests described above and recommended by the USPSTF to begin when the individual is age 45 instead of 50.

We also proposed to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3). We discussed in the proposed rule that while these tests were not recommended in the earlier mentioned May 2021 revised USPSTF recommendation, they are Medicare covered CRC screening tests and would be an important alternative to the stool based and direct visualization tests, especially for individuals with medical complexity and those in rural and underserved communities. We noted that aligning the minimum age requirements for certain Medicare covered CRC screening tests described in our proposal to consistently begin for individuals at age 45 would avoid confusion and reduce barriers for beneficiaries and healthcare professionals. The proposal reflected our belief that consistent coverage and payment policies would be important in promoting CRC screening, which would result in expanded prevention, early detection and improved health outcomes. As proposed, conforming changes to reduce the minimum age for certain CRC screening tests would be made at § 410.37 and NCD 210.3 authorities described earlier. We did not propose to modify existing conditions of coverage or payment for maximum age limitations and frequency limitations. We also retained the same existing frequency limitations except in the instance of a follow-on screening colonoscopy after a positive result from a non-invasive stool-based CRC screening test. We proposed to amend § 410.37 paragraph (c)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'', amend paragraph (c)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'', amend paragraph (e)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'', amend paragraph (e)(2) by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'', and amend paragraph (i)(1), by removing the phrase ''individual age 50'' and adding in its place the phrase ''individual age 45''. We also proposed to issue formal instructions that would revise the minimum age for the CRC screening tests described in NCD 210.3 from 50 to 45 years.

As explained in the proposed rule, we consulted with and reviewed recommendations from the following appropriate organizations in our proposal to uniformly reduce the minimum age for certain CRC screening tests from 50 to 45. ACS recommended that people of average risk of CRC start regular screening at age 45 and recommends stool-based tests and visual exam-based tests.[199] The American Society of Colon and Rectal Surgeons (ASCRS) recommended CRC screenings for individuals 45 years of age and older and identifies barium enema as one of multiple screening options.[200] The U.S. Multi-Society Task Force on Colorectal Cancer, which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, recently revised their recommendation that CRC screening for individuals of average risk of CRC begin at age 45 instead of 50.[201] The Centers for Disease Control and Prevention (CDC) website advised regular screening, beginning at age 45, as the key to preventing colorectal cancer and finding it early. The CDC website goes on to describe the earlier mentioned May 2021 revised USPSTF recommendations.[202]

We considered the importance of aligning the minimum age requirement for CRC screening across Medicare covered CRC screening tests, as well as private health plans and Medicaid impacted by the May 2021 revised USPSTF recommendation. We noted that we believe consistent policy across payers in terms of minimum age limits for CRC screening tests is critical to the public's understanding of evolving CRC screening recommendations. As added by section 2713 of the ACA, 42 U.S.C 300gg–13 requires a that group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements for evidence-based items or services that have in effect a rating of ''A'' or ''B'' by the USPSTF. In addition, we considered that section 1905(a)(13) of the Act, added by section 4106 of the ACA, which expands Medicaid coverage to include screening services that are assigned a grade of A or B by the USPSTF. We noted that expanding coverage for barium enema and blood-based biomarker CRC screening tests to a minimum age of 45, in alignment with the direct visualization and stool-based tests recommended in the May 2021 revised USPSTF recommendation, would allow additional, low burden options and alternatives that may be preferred by some health professionals and patients. While the recommendations from different professional societies and other appropriate organizations include varying detail in terms of specific tests, we noted that we understood the growing consensus in the health care community is that the pathology of CRC now requires that broad preventative screening should begin for individuals at age 45 instead of 50. We also noted that reducing the minimum age for the Medicare covered CRC screening tests barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3) from 50 to 45 years of age, in addition to and in alignment with the direct visualization and stool-based tests described in the 2021 USPSTF recommendation, is appropriate and consistent with our purpose of early detection of colorectal cancer described in § 410.37(a)(1). We discussed that we received public comment broadly supportive of reducing the minimum age for certain CRC screening tests in

[199] *https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html.*

[200] *https://fascrs.org/patients/diseases-and-conditions/frequently-asked-questions-about-colorectal-cancer.*

[201] Gastroenterology. 2022 Jan;162(1):285–299. doi: 10.1053/j.gastro.2021.10.007. Epub 2021 Nov 15.

[202] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

both the CY 2022 PFS final rule (86 FR 65179) and in the public comments in response to our Proposed Decisions Memo for NCD 210.3 Screening for Colorectal Cancer—Blood-Based Biomarker Tests (Final Decision Memo dated January 19, 2021). We noted that we look forward to further consultation with the public and appropriate organizations through the public comment period for this proposed rule. We invited public comment on this proposal.

The following is a summary of the comments we received and our responses on our above described proposal.

Comment: We received numerous public comments expressing approval of our proposal to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3). Commenters expressed agreement with our earlier expressed belief that our proposal would avoid confusion and reduce barriers for beneficiaries and healthcare professionals and that consistent coverage and payment policies would be important in promoting CRC screening, which would result in expanded prevention, early detection and improved health outcomes.

Response: We thank commenters for supporting our proposal to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3).

Comment: Some commenters recommended that CMS remove barium enema as a covered CRC screening test for all individuals because it is not recommended by the USPSTF, specialty society guidelines and is rarely performed in current times.

Response: The recommendation in this comment is out of scope for our proposals made in the CY 2023 PFS proposed rule, but we will take it into consideration for possible future rulemaking.

After consideration of public comments, we are finalizing our proposal made in the CY 2023 PFS proposed rule to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3).

We also proposed to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. In this scenario, we explained that we now understand the follow-on screening colonoscopy to be part of a continuum of a complete CRC screening and not a separate diagnostic, therapeutic or other procedure. Relatedly, we proposed that the frequency limitations described for screening colonoscopy in § 410.37(g) would not apply in the instance of a follow-on screening colonoscopy test after a positive result from a Medicare covered stool-based test. We proposed to add new paragraph (k) to § 410.37 to state that, effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. We aimed to avoid disruption to the existing conditions of coverage and payment for CRC screening for this unique scenario and include text noting the frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

We acknowledged that under current Medicare policy, a colonoscopy after a stool-based CRC screening test returns a positive result would be subject to beneficiary cost sharing because it would be considered a diagnostic, therapeutic or other non-screening procedure. We discussed that § 410.32(a) describes a diagnostic test as an instance when the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Under current policy, a positive result from the CRC screening stool-based test would be a sign of illness or disease and the subsequent colonoscopy would be for treatment and management of that specific medical problem. We explained that we now believe our current policy of CRC screening to not include a follow-on screening colonoscopy after a stool-based test returns a positive result is incomplete and not in full support of our definition of CRC screening test at § 410.37(a)(1) for the purpose of ''early detection of colorectal cancer''.

As proposed, the provision to expand the definition of CRC screening to include a follow-on screening colonoscopy after a stool-based test returns a positive result would include implications for beneficiary cost sharing. In many cases, beneficiary cost sharing (coinsurance and deductible) will not be applicable for the stool-based test nor the follow-on colonoscopy screening tests, as described at section 1833(1)(W)(ii) of the Act, as added by section 4104(b) of the Affordable Care Act. When the follow-on screening colonoscopy requires additional procedures furnished in the same clinical encounter, the phased-in Medicare payment percentages for colorectal cancer screening services described in regulation at § 410.152(l) and finalized in the CY 2022 PFS final rule (86 FR 65177 through 65179) will apply. That is, when the follow-on screening colonoscopy includes the removal of tissue or other related services during the same clinical encounter the beneficiary coinsurance would be reduced over time from 15 percent for services furnished during CY 2023 through CY 2026 to 10 percent for services furnished during CY 2027 through 2029 to zero percent beginning in CY 2030 and thereafter.

Our goal is that the patient and their healthcare professional make the most appropriate choice in CRC screening, which included considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and screening colonoscopy tests in terms of invasiveness and burdens to the patient and healthcare system. We recognized there are several advantages to choosing a non-invasive stool-based CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures. We discussed that it has been reported that a large proportion (46 percent) of screening colonoscopies found no polyps [203] so optimizing use of a non-invasive stool-based screening test as a first step (when determined appropriate by the patient and their healthcare professional) would benefit the patient and also the Medicare program. In many instances, a

[203] Lieberman DA, Weiss DG, Bond JH, Ahnen DJ, Garewal H, Chejfec G. Use of colonoscopy to screen asymptomatic adults for colorectal cancer. Veterans Affairs Cooperative Study Group 380. N Engl J Med. 2000 Jul 20;343(3):162–8. doi: 10.1056/NEJM200007203430301. Erratum in: N Engl J Med 2000 Oct 19;343(16):1204. PMID: 10900274.

colonoscopy is not the most appropriate first step in colorectal cancer screening and would represent an unnecessary burden and over-servicing for both the patient and healthcare system. The May 2021 revised USPSTF recommendation reads, ''stool-based screening requires persons to collect samples directly from their feces, which may be unpleasant for some, but the test is quick and noninvasive and can be done at home (the sample is mailed to the laboratory for testing), and no bowel preparation is needed to perform the screening test.'' [204] The May 2021 revised USPSTF recommendation goes on to described that direct visualization CRC screening tests such as screening colonoscopy and screening flexible sigmoidoscopy must be performed in a clinical setting rather than home and require bowel preparation prior to the test. In addition, sedation or anesthesia is usually used during screening colonoscopy and the patient requires additional recovery time and assistance with transportation home.

We discussed that we have heard from interested parties that CMS should consider a complete CRC screening to include a follow-on screening colonoscopy when a non-invasive stool-based test returns a positive result. We noted that we consulted with and reviewed recommendations from a number of professional societies in developing the proposal, including supportive letters and communications with representatives from American Gastroenterological Association, American Cancer Society Cancer Action Network, and Fight Colorectal Cancer. The proposal regarding a new understanding of a complete CRC screening aligns with a policy recommendation from the National Colorectal Cancer Roundtable, which was ''established by the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC) in 1997, is a national coalition of public organizations, private organizations, voluntary organizations, and invited individuals.'' [205] The proposal also aligned to a 2018 CRC screening guideline update from the American Cancer Society, which read ''Implementation of the screening options included in this guideline is premised on the requirement that the appropriate follow-up to a positive (noncolonoscopic) test is a timely colonoscopy. The follow-up colonoscopy should not be considered a ''diagnostic'' colonoscopy but, rather, an integral part of the screening process, which is not complete until the colonoscopy is performed. The information provided to patients to facilitate a choice among tests must include the importance of follow-up of a positive (noncolonoscopic) test with colonoscopy. Repeating a positive stool-based test to determine whether to proceed to colonoscopy is not an appropriate screening strategy.'' [206]

We also considered the May 2021 revised USPSTF recommendation, which includes the statement ''When stool-based tests reveal abnormal results, follow-up with colonoscopy is needed for further evaluation . . . Positive results on stool-based screening tests require follow-up colonoscopy for the screening benefits to be achieved.'' [207] We also note that the U.S. Departments of Labor, Health and Human Services (HHS), and the Treasury issued a Frequently Asked Questions guidance on January 10, 2022 that reads, ''A [non-grandfathered group health] plan or [health insurance issuers offering non-grandfathered group or individual health insurance coverage] must cover and may not impose cost sharing with respect to a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals described in the USPSTF recommendation. As stated in the May 18, 2021 USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.[208] The follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization screening test is therefore required to be covered without cost sharing in accordance with the requirements of PHS Act section 2713 and its implementing regulations.'' [209]

We believe that the proposal to update our regulations to align to our new understanding of a complete CRC screening would address the beneficiary cost sharing barrier that currently exists for most individuals for a subsequent colonoscopy after an initial stool-based test returns a positive result, would allow more options for healthcare professionals and patients, would help optimize non-invasive CRC screening test use, and improve health outcomes for Medicare beneficiaries. We received public comments supportive of the policy described in our proposal in both the CY 2022 PFS final rule (86 FR 65179) and in public comments to our Proposed Decision Memo for the NCD 210.3 Screening for Colorectal Cancer—Blood-Based Biomarker Tests (Final Decision Memo dated January 19, 2021).[210] We noted that we look forward to further consultation with the public and appropriate organizations through the public comment period for this proposed rule. We invited public comment on the proposal.

The following is a summary of the comments we received and our responses on our earlier described proposal.

Comment: Overall, commenters expressed support for our proposal to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Many commenters expressed agreement with our approach of a complete colorectal cancer screening that includes a follow-on screening colonoscopy along with a stool-based test (with a positive result). In addition, many commenters expressed agreement with our statement that beneficiary cost sharing for a follow-on colonoscopy after a stool-based test returns a positive result is a burdensome and significant barrier to expanding screening for colorectal cancer and, by extension, achieving better health outcomes through prevention, early detection, improved treatment and reduced mortality.

Response: We thank commenters for their support for our proposal to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result.

[204] *https://www.uspreventiveservices taskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[205] *https://nccrt.org/about/.*

[206] *https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21457.*

[207] *https://www.uspreventiveservices taskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[208] The quoted text from the January 10, 2022 Frequently Asked Questions guidance includes a footnote to this portion of the text that reads, ''In addition, in its 'Supporting Evidence' section, the USPSTF Full Recommendation Statement states: 'Several comments requested that colonoscopy to follow up an abnormal noncolonoscopy screening test result be considered part of screening. The USPSTF recognizes that the benefits of screening can only be fully achieved when follow-up of abnormal screening test results is performed. The USPSTF added language to the Practice Considerations section to clarify this.' ''

[209] *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.*

[210] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=299.*

Comment: Many commenters asked that we exercise our authority under section 1861(pp)(1)(D) of the Act to further expand our approach of a complete colorectal cancer screening. Many requested that we remove the text ''stool-based'' from our proposed regulatory text at § 410.37(k), resulting in a complete CRC screening including a follow-on screening colonoscopy after a Medicare covered non-invasive screening test. Many commenters requested that a complete CRC screening include a screening colonoscopy after a positive result from a blood-based biomarker test, as well as a stool-based test. A few requested that we include a follow-on screening colonoscopy after any non-colonoscopy CRC screening test. Many commenters cited our earlier reasoning of consistency of policies across CRC screening tests to promote CRC screening and avoid confusion among healthcare professionals and beneficiaries in support their request for an expanded definition of a complete colorectal cancer screening.

Response: We disagree with the commenters that requested a further expansion of a complete colorectal cancer screening that would include additional first step tests beyond a non-invasive stool-based test. We believe the stool-based tests are unique to other CRC screening tests in terms of their non-invasiveness, the fact that stool-based tests can be implemented by the patient at home and mailed into the lab, the absence of bowel preparation and anesthesia and the comparatively lighter burden and mitigated potential for over servicing of the patient and the healthcare system.

We agree that blood-based biomarker CRC screening tests have significant potential and we expanded coverage to include them in the reconsidered NCD 210.3, effective January 2021. We also recognize that blood-based biomarker CRC screening tests continue to be an emerging and quickly evolving technology. As of September 2022, no blood-based biomarker tests have achieved the sensitivity and specificity requirements of NCD 210.3. We also note that, as of September 2022, blood-based biomarker screening tests are not recommended by the USPSTF for CRC screening. The May 2021 USPSTF revised recommendation statement reads, ''Because of limited available evidence, the USPSTF recommendation does not include serum tests, urine tests, or capsule endoscopy for colorectal cancer screening.'' [211] The public comments have been informative and we will consider this feedback for future rulemaking.

Comment: A few commenters expressed concern that the narrative of our proposal inappropriately favors stool-based tests over colonoscopies and could discourage the use of colonoscopy as a first-line CRC screening test in the Medicare population.

Response: We clarify that our provision for a complete colorectal cancer screening does not change the coverage or payment requirements for screening colonoscopy as an optional first step in the patient screening process. We note that our proposal included the narrative, ''our goal is that the patient and their healthcare professional make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step.''

After consideration of public comments, we are finalizing our proposal made in the CY 2023 PFS proposed rule to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result.

The scope of the proposals is limited to CRC screening tests and does not address the coverage or payment status of other screening services or tests recommended by the USPSTF or covered by Medicare.

The following is a summary of the comments we received and our responses on our proposal as a whole.

Comment: Many commenters requested that CMS provide specific coding instructions and educational materials for the Medicare Administrative Contractors (MACs), healthcare systems, providers and beneficiaries to inform them of the significant changes in Medicare policy on CRC screening coverage and payment.

Response: We thank the commenters for the feedback and agree on the importance of implementation and educating stakeholders. We will provide implementation instructions, including coding and payment, through the CMS Transmittals online platform [212] and educational articles through the Medicare Learning Network online platform.[213]

Comment: We received several comments that were outside of the scope of the proposals made in the CY 2023 PFS proposed rule. Comments included requests that CMS end its national policy of non-coverage of Computed Tomography Colonography (CTC) for CRC screening (NCD 210.3), requests that CMS extend our approach of a complete colorectal cancer screening to breast, cervical, and lung cancer screenings, recommendations on coverage of anesthesia services furnished by anesthesia providers, and requests regarding the furnishing of colonoscopies by Physicians Assistants and Nurse Practitioners.

Response: Although we are not summarizing and responding to these comments in the final rule, we will take them into consideration for possible future rulemaking.

After considering public comments, we are finalizing the proposals made in the CY 2023 PFS proposed rule to expand coverage for CRC screening and reduce barriers to access to CRC cancer prevention, early detections and improved health outcomes.

6. Summary

In summary, we are exercising our authority in sections 1834(n) and 1861(pp)(1)(D) of the Act to expand CRC screening coverage by reducing the minimum age for CRC screening tests from 50 to 45 years of age for certain Medicare covered CRC screening tests that currently include a minimum age of 50 as a limitation of payment or coverage. As finalized, a screening colonoscopy would continue to not have a minimum age limitation.

We also are exercising our authority in section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a non-invasive stool-based test returns a positive result. As noted earlier in the rule, the outcome of our more appropriate and complete approach to CRC screening will be that, in many cases, beneficiary cost sharing for both the initial non-invasive screening stool-based test and the follow-on screening colonoscopy test will not apply because both tests will paid at 100 percent (no applicable copayment percentage) as specified preventive screening services under the statute.

We believe the proposals will expand access to quality care and improve

[211] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[212] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals.*

[213] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo.*

health outcomes for patients through prevention, early detection, more effective treatment and reduced mortality. Our policies to expand coverage of CRC screening tests will directly advance the Biden Administration's health equity goals. Rural communities and communities of color are especially impacted by the incidence of CRC. African Americans experience both new cases and deaths from colorectal cancer at rates significantly above those of all races. As noted earlier in the rule, the May 2021 revised USPSTF final recommendation statement reads, ''The causes for these health disparities are complex; recent evidence points to inequities in the access to and utilization and quality of colorectal cancer screening and treatment as the primary driver for this health disparity rather than genetic differences . . . Black adults across all age groups, including those younger than 50 years, continue to have higher incidence of and mortality from colorectal cancer than White adults.'' [214] We believe our policies to expand coverage of CRC screening will make significant progress in reducing barriers and addressing this inequity in healthcare.

E. Removal of Selected National Coverage Determinations

As discussed in the CY 2023 PFS proposed rule (87 FR 45860) on pages 46086 and 4087, we periodically identify and propose to remove National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries. In the proposed rule we explained that since the CY 2021 PFS final rule (85 FR 84472), we have used notice and comment rulemaking to obtain public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Eliminating an NCD for items and services means that the item or service will no longer be automatically, nationally covered or non-covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). We summarized the policy and explained the factors that we consider.

In addition to the six factors listed below, we also consider the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology development since the last determination, and availability and quality of clinical evidence and information to support removal of an NCD. We would consider proposing the removal of an NCD if any of the following factors are present:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.

For more detailed background information on the circumstances/factors we consider and methods of evaluation and sources of information, readers can review the CY 2023 PFS proposed rule, or read prior NCD removal discussions in the CY 2021 PFS final rule (85 FR 84472, December 28, 2020 on pages 84797 through 84802), and the CY 2022 PFS final rule (86 FR 64996, November 29, 2021) on pages 65241 through 65244.

We proposed the following NCD for removal and provided a summary of the rationale for removal. The current NCD below is available in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961*.

1. NCD 160.22 Ambulatory EEG Monitoring (06/12/1984)

- *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* Ambulatory, or prolonged electroencephalographic (EEG) monitoring is a diagnostic test that continuously records the brain's electrical activity during a patient's routine daily activities and sleep. Ambulatory EEG monitoring may be used to diagnose seizure disorders and metabolic, infectious, or inflammatory disorders that affect the brain's activity, particularly when a resting/routine EEG is not conclusive. The NCD currently defines ambulatory EEG monitoring as 24-hour EEG monitoring and provides coverage for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG. The NCD also provides that ambulatory EEG can be utilized in the differential diagnosis of syncope and transient ischemic attacks if not elucidated by conventional studies. Additionally, the NCD states that ambulatory EEG ''should always be preceded by a resting EEG''. External interested parties recommended removal of this NCD. The NCD contains outdated language that is inconsistent with, and contrary to current standards of care. For example, the NCD contains references to cassette tapes. This outmoded technology has been supplanted with more modern techniques that are more accurate and convenient for monitoring. The document uses the word ''ambulatory,'' implying certain sites of service whereas this diagnostic test is not site specific. The NCD makes mention of a 24-hour duration of monitoring. However, the more recent coding structures permit monitoring in increments including 36–60 hours, 60–84 hours, and >84 hours. Additionally, interested parties stated that the language ''should always be preceded by a resting EEG'' could potentially create waste and a burden. Interested parties indicated that in some clinical scenarios, a ''resting/routine'' EEG is unlikely to adequately detect seizure or other brain activity that would be useful for diagnostic purposes, but would be detected by prolonged EEG testing. Removing the outdated NCD will allow MACs to update guidance for this established diagnostic test.

In summary, we solicited comment on the proposal to remove NCD 160.22 Ambulatory EEG Monitoring. We outlined in the proposed rule that we would use the public comments to help inform our decision to take one of three actions on the NCD proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD by opening a National Coverage Analysis. Comments suggesting that the NCD should be revised, rather than eliminated, should include new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a change in national coverage.

[214] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

The following is a summary of the public comments received on the Removal of Selected National Coverage Determinations and our responses:

Comment: Four commenters supported removal of this NCD. Three of these were the coalition of original requestors for NCD removal.

Response: We thank commenters for their support.

Comment: One commenter, a beneficiary advocacy organization, disagreed with removing the Ambulatory EEG monitoring NCD based on the position that CMS should not remove any positive coverage NCDs so long as there are beneficiaries using that service. The commenter also expressed the general belief that local contractor discretion leads to inconsistency in coverage. The commenter requested that CMS keep and reconsider this NCD.

Response: We do not agree that it would be appropriate to reconsider the NCD, rather than removing the prior policy. EEG monitoring is currently a well-established service for which there are also existing local coverage documents that can be updated in a more expeditious way than undertaking our full NCD reconsideration process. Additionally, the commenter did not provide new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a reconsideration request.

Comment: Two commenters noted that we did not propose to remove NCDs they had previously requested be removed for CY 2023 via letters to the Coverage and Analysis Group. One commenter noted that we did not propose to remove the NCDs they had recommended for removal in a previous rulemaking comment.

Response: We did receive a number of NCD removal requests through email, letters and prior rulemaking comments. In proposing to remove one NCD in this rulemaking cycle, Ambulatory EEG monitoring, it is implicit that we did not agree that the others should be removed at this time. We believe the other NCDs continue to be valid and appropriate. We will contact interested parties directly for further discussion.

Timing of request letters and emails can also be a factor, because of the advanced work needed to review claims data, available literature, gather other information, as well as the timing to prepare for the PFS rulemaking process. Additionally, we have recommended in past rulemaking discussions, that to support requests for removal, stakeholders should include which of the 6 circumstances/factors for removal justify removal of an NCD; as well as thoughtful rationale for that conclusion, including any available literature and/or other supporting information such as claims denials (with PHI redacted) to support their justification. We also encourage stakeholders to contact the Coverage and Analysis Group in CCSQ to discuss their concerns and their supporting information. We have found through our evaluation of NCD removal requests that sometimes NCD removal is a perceived cure for an issue unrelated to the NCD, such as coding and payment issues. Or, there may be a misunderstanding or misinterpretation of an NCD. Instead of removing the NCD, these types of issues can often be resolved through communication with internal CMS components and external parties. Also, in some instances, the underlying concerns have related to benefit category or benefit policy concerns, which might not be resolved by removing the NCD; instead, benefit category and benefit policy issues are better resolved by connecting stakeholders with the appropriate groups within CMS.

Comment: One commenter requested that we provide clarification that, in appropriate circumstances, CMS would consider removing a non-coverage or limited coverage NCD through rulemaking even if we have already accepted a formal request for reconsideration of the same NCD. The commenter noted concerns about CMS's workload of current national coverage analyses and reconsiderations and limited capacity for completing NCAs each year.

Response: We decline the request to make an inflexible blanket statement on whether it would be appropriate to propose to remove an NCD once CMS has granted a complete formal request to reconsider that NCD. The situation would seem to be unusual, but we are not prepared at this point to announce a definitive blanket policy. This type of determination would need to be made on a case-by-case basis.

Comment: Two commenters submitted comments about the wider national coverage analysis process, NCD reconsideration process, transparency and CMS's administrative workload of NCAs waiting to be opened for new NCDs or NCD reconsiderations.

Response: Comments about the NCA process, transparency and NCD reconsideration administration are outside the scope of this rulemaking. This rulemaking pertains only to the removal of selected NCDs.

After evaluating all of the comments, we are finalizing as proposed, the removal of NCD 160.22 Ambulatory EEG Monitoring. As explained above, we believe that for this topic, allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. In the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone. We also revised the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met (86 FR 65342). As discussed in the CY 2023 PFS proposed rule (87 FR 46087), we continue to monitor Medicare enrollment by OTPs and utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care, as well as monitoring for fraud, waste, and abuse. For CY 2023, we proposed several modifications to the regulations and policies governing

Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Methadone Pricing

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy in § 410.67(d)(2)(i) under which the payment for the drug component of episodes of care would be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. Under the policy finalized at § 410.67(d)(2)(i)(B), for oral medications, if average sales price (ASP) data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart J and voluntarily-submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. Using this established method, we determined that the payment amount for methadone furnished by OTPs during an episode of care in CY 2021 was $37.38,[215] which was 100 percent of ASP, as determined based on voluntarily-submitted ASP data for methadone.

In early September 2021, while gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to the CY 2021 rate, from $37.38 to $17.64.[216] This reduction was due to inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. The ASP is volume-weighted; however, ASP reporting is not required for oral methadone and only a small subset of methadone manufacturers voluntarily submit ASP data. In September 2021, of the nearly 50 available NDCs for oral methadone preparations with available pricing in the Red Book® compendia, voluntarily-submitted ASP data was available for only three of these NDCs. Pricing for oral methadone is distinct from most other drug pricing based on ASP because oral methadone is not separately payable as a drug or biological under Medicare Part B, and manufacturers are not subject to ASP reporting requirements under section 1927(b)(3)(A)(iii) of the Act for those NDCs. Additionally, we do not have utilization data on the different forms of methadone that can be dispensed or administered at OTPs. That is, we do not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally. When we researched OTP practice patterns as we were preparing to implement the new benefit for OUD treatment services furnished by OTPs, we received anecdotal reports that several OTPs used the oral concentrate exclusively.

For these reasons, while performing our annual ratesetting exercise for CY 2022, we had concerns as to whether the ASP data available to us at that time, which reflected voluntarily reported data from only a very small subset of methadone manufacturers, was representative of utilization of the two forms of oral methadone by the Medicare beneficiaries receiving OUD treatment services in OTPs. Additionally, given reports regarding the effects of the public health emergency (PHE) for COVID–19 on individuals with substance use disorders (SUDs), including OUD, and the questions we had related to whether the ASP data we had for methadone was reflective of OTP utilization due to the distinct nature of methadone pricing, as described above, we believed it was in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue, seek input from the OTP community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. We noted that section 1834(w)(2) of the Act allows for flexibility to consider the scope of services furnished, the characteristics of the individuals receiving services, and such other factors as the Secretary determines appropriate, in determining the rates paid to OTPs under Medicare.

Therefore, we issued the ''Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception'' interim final rule with comment period (IFC) (hereafter referred to as ''Methadone IFC''), which appeared in the November 19, 2021 **Federal Register** (86 FR 66031 through 66036). In the Methadone IFC, we established a limited exception to the methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the $37.38 payment amount that was determined for CY 2021. We also revised the regulation at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception for CY 2022 and to make a conforming change to the reference to 42 CFR part 414, subpart J. We are finalizing these revisions in section V. of this final rule.

Under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 *(Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program))* and the methadone add-on code described by HCPCS code G2078 *(Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure)* was maintained at the CY 2021 rate of $37.38 for the duration of CY 2022. We also applied the annual update to the non-drug component of HCPCS G2067 for CY 2022 as required under § 410.67(d)(4)(iii). We stated that we believed maintaining the payment amount for methadone at the CY 2021 rate during CY 2022 would allow time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for CY 2023 (86 FR 66033). We solicited comments on this exception to the payment methodology for the drug component of an episode of care in order to maintain the payment rate for methadone at the CY 2021 payment amount during CY 2022. In addition, we sought comments on OTP utilization patterns for methadone, particularly the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic. We also stated that we would consider the comments received in determining how best to determine the payment rate for methadone in CY 2023, including

[215] *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.*

[216] The TRICARE rate for the drug portion of its weekly bundled payment for methadone treatment is $24.04 for 2022, which would also have been a decrease from the CY 2021 payment rate under Medicare and could not be used to set the Medicare payment rate for methadone in CY 2022 under § 410.67(d)(2)(i)(B) because ASP data was available for methadone.

whether we should propose changes to the structure of OTP coding and payment in order to account for differences in pricing and utilization of the different formulations of methadone.

We received several comments in response to the Methadone IFC from medical associations, national associations representing OTPs, and individual commenters that expressed strong support for stabilizing the payment rate for methadone. Please see full summary of comments on the Methadone IFC and our responses in section V.A. of this final rule. One commenter stated cutting reimbursements to providers who specialize in treatment for OUD in the middle of an OUD epidemic that has been exacerbated by the COVID–19 pandemic could have harmful consequences for beneficiaries and cited that the HHS Office of Inspector General (OIG) expressed concern that Medicare beneficiaries face challenges accessing OUD treatment. The commenter also stated that if Medicare reimbursements for methadone fall well below OTPs' costs of acquiring and administering the medication, OTPs may have no choice but to prescribe a much more expensive medication (buprenorphine or naloxone) as part of medication-assisted treatment (MAT)/Medications for Opioid Use Disorder (MOUD), which would result in higher costs for the Medicare program and taxpayers, while not necessarily improving care. For example, methadone is often more ideal for severe dependence or if there is a high risk of diversion, while buprenorphine may be more advantageous for mild to moderate dependence and when extensive supervision by a practitioner is not needed.[217] Another commenter stated that it is possible that freezing the payment rate for methadone at the current level could still result in some negative outcomes, as supply chain and logistics issues have generally resulted in increased prices across the country such that a payment rate increase may be necessary, but thought that freezing the rate at the current level was a prudent solution for 2022. A commenter representing a large number of OTPs across the country stated that OTPs rarely dispense methadone tablets and instead administer the oral concentrate formulation. This commenter stated that methadone oral concentrate is more expensive to acquire and administer than the tablet form, but that it has been shown to lead to better clinical outcomes for their patients, which is why it is their doctors' formulation of choice. This commenter went on to state that the existing methodology to calculate the payment rate for the drug component of the methadone weekly bundle does not accurately capture the extra costs associated with administration of the oral concentrate, explaining that oral concentrate formulations require careful measurement in addition to maintaining electric pumps and updating computer software. The commenter also noted that it is expensive to employ the necessary nursing staff, and stated that a number of States require full-time pharmacists for the dispensing and administration of medication. Another commenter noted that the National Association of State Alcohol and Drug Abuse Directors (NASADAD), in conjunction with the State Opioid Treatment Authorities (SOTAs), conducted a survey that was distributed to the 1,800 OTPs throughout the United States. As of December 31, 2021, NASADAD and the SOTAs had collected data from 1,550 OTPs. These data include the number of patients being treated at OTPs as of January 1, 2021, including the number of patients using one of the three FDA-approved medications to treat opioid use disorder (methadone, buprenorphine, and extended-release naltrexone) and the specific forms of the medication being used.

As discussed in the CY 2023 PFS proposed rule (87 FR 46089 through 46090), we appreciate the feedback received in response to the Methadone IFC. We agree with commenters that decreasing the payment amount for methadone in the middle of an OUD epidemic that has been exacerbated by the COVID–19 pandemic could have harmful consequences for beneficiaries as we discussed in the Methadone IFC (86 FR 66032). We also noted that we were looking forward to seeing the results of the survey initiated by NASADAD and the SOTA, so that we can better understand the utilization of methadone tablets and oral concentrate in OTPs.

In light of the comments received in response to the Methadone IFC, we considered how best to maintain access to treatment with methadone in the OTP setting for Medicare beneficiaries. We considered splitting the methadone bundled payment code into two codes—one for oral concentrate and one for the tablet. This would allow us to track Medicare utilization of each formulation. However, because of the inconsistency in available ASP data for orally administered methadone due to the fact that manufacturer reporting of sales data for these dosage forms of methadone is voluntary, (that is, orally administered methadone is not a drug that falls under the ASP reporting requirements under sections 1927(b)(3)(A)(iii) or 1847A(f)(2)(A) of the Act), we did not believe that voluntary reporting of ASP data for either form of orally administered methadone (oral concentrate or tablet) currently provides a reliable source for pricing the methadone codes. For example, for the first quarter of 2022, there was no ASP data reported for orally administered methadone. Under the policy at § 410.67(d)(2)(i)(B)(*1*), when ASP data are not available for methadone, we would base the payment amount for methadone on the TRICARE rate. We found that the applicable TRICARE payment amount for methadone for CY 2022 would be $24.04. Using the TRICARE payment amount for methadone for CY 2023 would result in a decrease of $13.34 compared to the rate that applied in CY 2021 and CY 2022. In the CY 2023 PFS proposed rule (87 FR 46089), we stated that this decrease would be problematic for all of the reasons that we expressed in the Methadone IFC (86 FR 66034 through 66035). For these reasons, we noted that we believed that it would be appropriate to propose an alternate methodology for pricing the drug component of the methadone bundle and the methadone add-on code in order to maintain payment stability, and therefore, maintain appropriate access to OUD treatment services furnished at OTPs for Medicare beneficiaries.

We referred to the CY 2020 PFS final rule (84 FR 62667), where we discussed the methods we had considered for providing an update each year to the drug component of the OTP bundled payment rates. We stated that we considered annually updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the Producer Price Index (PPI) for chemicals and allied products, analgesics (WPU06380202). We explained that the PPI for chemicals and allied products, analgesics is a subset of the PPI produced by the Bureau of Labor Statistics (BLS). At that time, we decided against proposing to update the pricing of the drug component of the OUD treatment services payment rate via an established update factor, such as the PPI, in favor of an update using the most recently available ASP data at the time of ratesetting for the applicable calendar year. We explained that we believed an ASP-based approach would update the pricing of the drug

[217] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3271614/.*

component of the OUD treatment services payment rate in a manner that would be more consistent with other Medicare payments under Part B. However, we also solicited comments on the alternative approach of using the PPI for chemicals and allied products, analgesics, but did not receive any comments.

In the CY 2023 PFS proposed rule, we stated that because we did not believe that ASP data can provide an appropriate reflection of the changes in methadone costs for OTPs until such a time that more complete and reliable ASP data are available for methadone, we had reconsidered the use of the PPI to update the payment rate for methadone. We noted that according to the U.S. BLS,[218] the PPI program measures the average change over time in the selling prices received by domestic producers for their output. The application of an annual adjustment factor would be consistent with Medicare payment policy in other areas, such as the outpatient prospective payment system, which updates the conversion factor used to set payment rates under that payment system by applying the outpatient department fee schedule increase factor, which is equal to the percentage change in the hospital inpatient market basket (86 FR 63498 through 63500). The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase to provide inpatient care.

We explained that the PPI for Pharmaceuticals for Human Use (Prescription) (WPUSI07003) reflects price changes associated with the average mix of all pharmaceuticals in the overall economy and is both publicly available and regularly published. We noted our belief that this PPI would be an appropriate factor to adjust the payment rate for methadone to reflect the changes in methadone costs for OTPs over time. Methadone is an established drug in the drug supply chain, and we believe that an overall price trend that incorporates price changes for prescription pharmaceuticals would provide an appropriate update to reflect any increase in the costs incurred by OTPs in furnishing methadone during episodes of care.

Accordingly, for CY 2023 and subsequent years, we proposed to revise our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. As proposed, we would base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription). Because we froze the payment amount for methadone at the 2021 amount for CY 2022, we proposed to account for the inflation for both CY 2022 and CY 2023 in setting the payment rate for CY 2023. Thus, we proposed to update the methadone payment amount for CY 2023 based on the projected increase in the PPI for Pharmaceuticals for Human Use (Prescription) to reflect the forecasted price growth for prescription drugs for the 2-year period from CY 2021 to 2022 and from CY 2022 to 2023. As explained in the proposed rule, based on the 2022 Q1 forecast from IHS Global Inc. (IGI), the CY 2023 methadone payment amount, as proposed, would be $39.29, which is the CY 2022 payment amount of $37.38 increased by a projected 5.1 percent growth in the PPI for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023 ($37.38 * 1.051 = $39.29). IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast various price proxies used in the CMS market baskets. Additionally, we proposed that if more recent data became available (for example, a more recent estimate of the PPI), we would use such data in the final rule to determine the final CY 2023 methadone payment amount. For subsequent years, we proposed to continue to update this rate annually using the PPI for Pharmaceuticals for Human Use (Prescription). We noted that under the proposal, we would continue to monitor methadone pricing in order to determine whether we may need to propose additional changes to this methodology through future rulemaking to account for any significant changes in the acquisition costs for methadone. We also noted that we may also revisit this policy in the event that new or more reliable data on methadone pricing become available. We solicited public comment on other potential data sources that could be used to estimate an OTP's cost for acquiring methadone.

Accordingly, we proposed to revise the regulation at § 410.67(d)(2)(i)(B)(*2*) to state that for CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount for methadone in CY 2021 as determined under § 410.67(d)(2)(i)(B)(*1*) and updated by the PPI for Pharmaceuticals for Human Use (Prescription). As proposed, the TRICARE rate would no longer be an alternative pricing methodology for methadone. We also proposed to correct an inadvertent error in the text of the current regulation at § 410.67(d)(2)(i)(B)(*2*), which includes an inaccurate cross-reference to paragraph (d)(2)(i)(B)(*1*).

The following is a summary of the public comments received on the methadone pricing proposals and our responses:

Comment: Many commenters supported our proposal to maintain the current methadone payment rate ($37.38) and update that amount by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription). Commenters stated this proposal would ensure payment rates keep pace with increasing practice costs, thereby ensuring patients are able to access OUD treatment services. Additionally, several commenters stated that methadone oral concentrate is the formulation that is primarily used in the OTP setting. One commenter noted that the tablet formulation of methadone is ''almost non-existent'' in the OTP setting and supported use of pricing data that reflects pricing for the oral concentrate. Another commenter stated that most OTPs in New York state routinely use oral concentrate methadone and all newly certified OTPs in New York administer oral concentrate methadone. This commenter noted that there are significant related costs associated with the use of methadone tablets which helps explains the migration over time from tablets to oral concentrate. They noted that methadone tablets are much more labor intensive than oral concentrate, as it takes longer to reconcile inventory with tablets, and longer to administer and dispense the tablets, which requires increased nursing time. The commenter stated that updating the rate using the PPI would avoid incentivizing use of methadone tablets. We did not receive any comments on other potential data sources that could be used to estimate an OTP's cost for acquiring methadone.

Response: We thank the commenters for their feedback and support for this proposal. After consideration of the comments, for CY 2023 and subsequent years, we are finalizing our proposal to revise our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone as proposed. Based on the 2022 Q4 forecast from IHS Global Inc. (IGI), the CY 2023 methadone payment amount will be

[218] *https://www.bls.gov/ppi/.*

$39.37, which is the CY 2022 payment amount of $37.38 increased by a projected 5.3 percent growth in the PPI for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023 ($37.38 * 1.053 = $39.37). We are also finalizing our proposal to revise the regulation at § 410.67(d)(2)(i)(B)(*2*) to state that for CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount for methadone in CY 2021 as determined under § 410.67(d)(2)(i)(B)(*1*) and updated by the PPI for Pharmaceuticals for Human Use (Prescription). We note that the TRICARE rate will no longer be an alternative pricing methodology for methadone. We also are finalizing our proposed correction to the text of the regulation at § 410.67(d)(2)(i)(B)(*2*), to correct an error in the cross-reference to paragraph (d)(2)(i)(B)(*1*).

3. Changes to the Rate for Individual Therapy in the Bundled Rate

In the CY 2020 PFS final rule (84 FR 62658), we finalized a payment rate for the non-drug component of the bundled payment for episodes of care that was calculated using a building block methodology in which we took the sum of rates for similar services paid under the PFS. The payment rate for individual therapy included in the non-drug component of the bundled payment for an episode of care is currently based on a crosswalk to CPT code 90832, which describes 30 minutes of psychotherapy.

As we discussed in the CY 2023 PFS proposed rule (87 FR 46090 through 46091), in its December 2021 report,[219] titled ''Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder,'' OIG indicated that approximately one million Medicare beneficiaries were diagnosed with OUD in 2020, but less than 16 percent of those beneficiaries received medication to treat OUD (in any setting), raising concerns that beneficiaries face challenges accessing treatment. In this report, OIG also stated that in 2020, less than 4 percent of Medicare beneficiaries with OUD received treatment from OTPs. We noted that 2020 was the first year of the Medicare OTP benefit and that OTPs had to submit applications for enrollment with Medicare and have those applications approved prior to billing services to Medicare. As a result, we indicated that we expect these numbers to improve in future years. However, we also noted that CMS has been working to identify and track drivers of disparities in the treatment of OUD.

Additionally, we explained that we have received feedback from interested parties, including associations and groups that represent OTPs, indicating that the current rate for individual therapy provided as part of the weekly bundle may not accurately reflect the resource costs involved with furnishing this service in the OTP setting and that for the first several months of treatment, patients typically receive weekly 50-minute individual therapy sessions. We stated that now that we have 2 years of utilization data, we have reviewed how we implemented the OTP benefit to determine whether refinements to the bundled rate may be warranted to reflect more accurately the level of services furnished by OTPs.

We noted that we believe that the severity of needs of the patient population diagnosed with OUD and receiving services in the OTP setting is generally greater than that of patients receiving 30-minute psychotherapy services paid under the PFS. For example, co-occurring substance use and mental health disorders are common among adults with OUD.[220] Individuals with co-occurring SUD and mental health disorders likely have complex treatment needs and may have different patterns of treatment than individuals diagnosed with a single condition.[221] During the first few months of treatment at an OTP, patients generally receive care at the OTP on a daily basis. Based on the generally greater severity of needs of the patient population receiving services at OTPs compared to patients receiving psychotherapy services billed under CPT code 90382 and paid under the PFS, and therefore, the greater intensity of the work, we explained our belief that it was appropriate to re-visit the rate for individual therapy that is included in the non-drug component of the weekly episodes of care.

Accordingly, we proposed to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 *(Psychotherapy, 45 minutes with patient),* instead of a crosswalk to CPT code 90832 *(Psychotherapy, 30 minutes with patient),* as is our current policy. We noted that we believe CPT code 90834 most closely corresponds to a 50-minute therapy session, which interested parties have indicated is the typical amount of therapy received by patients in the first few months of treatment at an OTP. In the CY 2020 PFS final rule (84 FR 62658), we stated that we based the rate for individual therapy in the bundled payment on the 2019 non-facility payment rate for CPT code 90832, which was $68.47. Therefore, in order to change the rate for individual therapy, we proposed to substitute the 2019 rate for CPT code 90832 included in the non-drug component of each of the bundled payments for an episode of care with the 2019 PFS non-facility payment rate for CPT code 90834, which was $91.18, to determine an adjusted payment rate for CY 2020 for the non-drug component of each applicable HCPCS code. As described in § 410.67(d)(4)(iii), we noted that we would then apply the Medicare Economic Index (MEI) updates for 2021, 2022, and 2023 to these adjusted payment rates to determine the CY 2023 payment amounts for the non-drug component of the bundled payments for an episode of care. We also noted that in section II.M. of the proposed rule, we had proposed to rebase and revise the MEI from a 2006-base year to a 2017-base year. The MEI for CY 2023 was projected to be 3.8 percent based on the proposed 2017-based MEI, which was based on the most current forecast of the percentage increase of the proposed 2017-based MEI for the second quarter of 2022 (4.2 percent), and the most recent estimate of the historical productivity adjustment for calendar year 2021 (0.4 percent) at the time of the CY 2023 PFS proposed rule. We stated that the MEI for CY 2023 would be revised for the final rule based on historical data through the second quarter of 2022 and the most recently available total factor productivity data.

We noted that in the CY 2020 PFS final rule (84 FR 62644), we also finalized an adjustment to the bundled payment rates through the use of an add-on code to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan. This adjustment is described by HCPCS code G2080 *(Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.).* We did not propose any changes to HCPCS code

[219] *https://oig.hhs.gov/oei/reports/OEI-02-20-00390.pdf.*

[220] *https://www.sciencedirect.com/science/article/pii/S0376871618305209.*

[221] *https://www.sciencedirect.com/science/article/pii/S0740547218304781.*

G2080. We noted that we believe the proposal to update the crosswalk we use to calculate the individual therapy portion of the non-drug component of the bundled payment to reflect 45 minutes of psychotherapy would not duplicate the add-on code for additional counseling. Rather, we noted that we believe the proposal to update the crosswalk for individual therapy would ensure that the payment for the non-drug component of the bundled payment is more representative of the typical case in the OTP setting and better reflects the resource costs involved in furnishing this service in the OTP setting compared to the current crosswalk.

Accordingly, we proposed to revise the regulation text at § 410.67(d)(2) to adjust the payment for the non-drug component of the bundled payment for an episode of care to reflect 45 minutes of psychotherapy beginning in CY 2023. We welcomed comments on this proposal.

The following is a summary of the public comments received on the proposed change to the rate for individual therapy included in the bundled rate and our responses:

Comment: Several commenters supported this proposal and urged CMS to finalize the proposed update to the rate for individual therapy in the non-drug component to reflect a 45-minute session. Several commenters agreed with CMS that the proposed update to account for 45-minutes of therapy instead of 30-minutes better aligns with current behavioral health practices and keeps pace with increasing practice costs. A few commenters emphasized the importance of therapy and behavioral health services in treatment and recovery and that by increasing reimbursements for therapy, OTPs will be better positioned to retain current staff and attract new professionals.

Response: We thank the commenters for their feedback and support for this proposal.

Comment: One commenter requested that CMS clarify whether this update to the bundled rate would prohibit OTPs from billing for the OTP bundle for therapy sessions lasting less than 45 minutes in duration.

Response: We note that in the CY 2020 PFS final rule, we finalized that the threshold to bill for an episode of care was that at least one opioid use disorder treatment service was furnished to the patient during the week that corresponds to the episode of care (84 FR 62641). As discussed above, we proposed to modify the rate for individual therapy included in the non-drug component to better account for the severity of needs of the patient population diagnosed with OUD and receiving treatment in the OTP setting, and therefore, the greater intensity of the work involved in furnishing these services. This crosswalk code is being used for the purposes of valuation, but we do not intend it to be a requirement regarding the number of minutes spent in an individual therapy session in order for the service to qualify as an OUD treatment service. Accordingly, an OTP would be able to bill for an episode of care, even if the only OUD treatment service furnished to the beneficiary during the episode of care was an individual therapy session lasting less than 45 minutes.

Comment: One commenter requested clarification related to subregulatory guidance that specifies the health care providers that are eligible to furnish substance use counseling services and individual and group therapy under the OTP benefit. Specifically, the commenter noted that the SUPPORT Act states MOUD services include ''substance use counseling by a professional to the extent authorized under State law to furnish such services'' and ''individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law.)'' The commenter further stated that licensed medical and family therapists (LMFTs) are authorized under laws in every state to provide these services to individuals with an OUD. Additionally, the commenter stated that current subregulatory guidance does not specifically list LMFTs as professionals who may provide these services within an OTP, which may make OTPs reluctant to utilize these professionals without more guidance from CMS.

Response: In the CY 2020 PFS final rule (84 FR 62633), we stated that under sections 1861(jjj)(1)(C) and (D) of the Act, substance use counseling for OUD treatment can be provided by ''a professional to the extent authorized under State law to furnish such services,'' while individual and group therapy can be ''with a physician or psychologist (or other mental health professional to the extent authorized under State law).'' Consistent with the statute, we did not limit the professionals that can provide these services in an OTP to physicians, psychologists, or other practitioners who can bill Medicare directly. Instead, we noted that the professionals that could provide such services could include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. We also stated that to the extent that the individuals furnishing therapy or counseling services are not authorized under State law to furnish such services, the therapy or counseling services provided by these professionals would not be covered as OUD treatment services. In response to the comment regarding LMFTs, we note that the lists of examples included in the CY 2020 PFS final rule and associated subregulatory guidance, such as the Medicare Benefit Policy Manual, Chapter 17, Section 40.1.1 [222] and in the Medicare Learning Network (MLN) OTP Medicare Billing and Payment Fact Sheet [223] were not intended to be comprehensive, and we reiterate that any professional authorized by State law and scope of practice to furnish this type of therapy or counseling may do so as part of the treatment included in the bundled payments to OTPs under Medicare and that this includes LMFTs, where authorized by State law and consistent with scope of practice.

Comment: One commenter supported this change for OTPs, but also urged CMS to consider adopting this modification for other bundled payments for SUD under the PFS, such as the bundled rate for office-based SUD treatment (HCPCS codes G2086–G2088) and general behavioral health integration (CPT code 99484) in order to reflect the complexity of treating these patients and ensure that there is consistent and sufficient access to counseling for SUD across settings of treatment. The commenter noted that some patients who are prescribed buprenorphine in non-OTP settings will have similarly complex care needs requiring more intensive therapeutic care and that by recognizing the appropriate complexity and intensity of the services in rate setting, CMS can incentivize more office-based practices to offer these services and build out the treatment teams that deliver this care.

Response: We thank the commenter for this feedback. We note that changes to the payment for HCPCS codes G2086–G2088 and the existing codes for General BHI are outside of the scope of the proposal, which was limited to the payment rate for OUD treatment services when furnished in OTPs. We may consider making similar changes to relevant bundled codes that include individual therapy in future rulemaking.

[222] *https://www.cms.gov/files/document/chapter-17-opioid-treatment-programs-otps.pdf.*

[223] *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.*

After consideration of the comments received, we are finalizing without modification our proposal to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 *(Psychotherapy, 45 minutes with patient),* instead of a crosswalk to CPT code 90832 *(Psychotherapy, 30 minutes with patient).* Accordingly, we are also finalizing our proposed revisions to the regulation text at § 410.67(d)(2) to adjust the payment for the non-drug component of the bundled payment for an episode of care to reflect 45 minutes of psychotherapy beginning in CY 2023. We note that the final OTP payment rates for CY 2023 can be found in the public use files for this final rule on the CMS website under downloads for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*.

In the CY 2023 PFS proposed rule (87 FR 46041 through 46055), we proposed to rebase and revise the MEI to a 2017 base year. As discussed in section II.M. of this final rule, we are finalizing the 2017-based MEI for CY 2023, with technical modifications based on public comments. The CY 2023 MEI update is 3.8 percent, which is based on the latest available historical data through the 2nd quarter of 2022.

4. Mobile Components Operated by OTPs

As discussed in the CY 2023 PFS proposed rule (87 FR 46091), effective July 28, 2021, the Drug Enforcement Administration (DEA) issued a final rule (86 FR 33861) that authorized OTPs to add a ''mobile component'' to their existing registration, which eliminated a requirement for mobile medication units of OTPs to have a separate registration. Additionally, SAMHSA has issued guidance to OTP Directors, State Opioid Treatment Authorities (SOTAs), and State Directors that revised and superseded related portions of SAMHSA's 2015 Federal Guidelines for OTPs by clarifying the range of services that can be provided by mobile units.[224]

In light of the new SAMHSA guidance, in the CY 2023 PFS proposed rule, we clarified that services furnished via OTP mobile units will be considered for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. We noted that we believe allowing OTPs to bill Medicare for services furnished via mobile units is an opportunity to expand access to medications for treatment of OUD for Medicare beneficiaries by extending the reach of OTPs, particularly in remote or underserved areas. Because OTPs receive a bundled payment, we also noted that we believe it would be appropriate to apply locality adjustments for services furnished via mobile units as if the service were furnished at the OTP registered with DEA and certified by SAMHSA. We noted that we anticipate that for beneficiaries receiving OUD treatment services from a mobile unit, some services included in the bundle for a given week may still be provided at the OTP, while some may be furnished via the mobile unit, which would make it difficult to determine which geographic locality adjustment to apply to the weekly bundle if the OTP and the location served by the mobile unit are subject to different geographic locality adjustments. Additionally, we noted that when services are furnished from a mobile unit, the OTP still incurs the cost of rent, staffing, supplies, etc. at the location of the OTP; therefore, we believe it is appropriate to apply the geographic locality adjustment as if the service were furnished at the OTP. Accordingly, we proposed to amend the regulation at § 410.67(d)(4)(ii) to clarify that, for purposes of the geographic adjustment, OUD treatment services furnished via an OTP mobile unit will be treated as if the services were furnished at the physical location of the OTP registered with DEA and certified by SAMHSA. As stated in the CY 2020 PFS final rule, because HCPCS codes G2067–G2075 cover episodes of care of 7 contiguous days, OTPs should not bill any of these codes for the same beneficiary more than once per 7 contiguous day period, with limited exceptions (84 FR 62649), and we did not propose any changes to this policy, regardless of the location(s) at which the services are provided. We also noted that we will continue monitoring the benefit for OUD treatment services furnished by OTPs, including services furnished by mobile units, for fraud, waste, and abuse, and will use existing administrative authorities to take necessary action, as appropriate.

The following is a summary of the public comments received on the discussion in the CY 2023 PFS proposed rule regarding mobile components operated by OTPs and our responses:

Comment: Several commenters expressed support for this policy, stating this will allow OTPs to better serve Medicare beneficiaries. Several commenters noted that allowing Medicare payment for services furnished by OTP mobile units is essential to expanding lifesaving access and filling detrimental treatment gaps, stating that mobile units will increase access to care exponentially for individuals who lack timely access to treatment, such as individuals who are experiencing homelessness, who are living with a disability, who do not have a caregiver that can assist them to appointments, or who lack reliable access to transportation. Commenters stated it will further expand treatment access to localities experiencing high overdose rates or experiencing OTP workforce shortages. One commenter cited a study that found that the average drive time to an OTP, a trip that patients who are prescribed methadone must make on a daily basis for months until any take-home medication is allowed, is nearly 50 minutes in rural communities compared to 8 minutes in urban settings.[225] The commenter applauded CMS's efforts to expand access to medications for OUD for Medicare beneficiaries, particularly in remote or underserved areas. Several commenters also supported applying the geographic locality adjustment as if the service were furnished at the OTP.

Response: We thank the commenters for their support and feedback. After consideration of the comments and as noted in the proposed rule, we are clarifying that services furnished via OTP mobile units will be considered for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. Additionally, we are finalizing without modification our proposal to amend the regulation at § 410.67(d)(4)(ii) to clarify that for purposes of the geographic adjustment, OUD treatment services furnished via an OTP mobile unit will be treated as if the services were furnished at the physical location of the OTP registered with DEA and certified by SAMHSA.

Comment: Several commenters stated that they support including payment for mobile services under the OTP bundled rate only to the extent that the bundled

[224] *https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf.*

[225] *https://jamanetwork.com/journals/jama/fullarticle/2752051.*

rate is sufficient. Commenters expressed concern that the decreases in reimbursement under Medicare due to sequestration requirements will be detrimental to the access and availability of behavioral health care and are concerned these decreases will impact elevated costs associated with operating mobile units. They noted, for example, that mobile units will have costs related to obtaining transportable supplies, fuel, and maintenance of mobile equipment. Therefore, the commenters urged CMS to ensure that the OTP bundled rate includes prospective costs for OTPs to establish mobile units as well as the continued maintenance of existing and newly established mobile units.

Response: We thank the commenters for these suggestions and may consider them for future rulemaking. However, we are not considering such changes for CY 2023 because we did not propose any changes to the OTP bundled rate or add-on codes to include prospective costs specifically associated with operating mobile units.

Comment: One commenter stated that a guidance statement from SAMHSA describes the services that can be provided through non-mobile medication units that are also affiliated with OTPs. In this case, and unlike the mobile van units, these are fixed brick and mortar sites, which can also expand access to treatment and rural and underserved areas of the United States. The commenter encouraged CMS to develop the appropriate reimbursement models under Medicare for these non-mobile medication units as they are further developed.

Response: We thank the commenter for highlighting this additional route of providing medication to OTP patients. We note that it is outside of the scope of the issues addressed in the proposed rule; however, we may consider this for future rulemaking.

5. Flexibilities for OTPs To Use Telecommunications for Initiation of Treatment With Buprenorphine

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the PHE for COVID–19 and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the IFC entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised § 410.67(b)(3) and (4) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when the beneficiary cannot access or does not consent to the use of audio and video.

In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise § 410.67(b)(7) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met, on a permanent basis. However, the flexibility for OTPs to furnish periodic assessments via audio-only communication is limited to the duration of the PHE for COVID–19. There are currently no flexibilities under Medicare for OTPs to furnish the intake add-on code via communication technology.

As discussed in the CY 2023 PFS proposed rule (87 FR 46092 through 46093), SAMHSA regulations under 42 CFR 8.12(f)(2) require a complete physical evaluation before a patient begins treatment at an OTP. However, during the PHE, DEA and SAMHSA have allowed OTPs to initiate treatment with buprenorphine via audio-video and audio-only communication without first conducting an in-person evaluation.[226] According to guidance issued by SAMHSA [227] regarding the treatment of OUD during the PHE, SAMHSA made the decision to exercise its authority to exempt OTPs from the requirement to perform an in-person physical evaluation (under 42 CFR 8.12(f)(2)) for any patient who will be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth. We noted that this exemption applies exclusively to OTP patients treated with buprenorphine and does not apply to new patients treated with methadone. This exemption will continue only for the duration of the declared PHE for COVID–19 unless regulations are issued making this flexibility permanent.

We explained that for services paid under the PFS, Medicare telehealth services fall under the authority of section 1834(m) of the Act, which generally limits payment for telehealth services to those furnished to patients located in specified types of medical care settings in mostly rural locations. The codes describing new patient office/outpatient visits (CPT codes 99202 through 99205) are on the Medicare Telehealth list. As discussed in the CY 2019 PFS final rule (83 FR 59496), section 2001(a) of the SUPPORT Act (Pub. L. 115–271, October 24, 2018) amended section 1834(m) of the Act, adding a new paragraph (7) that removed the geographic limitations for telehealth services furnished on or after July 1, 2019, to individuals with a diagnosed SUD for the purpose of treating the SUD or a co-occurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. In addition, as discussed in the CY 2022 PFS final rule (86 FR 65055), section 123 of the Consolidated Appropriations

[226] *https://www.deadiversion.usdoj.gov/coronavirus.html.*

[227] *https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.*

Act, 2021 (CAA 2021) (Pub. L. 116–260, December 27, 2020) modified the circumstances under which Medicare makes payment under the PFS for mental health services furnished via telehealth following the PHE. Specifically, it removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. In addition to the flexibilities authorized by section 2001(a) of the SUPPORT Act and section 123 of the CAA 2021, in the CY 2022 PFS final rule (86 FR 65055), for services for the diagnosis, evaluation or treatment of mental health conditions, including SUDs, CMS revised the regulatory definition of an ''interactive telecommunications system'' to permit the use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home.

Given these flexibilities for the treatment, diagnosis, or evaluation of mental health disorders, including SUDs, under the PFS, in the CY 2023 PFS proposed rule we proposed to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also proposed to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpreted the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. We noted that under this proposal, the initiation of treatment with buprenorphine using telecommunications technology would be considered an intake activity for purposes of § 410.67(b)(6) only to the extent that the use of such telecommunications technology is permitted under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished.

Accordingly, we proposed to revise the regulation at § 410.67(b)(6) to state that services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where two-way audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine can be furnished using audio-only telephone calls if all other applicable requirements are met.

Finally, we sought comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone.

The following is a summary of the public comments received in response to our proposal to permit OTPs to use telecommunications for initiation of treatment with buprenorphine and our solicitation of comments on the use of audio-only communication technology to furnish periodic assessments following the end of the PHE for COVID–19 and our responses:

Comment: Several commenters expressed support for our proposal to allow the add-on code for intake activities to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine. Commenters noted that the ability to initiate treatment for OUD via telehealth modalities is of critical importance to individuals who have limited ability to attend in-person appointments or who are disincentivized to do so due to perceived stigma and fear. A few commenters noted support for clinicians making the determination as to when virtual platforms can be used and when in-person visits are advised.

Response: We thank the commenters for their input. After consideration of the comments, we are finalizing our proposal to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished and to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. Accordingly, we are finalizing our proposal to revise the regulation at § 410.67(b)(6) to state that services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where two-way audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine can be furnished using audio-only telephone calls if all other applicable requirements are met.

Comment: Several commenters requested that CMS continue to allow periodic assessments to be furnished audio-only when video is not available after the end of the PHE. Commenters noted that allowing audio-only flexibilities would further promote equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video functions. Furthermore, one commenter noted that this flexibility is particularly important for the elderly population served under Medicare. Specifically, the commenter cited a 2020 HHS Issue Brief showing that the proportion of telephonic audio-only visits increases with the age of the patient, with ''17% of visits delivered via audio-only interaction for patients 41–60 years of age, 30% for patients 61–80 years of age, and 47% of visits for patients over 81.'' [228] One commenter stated that these reassessments are no more complex than initial assessments, and thus are equally appropriate for audio-video and audio-only care. Additionally, a few commenters requested that these flexibilities be

[228] HHS ASPE Issue Brief: Medicare beneficiary use of telehealth visits: Early Data from the Start of the COVID–19 Pandemic (July 27, 2020). *https://aspe.hhs.gov/reports/medicare-beneficiary-use-telehealth-visits-early-data-start-covid-19-pandemic.*

extended to treatment with methadone and naltrexone, noting that if CMS begins to bifurcate flexibilities and coverage based solely on medication, CMS will indirectly steer patients towards certain medication. Several comments expressed support for the use of telecommunications in circumstances when the provider and patient have together determined that the patient would individually benefit from telehealth services and a high quality of care is maintained. The commenters stated that the success of flexibilities extended during the PHE, such as take-home methadone, along with the demand for these services, have illustrated that the ability to furnish SUD services via telecommunications modalities is within reach. They encouraged CMS to expand flexibilities to furnish SUD services via telecommunications to allow providers and patients to decide collaboratively the best modality for individualized care.

Response: We thank the commenters for this feedback. After consideration of the comments, we have determined that it would be appropriate to revise our regulations to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished. We believe it is important to limit this flexibility to situations in which the use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements to ensure that services furnished to Medicare beneficiaries are furnished in a manner consistent with all applicable requirements. This modification will allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE for COVID–19 terminates before the end of 2023, while also allowing additional time for CMS to further consider this issue. Accordingly, we are finalizing a revision to the regulation text at § 410.67(b)(7) to add that through the end of CY 2023, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

Comment: We received comments on several topics that were outside the scope of the proposed rule. Those topics included the following: a suggestion that CMS should update the non-drug component of the OTP bundled rate annually using the IPPS market basket update, which the commenters believe more accurately reflects the kind of care that is provided to patients in OTPs compared to the Medicare Economic Index (MEI), stating that OTPs are structured more like a hospital outpatient clinic in terms of services and staffing and additionally have to comply with a heightened regulatory regime compared to what physician offices are subject to; a recommendation that CMS create a rural-specific add-on payment to be applied to the non-drug component of the bundled payment for low population density areas where it is difficult to find practitioners, nurses, and counselors to treat OUD; a recommendation that CMS allow prescribers to initiate buprenorphine treatment for SUDs in other settings, including hospital outpatient departments, offices, RHCs, FQHCs, and Rural Emergency Hospital (REH) outpatient departments; a recommendation that CMS coordinate with the DEA to create a special registration for telehealth providers under the DEA's existing legal authority under the Ryan Haight Act, stating that a special registration program for telehealth providers would continue to expand patient access while offering an enforcement mechanism to limit overprescribing; a request that CMS develop an add-on code for the use of Contingency Management, which is a type of behavioral therapy in which certain behaviors are incentivized, in OTPs in response to increases in overdoses involving psychostimulants reflecting a high level of co-use of opioids and stimulants; and a suggestion that CMS consider making an adjustment to the bundled payment for an episode of care due to the increased cost of toxicology testing when testing for fentanyl or that an add-on code for fentanyl tests should be established.

Response: While these comments are out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As of January 1, 2022, over 11 million people with Medicare receive care from one of the 528,966 health care providers in the 483 accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (Shared Savings Program), the largest value-based purchasing program in the country.[229] Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending. To advance Medicare's value-based care strategy of growth, alignment, and equity, we proposed changes to the Shared Savings Program as described in section III.G. of the CY 2023 PFS proposed rule (87 FR 46093 through 46218) and sought public comments which we summarize and respond to in this section of this final rule.

The Shared Savings Program offers different participation options (tracks) that allow ACOs to assume various levels of risk. The BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings and shared losses models[230] within a single 5-year agreement period.[231] ACOs that enter the ENHANCED track accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards. For the performance year (PY) beginning on January 1, 2022, 59 percent of Shared Savings Program ACOs are under two-sided models. Historically, we have observed that ACOs in performance-

[229] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2022, available at *https://www.cms.gov/sites/default/files/2022-01/2022_Shared_Savings_Program_Fast_Facts.pdf*.

[230] As explained in earlier rulemaking, we have tended to use the terms ''two-sided model'' and ''performance-based risk'' interchangeably, considering them to be synonymous when describing payment models offered under the Shared Savings Program and Medicare ACO initiatives more broadly (83 FR 67827).

[231] As explained in earlier rulemaking (for example, 83 FR 67844), the BASIC track's glide path includes 5 levels: a one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E).

based risk tracks have better financial performance than ACOs in shared savings only tracks and that low revenue ACOs (which may tend to be small, physician only ACOs) have better financial performance than high revenue ACOs (whose composition likely includes institutional providers, particularly hospitals and health systems).[232] We have also observed that the highest earning ACOs had a higher proportion of beneficiaries that were members of racial and ethnic minority communities and included a greater proportion of ESRD, disabled, and aged/dually eligible Medicare and Medicaid beneficiaries than the lowest earning ACOs.

As we explained in the CY 2023 PFS proposed rule (87 FR 46093), we proposed changes seeking to reverse certain recent trends [233] [234] in the Shared Savings Program: in recent years growth in the number of beneficiaries assigned to ACOs has plateaued; higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks; and access to ACOs appears inequitable as shown by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO than their Non-Hispanic White counterparts.

Several of the proposals we included in the proposed rule were expected to advance equity within the Shared Savings Program. Based on feedback from health care providers treating underserved populations that they require upfront capital to make the necessary investments to succeed in accountable care and may also need additional time under a one-sided model before transitioning to performance-based risk, we proposed to provide advance shared savings payments to low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program (that is, not a renewing ACO or a re-entering ACO), and that serve underserved populations. As proposed, these advance investment payments (AIPs) would increase when more beneficiaries who are dually eligible for Medicare and Medicaid or who live in areas with high deprivation (measured by the area deprivation index (ADI)), or both, are assigned to the ACO. Subject to certain limitations, these funds would be available to address the social needs of people with Medicare, as well as health care provider staffing and infrastructure. We also proposed other modifications to certain existing policies under the Shared Savings Program to support organizations new to accountable care by providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign their care processes to be successful under risk arrangements. We also proposed a health equity adjustment that would upwardly adjust ACOs' quality performance scores to continue encouraging high ACO quality performance, transition ACOs to all-payer eCQMs/MIPS CQMs, and support those ACOs serving a high proportion of underserved beneficiaries while also encouraging all ACOs to treat underserved populations. Finally, we proposed certain changes to our benchmarking methodologies designed to encourage participation by health care providers who care for populations that include a high percentage of beneficiaries with high clinical risk factors and beneficiaries dually eligible for Medicare and Medicaid.

Many of the proposals outlined in the proposed rule were the result of our efforts to align policies under the Shared Savings Program and under the Innovation Center's ACO models. For example, as proposed (87 FR 46098 through 46110), the AIPs were derived from learnings from the ACO Investment Model (AIM), an Innovation Center model that tested the effects of making advanced payments to certain ACOs participating in the Shared Savings Program. We proposed to incorporate AIPs into the Shared Savings Program payment methodology as an example of how our larger ACO strategy of having the Innovation Center test new payment and service delivery models on the Shared Savings Program ''chassis'' can better harmonize policies across Medicare ACO initiatives and enable us to scale any findings.

We explained in the CY 2023 PFS proposed rule that the Innovation Center had recently announced the elimination of the ACO Track of the Community Health and Rural Transformation (CHART) Model, which would have provided advance shared savings payments to new rural ACOs participating in the Shared Savings Program, similar to AIM. Therefore, we believed the proposal to incorporate AIPs into the Shared Savings Program would make the Shared Savings Program attractive to organizations that were previously considering participation in the ACO Track of the CHART Model. The CHART Model ACO Track specifically targeted ACOs whose providers and suppliers were located in rural areas. We also noted our belief that the methodology to determine payments based upon a beneficiary's risk factors-based score, as proposed, would allow for greater reach to ACOs operating in under-resourced communities and encourage providers and suppliers in rural areas to form ACOs.

As we explained in the CY 2023 PFS proposed rule, as we seek to increase the percentage of people with Medicare in accountable care arrangements, we are balancing incentives and participation options to serve a dual purpose of sustaining participation by existing ACOs and increasing program growth, recognizing that ACOs vary in their composition of providers/suppliers, the needs of the populations they serve, and have varying degrees of efficiency relative to their region and experience with accountable care initiatives. We proposed modifications that would build on the existing Shared Savings Program benchmarking methodology by strengthening financial incentives for long term participation by reducing the impact of ACOs' performance on their benchmarks, addressing the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks, and supporting the business case for ACOs serving high risk and high dually eligible populations to participate, which we believed would help sustain participation and grow the program. Additionally, we proposed modifications to the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment. We explained that the changes we had proposed to the benchmarking methodology used in the Shared Savings Program would align with our consideration of more long-term benchmarking concepts that would move toward the use of administratively set benchmarks in order to grow and sustain long term program participation as discussed in the Comment Solicitation that we included in the CY 2023 PFS proposed rule. We also proposed to expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings even if they do not meet the minimum savings rate (MSR) to allow for investments in care redesign and quality

[232] See for example, 83 FR 67820.

[233] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2022, available at *https://www.cms.gov/sites/default/files/2022-01/2022_Shared_Savings_Program_Fast_Facts.pdf*.

[234] Refer to the ''Performance Year Financial and Quality Results'' Public Use Files available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results*.

improvement activities among less capitalized ACOs.

We proposed changes to the Shared Savings Program quality reporting and the quality performance requirements that were responsive to interested parties' feedback, and designed to support the transition of ACOs to all payer quality measure reporting. These proposals included reinstitution of a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, regardless of how they report quality data, and revisions to the approach for determining shared losses for ENHANCED track ACOs. We proposed to implement a health equity adjustment to an ACO's quality performance score to recognize high quality performance by ACOs with high underserved populations. We also proposed to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the sunsetting of the CMS Web Interface reporting option. In addition, we solicited comment from interested parties to inform future rulemaking through requests for information addressing social determinants of health in ACO populations, and the addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) survey questions. We also proposed to resolve a gap in our current policy for benchmarking quality measures reported through the CMS Web Interface.

We proposed changes that we believed were important for improved operations of the Shared Savings Program, including policies to reduce ACO administrative burden. Specifically, we proposed to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating materials to beneficiaries and ACO participants, and modifications to streamline the SNF 3-day rule waiver application review process. We also proposed modifications to the beneficiary notification requirements, including to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period, with a proposed follow-up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice. Further, we proposed to revise the data sharing requirements to recognize ACOs structured as organized health care arrangements (OHCAs) for data sharing purposes.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in PY 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule and the CY 2022 PFS final rule for a summary of policies finalized in prior PFS rules (84 FR 40705 and 86 FR 65253). In the CY 2022 PFS final rule (86 FR 65253 through 65306), we finalized changes to Shared Savings Program policies, including to amend the reporting requirements under the APM Performance Pathway (APP) for PY 2022 and subsequent performance years, to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for PY 2023, to update the definition of primary care services used in beneficiary assignment at § 425.400(c), to revise the repayment mechanism arrangement policy, to streamline the application process, and to amend the beneficiary notification process.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Provisions

In sections III.G.2. through III.G.6. of this final rule, we summarize and respond to public comments received on proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2023 PFS proposed rule (87 FR 46093 through 46218). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the proposals discussed in section III.G. of the CY 2023 PFS proposed rule, and will not be addressed in this section of this final rule. As a general summary, we are finalizing the following changes to Shared Savings Program policies to:

- Allow low revenue ACOs, inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program (that is, not a renewing or re-entering ACO) to receive AIPs. ACOs wishing to receive AIPs must submit a supplemental application and proposed spend plan for CMS review. If approved to receive AIPs, the ACO will receive a one-time fixed payment of $250,000 and per beneficiary quarterly payments for the first 2 years of an ACO's 5-year agreement period. The quarterly payment amount is based on whether the beneficiary is enrolled in the Medicare Part D low-income subsidy (LIS) or is dually eligible for Medicare and Medicaid or the ADI national percentile rank of the census block group in which the beneficiary resides (section III.G.2.a. of this final rule). We are finalizing our proposal regarding quarterly payments with the modification that the risk factors-based score for a beneficiary will be set to 100 if the beneficiary is enrolled in the LIS or is dually eligible for Medicare and Medicaid or set to the ADI national percentile rank (an integer between 1 and 100) of the census block group in which the beneficiary resides if the beneficiary is not enrolled in the LIS or dually eligible. ACOs will receive higher payment amounts for assigned beneficiaries with higher risk factors-based scores.
- Allow ACOs applying to the program that are inexperienced with performance-based risk to participate in one 5-year agreement under a one-sided shared savings model, in order to provide these ACOs more time to invest in infrastructure and redesigned care processes for high quality and efficient health care service delivery before transitioning to performance-based risk (section III.G.2.b.(2) of this final rule). These ACOs may also be eligible for a subsequent agreement under the BASIC track glide path.
- Revise the limitation on the number of agreement periods an ACO can participate in BASIC track Level E (section III.G.2.b.(3) of this final rule).
- Revise the policies for determining beneficiary assignment (section III.G.3. of this final rule).

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c).

++ Identify how CMS certification numbers will be used in beneficiary assignment.

• Revise the quality reporting and the quality performance requirements for PY 2023 and subsequent performance years (section III.G.4. of this final rule).

++ Establish an alternative quality performance standard for ACOs that do not meet the quality performance standard to share in savings at the maximum rate by reinstating a sliding scale approach for determining shared savings for ACOs, regardless of how they report quality data and revise the approach for determining shared losses for ENHANCED track ACOs.

++ Establish a health equity adjustment that will upwardly adjust an ACO's quality performance score, to reward ACOs that report all-payer eCQMs/MIPS CQMs, that are high performing on quality, and serve a high proportion of underserved beneficiaries. This adjustment will add up to 10 bonus points to the ACO's MIPS Quality performance category score. We are finalizing the proposed methodology for calculating the underserved multiplier with a modification to use enrollment in the LIS, in addition to Medicare and Medicaid dually eligibility and ADI score. The resulting health equity adjusted quality performance score will be used to determine whether the ACO meets the quality performance standard set at the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent years) across all MIPS Quality performance category scores; the final sharing rate for calculating shared savings payments under the BASIC track and the ENHANCED track for an ACO that meets the alternative quality performance standard we are finalizing that allows for application of a sliding scale based on quality performance; and the shared loss rate for calculating shared losses under the ENHANCED track under the modified approach to the scaling of shared losses we are also finalizing in this final rule. The health equity adjusted quality performance score will also be used when applying the extreme and uncontrollable circumstances policy for ACOs that report quality data via the APP and meet data completeness and case minimum requirements.

++ Extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the sunsetting of the CMS Web Interface reporting option.

++ Change the nomenclature of the administrative claims measure Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS to Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions to align with the MIPS program.

++ Clarify use of unweighted MIPS Quality performance category scores to determine the quality performance standard under the Shared Savings Program.

++ Clarify our policies on reopenings to address changes to MIPS quality performance category scores.

++ Establish policies for benchmarking quality measures reported through the CMS Web Interface for PY 2022 through PY 2024.

• Revise the benchmarking methodology to reduce the effect of ACO performance on ACO historical benchmarks, increase opportunities for ACOs caring for medically complex, high cost beneficiaries, and strengthen incentives for ACOs to enter and remain in the Shared Savings Program, and meet the programmatic goals of improving quality of care and lowering growth in FFS expenditures:

++ Incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in this final rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark and address increasing market saturation by ACOs in a regional service area (section III.G.5.c.(3) of this final rule).

++ Adjust benchmarks to account for prior savings, helping to mitigate lowering of an ACO's benchmark over time by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures from the previous agreement period (section III.G.5.c.(4) of this final rule).

++ Reduce the impact of negative regional adjustments on ACO benchmarks by reducing the cap on negative regional adjustments and gradually decreasing the negative regional adjustment amount as an ACO's weighted-average prospective HCC risk score increases, or the proportion of dually eligible Medicare and Medicaid beneficiaries increases, or both (section III.G.5.c.(5) of this final rule).

• Change how we calculate regional factors used in benchmarking to increase internal consistency of benchmark calculations for ACOs under prospective beneficiary assignment by using an assignment window that is consistent with an ACO's selected assignment methodology to identify the assignable population used to calculate regional FFS expenditures (section III.G.5.d. of this final rule).

• Revise how we cap positive prospective HCC risk score growth to better account for medically complex, high cost populations while continuing to guard against coding initiatives (section III.G.5.e. of this final rule).

• Increase opportunities for low revenue ACOs participating in the BASIC track to share in savings by expanding the criteria ACOs can meet to qualify for shared savings payments as described in § 425.605 (section III.G.5.f. of this final rule).

• Discuss ongoing considerations regarding the impact of the PHE for COVID–19 on ACO expenditures (section III.G.5.g. of this final rule), although there are no associated revisions to the regulations at this time.

• Exclude the new supplemental payment under the Medicare Hospital Inpatient Prospective Payment System (IPPS) for Indian Health Service (IHS)/Tribal hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program and include this new supplemental payment in calculations of ACO participant revenue for the performance year beginning January 1, 2023, and subsequent performance years (section III.G.5.h. of this final rule).

• Remove the requirement to submit marketing materials prior to use (section III.G.6.b. of this final rule). ACOs will be required to submit marketing materials only upon request from CMS, but we are retaining the requirement that an ACO must discontinue use of any marketing materials or activities for which CMS has issued a notice of disapproval.

• Amend the beneficiary notification requirements to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period, with a follow up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice and occurring no later than 180 days following the date that the standardized written notice was provided to the beneficiary (section III.G.6.c. of this final rule).

• Amend the beneficiary notification requirements to clarify that ACOs and ACO participants are required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services (section III.G.6.c. of this final rule).

• Remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver and replace with a requirement that an ACO submit an attestation that it has

established the narratives and will make them available to CMS upon request (section III.G.6.d. of this final rule).

- Amend the data sharing regulations to recognize ACOs structured as OHCAs for data sharing purposes (section III.G.6.e. of this final rule).

We also solicited comments on the following:

- On two potential social determinants of health (SDOH) measures for future measure development, and the addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) survey questions, as discussed in section III.G.4. of this final rule.
- On an alternative approach to calculating ACO historical benchmarks that would use administratively-set benchmarks that are decoupled from ongoing observed FFS spending, as discussed in section III.G.7. of this final rule.

In combination, the policies we are adopting for the Shared Savings Program in this final rule are anticipated to grow participation particularly from ACOs serving beneficiaries with greater needs and higher baseline spending. The incentive for ACOs to reduce spending over multiple agreement periods is also expected to be bolstered, for example by reducing the weighting on the regional component of the benchmark update and by providing a prior savings adjustment at rebasing. A further change will prevent an assignment bias from inflating benchmark adjustments for ACOs electing prospective assignment. In summary, as described in section VII of this final rule, we project a $15.5 billion decrease in spending on benefits (that is, savings from efficiency) and $650 million in higher net shared savings payments to ACOs, or $14.8 billion lower overall spending compared to the program baseline (which would have been projected to be a $4.2 billion net cost absent these changes).

Certain policies, including both existing policies and the new policies adopted in this final rule, as described in section III.G. of this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: allowing for AIPs as described in section III.G.2. of this final rule: the modifications to the calculation of the shared loss rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard as described in section III.G.4. of this final rule; use of the ACPT/national-regional three-way blended benchmark update factor as described in section III.G.5.c.(3) of this final rule; the expansion of the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act as described in section III.G.5.f. of this final rule; and the exclusion of the new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program as described in section III.G.5.h. of this final rule. As described in the Regulatory Impact Analysis in section VII. of this final rule, the changes we are finalizing to our payment methodology are expected to improve the quality and efficiency of care under the Medicare program and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets the requirements of section 1899(i)(3) of the Act, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Shared Savings Program Participation Options

a. Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

(1) Background

In the November 2011 final rule (76 FR 67969), we estimated an average of $0.58 million for the start-up investment costs and $1.27 million in ongoing annual operating costs for an ACO participating in the Shared Savings Program. This can be a substantial investment particularly for a small organization or an organization caring for underserved or more medically complex patients. The CMS Innovation Center has tested two models designed to support new ACOs in joining and succeeding in the Shared Savings Program. The Advance Payment (AP) ACO Model operated from 2012 to 2015, and the AIM operated from 2015 to 2018. The models tested whether upfront payments would increase participation in the Shared Savings Program by ACOs serving rural or underserved regions. The models also tested whether such payments would improve quality or reduce Medicare spending without negatively affecting quality.[235] Both models operated by pre-paying shared savings to ACOs participating in the Shared Savings Program and later recouping such amounts from earned shared savings.

The AP ACO model tested whether the pre-payment of shared savings would increase participation in the Shared Savings Program by smaller providers and suppliers in rural and underserved areas, and whether these payments would allow ACOs to improve care for beneficiaries, generate Medicare savings more quickly, and increase the amount of total Medicare savings.[236] The eligibility standards for the AP ACO model required that an ACO enter the Shared Savings Program in April 2012 or July 2012. The ACO also had to meet one of the following standards: (1) not include any inpatient facilities and have less than $50 million in total annual revenue; or (2) not include any inpatient facilities other than critical access hospitals (CAHs) and/or Medicare low-volume rural hospitals and have less than $80 million in total annual revenue.[237] Prepaid

[235] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model (updated January 10, 2013), available at *https://innovation.cms.gov/files/fact-sheet/advanced-payment-aco-model-fact-sheet.pdf*; Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014), available at *https://innovation.cms.gov/files/x/aim-rfa.pdf*.

[236] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model (updated January 10, 2013), available at *https://innovation.cms.gov/files/fact-sheet/advanced-payment-aco-model-fact-sheet.pdf*.

[237] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model Application Process (updated January 5, 2012), available at *https://innovation.cms.gov/files/slides/advance-payment-model-aco-odf-application-process-slides.pdf*.

shared savings included an upfront payment of $250,000 and a one-time payment of $36 per beneficiary, followed by an $8 per beneficiary per month payment for 2 years. AP ACOs received between $1.3–$2.7M in total prepaid shared savings.[238] CMS recovered pre-paid shared savings from an ACO's earned shared savings only if the ACO terminated before 3 years, in which case the ACO was required to immediately repay its prepaid shared savings payments in full.[239]

AIM tested whether the pre-payment of shared savings helped to recruit and accelerated favorable outcomes for new ACOs in the Shared Savings Program from rural, low-penetration and underserved geographies.[240] There were two cohorts of AIM, referred to as Test 1 and Test 2. The eligibility standards to join Test 1 of AIM required that an ACO be: (1) new to the Shared Savings Program; (2) not include a hospital unless it was a critical access hospital or a small Inpatient Prospective Payment System (IPPS) hospital; and (3) not owned or operated by a health plan.[241] The prepaid shared savings amounts were distributed and recouped in the same amounts and manner as the AP ACO model for the majority of model participants.[242] ACOs joining Test 2 of AIM were not new to the Shared Savings Program and were required to directly repay any unrecouped prepaid shared savings at the end of their second Shared Savings Program agreement period. Conclusions from Test 2 of AIM were unable to be drawn due to low participation.[243] All further references to AIM refer to Test 1 of the model, unless otherwise specified.

The results of the Innovation Center's evaluation of the AP ACO Model were inconclusive regarding the impact on quality or cost of care. While most ACOs included in the test continued to participate in the Shared Savings Program after the AP ACO Model ended, the Model did not significantly improve the quality or cost of care when compared to care provided outside the Shared Savings Program.[244] The results of the evaluation of AIM, however, found that the model was successful in meeting both its goals. AIM successfully encouraged ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present.[245] AIM also generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and ACOs' earned shared savings.[246] AIM did not reduce the quality of care provided to beneficiaries.[247]

We have received continued interest in the AIM and AP ACO models and ongoing requests to implement policies with similar upfront and ongoing payments for ACOs newly participating in the Shared Savings Program. Interested parties believe these models were valuable for transitioning small and rural practices into ACOs and believe there is ongoing need for this type of support. We agree, and we also believe that the Shared Savings Program should provide an entry point for all willing organizations that wish to move towards providing value-driven healthcare.

Section 1899(i) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. In accordance with the authority provided to the Secretary by section 1899(i) of the Act, we proposed to make advance shared savings payments, referred to herein as advance investment payments (AIPs), to certain ACOs participating in the Shared Savings Program to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program (87 FR 45860). Such payments would be made pursuant to the standards we proposed to establish in new § 425.630.

As discussed in the CY 2023 PFS proposed rule (87 FR 45860 at 46450), we envision that this new payment option would distribute AIPs to ACOs for 2 years in order to reduce the financial barriers encountered by small providers and suppliers as they join the Shared Savings Program. These payments would be recouped from any shared savings the ACO earned. Funding the ACOs for 2 years would align with the policy in AIM. The AIPs are designed to reduce upfront costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program.

Section 1899(i)(3)(A) of the Act requires CMS to determine that AIPs would improve the quality and efficiency of items furnished to Medicare in order to make such payments. We believe that AIPs meet this standard because such payments would be modeled on the AIM payments, which were shown to improve the quality and efficiency of care. The AIM evaluation report concluded that AIM successfully encouraged ACOs to form in geographic areas where ACOs may not otherwise have formed, the upfront funding provided by CMS assisted in the formation of the ACOs, and there was a reduction in Medicare spending and utilization without a reduction in the quality of care provided or patient and caregiver experiences.[248] The AIM evaluation found that, across all AIM Test 1 ACOs, the model reduced per beneficiary per month (PBPM) total Medicare spending by an estimated $28.21 in PY1, $36.94 in PY2, and $38.73 in PY3 compared to beneficiaries in the AIM ACOs' non-ACO FFS market comparison group.[249] The estimates translated to an aggregate Medicare spending reduction of $131.0M in 2016, $187.7M in 2017, and $207.7 in 2018.[250]

Section 1899(i)(3)(B) of the Act requires CMS to determine that AIPs, when implemented in combination with existing modifications made to the Shared Savings Program payment model specified in section 1899(d) of the Act, will not result in additional program expenditures. The addition of AIP meets this standard. Please review section

[238] L&M Policy Research, Evaluation of CMMI Accountable Care Organization Initiatives: Advance Payment ACO Final Report 39–41 (November 25, 2016), available at *https://innovation.cms.gov/files/reports/advpayaco-fnevalrpt.pdf*.

[239] Ibid at 14.

[240] Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014), available at *https://innovation.cms.gov/files/x/aim-rfa.pdf*.

[241] Ibid.

[242] Ibid.

[243] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt*.

[244] L&M Policy Research, Evaluation of CMMI Accountable Care Organization Initiatives: Advance Payment ACO Final Report 39–41 (November 25, 2016), available at *https://innovation.cms.gov/files/reports/advpayaco-fnevalrpt.pdf*.

[245] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt*.

[246] Ibid. at 39.

[247] Ibid. at 57–60.

[248] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 2–3 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt*.

[249] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 2 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt*.

[250] Ibid. at 41.

VI.E.7 of this final rule for a fuller discussion of the financial impact of the Shared Savings Program payment model, including the findings necessary to demonstrate compliance with section 1899(i)(3)(B) of the Act.

We intend to periodically reassess whether a payment model established under section 1899(i)(3) of the Act, including the payment of advance investments, continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. If we determine that the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the payment model results in net program costs, we would undertake additional notice and comment rulemaking to adjust our payment methodology to assure continued compliance with the statutory requirements.

We received hundreds of public comments on the proposal to implement AIP beginning in PY 2024. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported the implementation of AIPs for the Shared Savings Program. Many commenters agreed that AIPs will enable clinical practices to partner with community-based organizations to identify and meet the needs of underserved beneficiaries.

MedPAC supported the AIP and the approach of basing payments on caring for underserved beneficiaries. MedPAC cautioned, however, that the impacts of the AIP may not be the same as those found in AIM or the Advance Payment Model given the different criteria for eligibility and how the funds should be spent. MedPAC urged CMS to continue to monitor and evaluate the impact of providing these funds on program spending and quality of care.

Response: We agree with commenters that AIPs are a critical step in enabling clinical practices to partner with community-based organizations when identifying and providing care to underserved beneficiaries, which we note may include those who are impacted by SDOH factors that contribute to poor health outcomes. We appreciate MedPAC's support for this policy, and we will monitor and evaluate the impact of providing AIPs to ensure the program meets the requirements under section 1899(i)(3) of the Act.

Comment: One commenter supported our proposal to implement AIPs, as the payments would encourage provider-led ACOs to successfully participate in the Shared Savings Program and level the playing field between physician-led and hospital-led ACOs. One commenter noted that many independent home care medicine (HCM) practices are interested in engaging in value-based care but often do not have the infrastructure or technology needed to be able to successfully participate and report important data.

Response: We appreciate the commenter noting that this proposal encourages participation among physician-led ACOs and agree that AIPs will provide important start-up funding to establish ACO provider networks in underserved communities. We appreciate the commenter for reminding CMS of the importance of HCMs in improving outcomes for patients when they are discharged to the community.

(2) Eligibility

In October of 2021, CMS outlined a renewed vision and strategy for how the Innovation Center will drive health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries.[251] We believe accountable care reduces fragmentation in patient care and lowers costs by giving providers and suppliers the incentives and tools to deliver high-quality, coordinated, team-based care. In partnership with the Innovation Center and in support of our shared goal of increasing the number of beneficiaries in a care relationship with accountability for quality and total cost of care, we proposed broad eligibility requirements for AIPs that will lower the barrier of entry to the Shared Savings Program for low revenue ACOs that are inexperienced with risk.

As discussed above, the AIPs are designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program. Building upon AIM's success with new ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives, we proposed to limit the eligibility for AIPs to these same groups. Our experience administering the Shared Savings Program suggests that re-entering and renewing ACOs have alternative payment model (APM) experience and would not need, or benefit as significantly from, the start-up funds that AIPs provide because they have already invested in creating an ACO. Additionally, we do not have data from our experience with AIM to conclude that previously established ACOs need or benefit from upfront shared savings. The final evaluation report for AIM could not draw conclusions for AIM Test 2 ACOs, which involved only previously established ACOs, because of the small number of AIM Test 2 ACOs and the variation in results between them. Six AIM Test 2 ACOs started AIM in April 2015 or January 2016. Two AIM Test 2 ACOs ceased participating in the Shared Savings Program at the end of 2015, leaving four AIM Test 2 ACOs evaluated in each of three performance years.[252]

In the CY 2023 PFS proposed rule (87 FR 45860), we proposed eligibility criteria modified from the AIM eligibility criteria. The eligibility standards to join Test 1 of AIM required that an ACO be: (1) new to the Shared Savings Program; (2) not include a hospital unless it was a critical access hospital or a small IPPS hospital; and (3) not owned or operated by a health plan.[253] The model also prioritized ACOs in rural locations and those in locations with low ACO penetration through the use of scoring criteria.[254] We believe certain eligibility modifications are necessary to scale advance payments from a model to a regular component of the Shared Savings Program and to align with the Innovation Center's stated vision for health care transformation. As AIM was only available to a limited number of ACOs, it relied on scoring criteria in addition to its eligibility standards to select the highest scoring applicants. The Shared Savings Program does not have a similar limitation; therefore, we proposed more inclusive eligibility criteria.

We are also broadening the eligibility criteria compared to AIM to reflect our belief that it is important to provide an incentive for providers and suppliers who serve high need beneficiaries in all areas to form ACOs. Similar to AIM, we intend for AIPs to encourage the formation of new ACOs in rural areas; however, unlike AIM we also want to recognize that there are underserved beneficiaries who reside in urban areas and who can also benefit from the high-quality coordinated care an ACO can provide. Additionally, underserved beneficiaries may receive care from

[251] *https://innovation.cms.gov/strategic-direction.*

[252] Centers for Medicare & Medicaid Services, ACO Investment Model (AIM) Final Evaluation Report (September 2020) available at *https://innovation.cms.gov/data-and-reports/2020/aim-finalannrpt-perspective.*

[253] Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014), available at *https://innovation.cms.gov/files/x/aim-rfa.pdf.*

[254] Ibid.

providers and suppliers within a geographic area with high alternative payment model penetration. Generally, such providers and suppliers and the beneficiaries they serve are not or have not been part of an ACO previously. Therefore, as explained in the CY 2023 PFS proposed rule, we do not believe we should limit AIP eligibility only to ACOs in rural communities or in areas with low ACO penetration.

In the CY 2023 PFS proposed rule (87 FR 45860 at 46099), we proposed to establish the eligibility criteria for AIPs in § 425.630(b). Specifically, we proposed that CMS must determine that an ACO meets all of the following criteria for the ACO to be eligible to begin receiving AIPs:

- The ACO is not a renewing ACO or re-entering ACO (as such terms are defined under § 425.20).
- The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track glide path and is eligible to participate in the Shared Savings Program.
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.
- The ACO is a low revenue ACO.

AIM required applicants to demonstrate an exceptional need for prepaid shared savings. In the Shared Savings Program, the definition of low revenue is a similar criterion for determining ACO funding needs. Under § 425.20, a low revenue ACO means an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available. Low revenue ACOs tend to be small, physician-led ACOs that are less well capitalized organizations. These ACOs may be encouraged to participate and remain in the program based on the availability of additional incentives, such as the opportunity to receive AIPs.

We proposed conforming changes to § 425.611(c)(4) to limit eligibility to low revenue ACOs (87 FR 45860 at 46100). In accordance with § 425.611(c)(4), we adjust Shared Savings Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episodes of care for treatment of COVID–19 from expenditure and revenue calculations for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO and determining an ACO's eligibility for participation options. We proposed to revise § 425.611(c)(4) to exclude all Parts A and B FFS payment amounts for a beneficiary's episodes of care for treatment of COVID–19 from expenditure and revenue calculations for purposes of determining an ACO's eligibility to receive AIPs.

We proposed to limit eligibility to ACOs applying to participate under any level of the BASIC track glide path because this participation option is indicative of an ACO's inexperience with performance-based risk (87 FR 45860 at 46100). ACOs in the BASIC track are typically less experienced with risk and are more likely to benefit from upfront funding or ongoing financial assistance.

In summary, we proposed to create a new paragraph in § 425.100(d) to establish that an ACO may receive AIPs. We also proposed in § 425.630(b) to specify the eligibility criteria for an ACO to begin receiving receive AIPs, and we proposed conforming changes to § 425.630(c)(4). We sought comments on these proposals.

The following is a summary of the public comments received on the proposed eligibility criteria for an ACO to receive AIPs and our responses:

Comment: Many commenters supported additional opportunities for ACOs to participate in AIPs, and contended that expanding eligibility to existing ACOs would benefit underserved beneficiaries and work to combat health inequities. They stated that AIPs would benefit ACO beneficiaries in underserved communities who lack adequate healthcare access as the revenue status of an ACO does not reflect these costs. Several commenters noted that AIP funds should be available to all ACOs to address SDOH and improve health outcomes by providing preventative and social services.

Two commenters encouraged CMS to consider the expansion of AIP eligibility to those ACOs that can demonstrate need among patient populations. One commenter suggested CMS could require high revenue ACOs to provide a plan to CMS on how they would use the payments to address SDOH among underserved populations. Examples of appropriate investments could be the launch of a food as medicine program, further investments on affordable housing, and adopting or expanding the use of community health workers.

Response: We agree with commenters that AIPs will improve ACO participation and assist in providing coordinated care to underserved populations. However, expanding AIP eligibility to all ACOs or even all ACOs that can demonstrate need among their patient populations is not consistent with the purpose of AIP and we do not believe it would be an appropriate use of the Trust Funds. AIP is not intended to provide indefinite support to ACOs or to ACOs of all sizes, but to help provide start-up funding needed prior to earning shared savings for those ACOs that face difficulty finding such funding. Historically, the Shared Savings Program has shown that re-entering and renewing ACOs have already benefited from APM experience, and therefore, would be less likely to need financial support to become operational or develop programs targeting SDOH. We expect that existing ACOs already participating and earning shared savings have access to more resources to serve their aligned beneficiaries. Additionally, we believe that many existing ACOs already have developed health IT infrastructures in place to support and coordinate quality care.

Comment: Many commenters advocated that CMS should expand AIP eligibility criteria to include all ACOs regardless of an ACO's high or low revenue status. These commenters requested that CMS remove the low revenue AIP eligibility criterion. The commenters contended that the exclusion of high revenue ACOs from the eligibility criteria would preclude from participation in AIP many ACOs with key safety-net providers such as teaching hospitals, federally qualified health centers (FQHCs), rural health clinics (RHCs), and CAHs. One commenter noted that the distinction between high and low revenue ACOs creates a two-tier system for ACOs, leading to an unlevel playing field between physician-led and hospital-led ACOs that could reduce participation of hospital-led ACOs. One commenter reminded CMS that most high revenue ACOs include a hospital in their composition and would not be eligible to receive AIPs. A few commenters noted in the alternative that CMS should broaden the eligibility criteria to allow ACOs with safety net providers on their participation lists to receive AIPs, even if they did not otherwise meet all of the proposed eligibility criteria. Another commenter contended that the low revenue eligibility requirement would prevent some ACOs with underserved patient populations from receiving AIPs. Several commenters supported the low revenue eligibility requirement as it captures smaller ACOs with diverse beneficiary populations, which specifically targets safety net providers, those serving underserved communities, and less financially

resourced organizations. Several commenters supported CMS' decision not to limit AIPs to rural areas or areas with low ACO penetration because an urban area could also include ACOs with underserved populations and meet the AIP eligibility criteria.

Response: We agree that safety-net providers and high revenue ACOs serve vulnerable communities, but we disagree with commenters that CMS should remove the low revenue eligibility criterion. The AIP eligibility requirements are intended to incentivize greater participation for ACOs that: (1) are inexperienced with performance-based risk Medicare ACO initiatives; and (2) have limited capital and insufficient resources to fund start-up costs. The intent of the AIP payment is to advance shared savings in order to provide start-up funding for ACOs that are less well capitalized than a high revenue ACO. We disagree that the eligibility criteria penalizes high revenue ACOs, as we believe that high revenue ACOs should not need advance funding from CMS to increase staffing, improve health care infrastructure, and provide accountable care for underserved beneficiaries. We expect that AIPs will enable the formation of more ACOs with underserved beneficiaries who receive care from providers and suppliers that have not been ACO participants previously.

While we agree with commenters that safety-net facilities, such as FQHCs, RHCs, and CAHs provide important primary care services to rural and underserved communities, we disagree that the AIP eligibility criteria should include an exception for high revenue ACOs that include safety-net providers as ACO participants. We believe this would result in many ACOs receiving AIPs that do not need access to start-up capital. The vast majority of FQHCs and RHCs participating in Shared Savings Program ACOs without a hospital are in low revenue ACOs, so CMS does not believe this requirement will preclude participation of FQHCs or RHCs. CMS plans to monitor the impact of AIP on ACO formation and program participation, including the impact on CAHs.

Comment: One commenter cautioned CMS that the proposed eligibility criteria for low revenue ACOs may be too limited as high revenue facilities may also serve specific populations that have been historically underrepresented in value-based programs. The commenter encouraged CMS to reevaluate if the definition of low revenue ACO best captures the ACOs that lack upfront capital and sufficiently excludes providers that have the capital to join without AIPs.

Response: We believe the AIP eligibility criteria will sufficiently limit access to AIP to those ACOs that are most likely to need start-up funding, including those serving underrepresented populations. CMS will conduct monitoring and evaluation activities to determine the impact of the AIP eligibility criteria on ACO participation and to ensure that the program meets the requirements under section 1899(i)(3) of the Act. Limiting the eligibility criteria to low revenue ACOs will encourage the formation of new ACOs that would not otherwise join the Shared Savings Program due to the lack of start-up funds. AIPs address barriers to entry by providing advance payments of shared savings.

Comment: Several commenters encouraged CMS to consider expanding the types of ACOs that would be eligible to receive AIPs. Specifically, these commenters advocated that CMS permit ACOs entering the ENHANCED track to be eligible to participate in AIP. The commenters indicated that such a policy would encourage ACOs that have accepted downside risk to implement strategies that would effectively create savings for the program. Other commenters noted that even ACOs that are experienced with performance-based risk may lack resources and infrastructure to meaningfully address SDOH and overcome health care inequities for underserved beneficiaries.

Response: We disagree that ACOs participating in the ENHANCED track should be eligible to apply for AIPs. Given the level of risk involved in the ENHANCED track, ACOs in that track are generally well established and confident in their ability to coordinate care for their beneficiary population. Moreover, with effective management and planning, such ACOs should not need additional advance funding from CMS to increase staffing, improve health care infrastructure, and provide accountable care for underserved beneficiaries. We note that, depending on the circumstances, not all AIPs will be recouped from an ACO. Accordingly, we prefer to finalize more limited eligibility criteria at this time because such a policy is more fiscally prudent.

For the reasons discussed above, we are finalizing our proposed eligibility criteria without change. AIP eligibility is limited to new, low revenue ACOs that are inexperienced with performance-based risk and have applied to participate in the Shared Savings Program under any level of the BASIC track's glide path. Specifically, we are finalizing as proposed § 425.630(b) to describe the eligibility criteria for an ACO to receive AIPs. Beginning January 1, 2024, an ACO is eligible to receive AIPs if CMS determines that all of the following criteria are met: (1) the ACO is not a renewing or a re-entering ACO; (2) the ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program; (3) the ACO is inexperienced with performance-based risk Medicare ACO initiatives; and (4) the ACO is a low revenue ACO.

(3) Application Procedure & Contents

We proposed to address the process for an ACO to apply for AIPs in § 425.630(c). Specifically, we proposed that, to obtain a determination regarding whether an ACO may receive AIPs, the ACO must submit, as part of its application to participate in the Shared Savings Program, complete supplemental application information in the form and manner and by a deadline specified by CMS. The application cycle for AIPs would be conducted as part of and in conjunction with the Shared Savings Program application process under § 425.202 with instructions and timeline published through the Shared Savings Program website. We proposed that the initial application cycle to apply for AIPs would be for a January 1, 2024, start date. As noted in section III.G.2.a.(2) of the CY 2023 PFS proposed rule, ACOs currently participating in the Shared Savings Program or applying to renew their participation agreement would not be eligible to apply. We noted in the CY 2023 PFS proposed rule that we intended to provide further information regarding the process, including the application and specific requirements such as the deadline for submitting applications, through subregulatory guidance and would also provide a feedback process to afford an opportunity for the applicant to clarify or revise its application.

We proposed in § 425.630(d)(1) that an ACO must submit sufficient information for CMS to determine whether the ACO is eligible to receive such payments. We also noted that CMS would provide preliminary information to the applicant ACO about its eligibility to receive AIPs during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive AIPs at the time of final application dispositions. For example, we would provide preliminary information identifying whether an ACO is low revenue and

inexperienced with performance-based risk through the ACO's application to participate in the Shared Savings Program.

We further proposed at § 425.630(d)(1) that an ACO would be required to submit a spend plan as part of its application for AIPs. At § 425.630(d)(2), we proposed content requirements for spend plans. We proposed that the plan must identify how the ACO will spend the AIPs during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under § 425.630. In addition, we proposed that the spend plan must identify the categories of goods and services that will be purchased, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS. As more fully explained in section III.G.2.a.(4) of the CY 2023 PFS proposed rule, we proposed at § 425.630(e)(4) to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs. Accordingly, we also proposed at § 425.630(d)(2)(iii) that the spend plan must include a statement that the ACO has established a separate designated account for the deposit and expenditure of all AIPs in accordance with § 425.630(e)(4).

As explained in the CY 2023 PFS proposed rule (87 FR 45860), we did not intend for the spend plan requirement, as proposed, to create a benchmark requirement against which we would hold the ACO accountable. Instead, we intended it to aid CMS in tracking ACO progress toward implementing their spend plan and any challenges or changes in strategy that occur following their receipt of AIPs. We noted that we believe that ACOs have the flexibility to better understand their needs over time and evolve their spending accordingly.

In the CY 2023 PFS proposed rule, we also explained that while we do not intend an ACO's spend plan to limit the ACO to specific uses of AIPs within the broad categories of acceptable uses, we would reserve the right to terminate an ACO's ability to receive AIPs if it is not in compliance with requirements of the Shared Savings Program (see our proposal described in section III.G.2.a.(7).(b) of the CY 2023 PFS proposed rule). In addition, by certifying its application under § 425.202(a)(2), the ACO certifies that the information contained in the application, including the information necessary to determine eligibility for AIPs, is accurate, complete, and truthful.

We proposed at § 425.630(d)(3) that we would review the information submitted in the ACO's application to determine whether an ACO meets the eligibility criteria and other requirements for AIP and would approve or deny the application for AIPs accordingly. We noted that we would review the ACO's Shared Savings Program application simultaneously with the supplemental information in its AIP application. We also noted that the denial of an AIP application would be subject to reconsideration review in accordance with the standards specified in subpart I of part 425.

In addition, we proposed at § 425.630(d)(3) that CMS may review the spend plan at any time and require the ACO to make changes to its spend plan comply with § 425.630(e)(1) as a result of that review. Examples of permitted uses are described in section III.G.2.a.(4) of the CY 2023 PFS proposed rule. As proposed, if the ACO fails to provide a spend plan that complies with § 425.630(e), CMS could terminate the ACO's AIPs pursuant to § 425.630(h)(1)(i) and take other remedial action under § 425.216 or § 425.218.

We also proposed to update our public reporting requirements under § 425.308 by adding new paragraph (b)(8) to require an ACO to publicly report its spend plan. We proposed to require that the ACO post on its dedicated public reporting web page: (1) the total amount of AIPs received from CMS for each performance year; (2) the ACO's spend plan; and (3) an itemization of how the AIPs were actually spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan as submitted under § 425.630(d)(1), and such other information as may be specified by CMS. The public reporting template that CMS provides to ACOs annually would be updated to reflect the new information categories that an ACO must report.

We proposed to add § 425.630(c) and (d) to establish standards for the contents of an application to be determined eligible for AIPs, as well as the procedures for filing such an application. We solicited comments on these proposals.

The following is a summary of the public comments received on the proposed application procedure and content requirements and our responses:

Comment: Several commenters requested that CMS provide guidance (that is, FAQs, sample application, templates) for spend plans in preparation for application cycles. One commenter suggested that CMS offer technical assistance on spend plan development, inform providers of this opportunity, and support them through the application process for the program.

Response: Prior to the start of the application process, we intend to provide further guidance regarding the PY 2024 application process, including the content of the application and specific requirements such as the deadline for submitting applications and the contents of spend plans. We would also provide a feedback process to afford an opportunity for the applicant to clarify or revise its application.

Comment: Several commenters recognized that AIP would take time to implement, but thought that AIP funding should be available to new ACOs that began participating in the Shared Savings Program before January 1, 2024. One commenter advocated that new ACOs that begin participating in the Shared Savings Program in 2023 (''2023 Starters'') should be allowed to apply for AIPs in 2024. Another commenter suggested that CMS provide an opportunity for 2023 Starters to submit supplemental application materials for AIPs during the first AIP application cycle and, if approved, to receive AIPs for the second and third years of their agreement periods (PY 2024 and PY 2025). According to commenters, implementing such a transitional policy would ensure that 2023 Starters would not delay participation in the Shared Savings Program until 2024 when the AIPs become available.

Multiple commenters recommended that CMS establish a process for inexperienced ACOs that joined prior to 2024 to apply for AIP, including those that began participating before 2023. These commenters suggested that if certain existing ACOs are permitted to apply for AIP, CMS could shorten the period during which funds must be used and repaid to align with the ACO's remaining agreement period, extend the period for using and repaying funds into a second agreement period, or allow an ACO to end its current agreement period early and enter a new 5-year agreement that aligns with the planned AIP timeline.

Response: We are aware of the timing concerns expressed by stakeholders and strive to give ACOs ample time to make decisions that are in the best interest of their patients, providers and organization. The application cycle for AIPs will be conducted annually as part

of and in conjunction with the Shared Savings Program application process under § 425.202 with instructions and timeline published through the Shared Savings Program website. While CMS believes that many ACOs currently participating in the Shared Savings Program will have begun to earn shared savings by the time AIP begins in 2024, and therefore, are less likely to need upfront funding, CMS understands the commenters' concerns regarding relatively new, inexperienced ACOs that will not have access to AIPs under this final rule. We may address this concern in future rulemaking.

For the reasons discussed above, we are finalizing our proposed policies without change. AIP supplemental application information would be processed for the first time in CY 2023 for a January 1, 2024 start date, and annually thereafter. The AIP supplemental application information would be submitted as part of the Shared Savings Program application, and we intend to issue subregulatory guidance to support new applicants in completing the supplemental application information, including spend plan development. Specifically, we are adopting as proposed § 425.630(c) and (d). Section 425.630(c) requires an ACO to submit to CMS complete supplemental information as part of its application to participate in the Shared Savings Program; such information must be submitted in the form and manner and by the deadline specified by CMS. Under § 425.630(d)(1), the supplemental application information must be sufficient for CMS to determine whether the ACO is eligible to receive AIPs, and the ACO must submit a spend plan as part of the supplemental application information. Under § 425.630(d)(2), the spend plan must: (1) describe how the ACO will spend its AIPs during the agreement period to build care coordination capabilities, address specific health disparities, and meet other criteria specified in § 425.630; (2) identify the categories of goods and services that will be purchased with AIPs, including the dollar amounts to be spent on the various categories and such other information a may be specified by CMS; and (3) state that the ACO has established a separate designated account for the deposit and expenditure of AIPs. Under § 425.630(d)(3), CMS would review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements for advance investment payments and will approve or deny the advance investment payment application accordingly. CMS may review an ACO's spend plan at any time and may require the ACO to modify its spend plan to comply with the requirements of § 425.630.

(4) Use and Management of Payments

Under section § 425.308(b)(4), ACOs are required to publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the goals of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion of shared savings distributed among ACO participants. Although ACOs are required to report this information, our regulations do not require an ACO to spend its shared savings in any particular way. However, given the purpose of AIPs, the fact that they are made before any shared savings are actually earned by an ACO, and our proposed limitations on the recovery of these funds in the absence of any earned shared savings, we proposed at § 425.630(e) to specify how an ACO may use AIPs.

Similar to our experience with AIM, AIPs are intended to provide the means to build the ACO's population health management capabilities, including the provision of accountable care for underserved beneficiaries. AIPs are not intended to sit idle in an investment account or to serve purposes unrelated to the goals of AIPs. We proposed at § 425.630(e) that AIPs must be used to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. However, as noted in the CY 2023 PFS proposed rule, we emphasized that AIP amounts are advance shared savings, and not payment or reimbursement for items or services under the three specified categories. We proposed that expenditures of AIPs must comply with the beneficiary incentive provision at § 425.304 and all other applicable laws and regulations. The proposal was intended to provide ACOs with flexibility to use payments within three specified categories of allowable uses. We solicited comment on whether there are additional categories of expenses that should be permitted in light of the purposes of AIPs. We noted in the CY 2023 PFS proposed rule that we will monitor how ACOs are spending these funds and would revisit these categories in future rulemaking if additional flexibilities or boundaries are required.

As discussed in the CY 2023 PFS proposed rule, we recognize that there are many ways to improve population health management and support the provision of accountable care for underserved beneficiaries. The most effective ways will vary by ACO. We believe ACOs know best the needs of their populations and how to use funds to meet program goals. We offered the following examples of permitted uses within the three categories:

Increased staffing. Hiring nurse case managers or other relevant support staff to implement screening for social determinants of health; hiring community health workers, certified peer recovery specialists, other health care professionals with training in delivering culturally and linguistically tailored services; hiring a health equity officer; hiring behavioral health clinicians and case managers to integrate behavioral health treatment into the primary care setting; hiring oral health providers to integrate dental services into the primary care setting; or encouraging partnerships with healthcare systems and local, community-based organizations (such as Area Agencies on Aging, Aging and Disability Resource Centers, and Centers for Independent Living) to increase organizational capacity to identify and address SDOH and connect individuals with culturally and linguistically tailored, accessible health care services, supports, and information at an appropriate literacy level.

SDOH strategies. Examples include developing or securing transportation services; housing-related services to address housing insecurity or homelessness, home or environmental modifications to support a healthy lifestyle, legal aid services to help patients' address social needs, employment-related services, food-related services, utilities-related supports, services to support personal safety, services to reduce social isolation, services to help patients cope with or address financial strain or poverty, patient caregiver supports, providing remote access technologies, telemonitoring, and meals; ensuring individuals are able to access culturally and linguistically tailored, accessible health care services and supports that meet their needs, partnering with community-based organizations to address SDOH needs; or implementing systems to provide and track patient referrals to available community-based social services that assess and address social needs, as well as enable coordination and measurement of health

and social care across the community where beneficiaries reside.

Health Care Provider Infrastructure. Examples include investment in certified electronic health record technology (CEHRT) (including system enhancements and upgrades), connections to clinical data registries and networks that support health information exchange across disparate providers and systems involved in patient care, integration of ACO participant systems including tools to share and analyze operational and quality data, remote access technologies, telemonitoring, screening tools, case management or practice management systems to improve care coordination operations across the health and social care continuum, physical accessibility improvements, and tools to further integrate behavioral health or dental services into primary care settings.

In the proposed rule, we elaborated on the permitted and prohibited uses of AIP funds. Similar to AIM, we explained that we intended for advance investment payments to encourage the formation of new ACOs that provide care to underserved beneficiaries, not simply to fund another business venture of an established company or to furnish items or services unrelated to the ACO or the beneficiaries it serves. At § 425.630(e)(2), we proposed that AIPs may not be used for any expense other than allowable uses under proposed § 425.630(e)(1). We provided examples of prohibited uses of AIPs, including management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicare, or items or activities unrelated to ACO operations that improve the quality and efficiency of items and services furnished to beneficiaries. We stated that performance bonuses could be tied to the successful implementation of SDOH screenings or care management guidelines, or ACOs could pay a higher salary as necessary to retain a clinician who treats underserved beneficiaries. We solicited comments on these examples of prohibited uses and whether there are additional categories of expenses that should be prohibited in light of the purpose of AIPs. We noted that we would monitor how ACOs are spending AIPs and would revisit allowable uses in future rulemaking if additional flexibilities or boundaries are required.

Additionally, we proposed at § 425.630(e)(2) that an ACO participating in Level E of the BASIC track may not use any advance investment payments to pay back any shared losses that it would have incurred as specified in a written notice from CMS under § 425.605(e)(2). Because Level E is an Advanced APM that must, under § 414.1415(c), involve the acceptance of more than a nominal amount of risk, prohibiting use of AIPs to repay shared losses ensures that an ACO eligible to receive AIPs that is willing to take on such risk remains fully accountable for any shared losses it incurs. To ensure compliance with the standards for use of AIPs, we proposed updating the annual certification requirements under § 425.302(a)(3) to require that the ACO certify that the payments were disbursed only for allowable uses.

We also proposed at § 425.630(e)(4) to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs, and from which all disbursements of such funds are made only for allowable uses. This would allow us to monitor whether the funds are used only for allowable uses and to ensure that AIPs do not pay for any prohibited uses under § 425.630(e)(2). We noted that CMS would deposit AIPs into the same account used for the deposit of shared savings payments; that account must be specified in an ACO's Electronic Funds Transfer form submitted with its application. We proposed that, upon receipt of AIPs, the ACO must immediately deposit the funds into the separate account designated for maintaining AIPs.

We also proposed that the ACO's spend plan must also include a statement that the ACO has established a separate account for the purpose of segregating AIPs. Additionally, we proposed to update our annual certification requirements under § 425.302 by adding new paragraph (a)(3)(iv) to require an ACO to certify at the end of each performance year that it has moved all AIPs received during that performance year into a designated AIP account, where the funds remained until spent as required under § 425.630(d).

The following is a summary of the public comments received on the proposed provisions regarding the use and management of AIPs and our responses:

Comment: A few commenters considered staffing needs as an appropriate use of AIP funds. One commenter suggested CMS consider modifying the regulatory language for AIP allowable uses (at § 425.630(e)(1)) to permit not only increased staffing, but also investing in training and education for existing staff. A few commenters explained that in healthcare workforce shortage areas, eligible ACOs may face challenges in recruiting additional staff and noted that in these cases, it may be possible for existing staff to be trained and educated to improve the quality and efficiency of services furnished to ACO beneficiaries. One commenter suggested that allowable uses of AIP funds include training opportunities for all staff, not only physicians or advanced practice clinicians, if such training addresses infrastructure needs such as implementation of electronic health records.

Response: We believe that increased staffing may include hiring new staff. We also believe that providing additional training and education to existing staff working with the ACO would constitute an investment in health care provider infrastructure, and therefore, be a permissible use of AIP funds. AIP funding can be used for a wide variety of ACO staffing needs, including health equity officers, peer support specialists, peer recovery specialists, behavioral health clinicians, case managers, community health workers and other health care professionals with training in delivering culturally and linguistically tailored services.

Comment: Many commenters requested that CMS clarify the types of additional staffing that would constitute an appropriate use of AIP funds. Specifically, in response to our preamble reference to hiring ''certified peer recovery specialists'' (87 FR 46101), commenters noted that ''peer support specialists,'' as well as peer recovery support specialists, would benefit ACOs in treating beneficiaries with mental health needs. One commenter contended that States certify providers of peer support services for mental health and substance use conditions and the certifications use a variety of terms for peer support personnel. The commenter suggested that CMS work with Medicaid, CHIP and SAMHSA to ensure consistent and inclusive nomenclature that includes all peers who work with beneficiaries with mental health conditions, substance use disorders, or both conditions. Many commenters recommended that CMS specify that hiring both peer support specialists and peer recovery support specialists is a permissible use of AIP funds for mental health and substance use conditions. Additionally, the commenters suggested CMS hold all ACOs accountable for providing integrated behavioral health care.

Response: We appreciate the comments providing examples of how ACOs may consider spending AIPs to

enhance staffing, to support behavioral health integration and meet the mental health needs of underserved communities. Our reference in preamble to ''certified peer recovery specialists'' was merely one example of a permitted use of AIP funds for increased staffing; ACOs can use AIP funds to improve the quality and efficiency of care furnished to beneficiaries by increasing staffing of peer support specialists or other peer support personnel regardless of nomenclature. We agree that behavioral health services are important to an individual's wellbeing and believe that the Shared Savings Program provides ACOs the flexibility to include behavioral health services in their care coordination plans and use AIP funding for these purposes. However, developing a specific methodology for holding all ACOs accountable for providing integrated behavior health care is beyond the scope of this rulemaking.

Comment: A few commenters encouraged CMS to consider allowing physician-led ACOs to use AIPs to pay for retention bonuses of clinical and administrative staff. One commenter contended that independent practices often compete with larger provider networks and hospital systems in attracting and maintaining qualified staff members.

Response: We appreciate the concerns of the commenters and recognize that expanding staffing to better coordinate quality care, especially in underserved communities, would promote program goals and increase ACO participation among provider types. However, after further consideration, we do not believe that the payment of retention bonuses should be an allowable use of AIP funds because of the potential for abuse. We may consider this issue in future rulemaking that would promulgate appropriate safeguards against abuse.

Comment: Some commenters supported CMS proposals to use AIP funding to help close the health equity gap and contended that SDOH are primary drivers of health inequities. Other commenters recognized that CMS is working to reduce health inequalities by implementing SDOH measures in a regulatory program and in implementing AIPs to help support and develop community health partnerships. Commenters identified barriers to successful care coordination such as, insufficient community resources and capacity for care referrals in the community. Commenters suggested that CMS consider incentivizing (or requiring) ACOs to invest a portion of their AIPs in community resources where they are most needed, aligned with their decile (for example, ACOs in ADI decile 1–2 must spend 5 percent on community resources, whereas those in deciles 9–10 must spend 25 percent). One commenter requested that CMS allow AIP funds to be used to maintain an up-to-date community resource inventory and noted that clinical practices often struggle to partner with community-based organizations because they lack the technological, human, or other infrastructure required to deliver sufficient services or enter into contractual arrangements with ACOs. Other commenters contended that screening for social needs requires new workflows, dedicated and trained staff capable of engaging and navigating patients to resources, and partnerships with community-based organizations.

Response: ACOs can use AIP funding to assist in developing new strategies to identify underserved beneficiaries and connect them to additional resources such as housing and food security. In the CY 2023 PFS proposed rule we identified many areas for the appropriate use of AIP funds in addressing social needs, as well as enabling coordination of healthcare and social services across the community. We disagree with the commenters who advocated that CMS should incentivize or require ACOs to invest a portion of their AIPs in community resources where they are most needed. We prefer to establish fundamental parameters for the use of AIP funds and to permit ACOs to have the discretion to decide how the funds can be best used to improve the quality and efficiency of care in the communities they serve. Although CMS is granting ACOs discretion regarding the use of AIPs funds to meet the needs of underserved communities, we reserve the right to review any ACO SDOH strategies as part of the spend plan to determine whether the use of AIP funds to implement such strategies would constitute a prohibited use of AIP funds. If CMS finds that an ACO's planned spending on SDOH will not (or is unlikely to) improve the quality and efficiency of items and services furnished to beneficiaries, we would require the ACO to make changes to the strategy.

As explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control, or other State-funded grants to provide social services. Generally, we believe such organizations know the populations they serve and their communities, and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a source with which to share information. We recognize that ACOs wishing to address social needs may want to make investments that would enable their ACO participants and ACO providers/suppliers to work with community-based organizations that have expertise in identifying and providing the types of social services that the ACO's beneficiary population requires.

The Shared Savings Program does not prohibit ACOs from partnering with community-based organizations. Currently, if a community-based organization is enrolled in Medicare, it may already be an ACO participant or an ACO provider or supplier. We believe community-based organizations could play an important role in identifying and addressing gaps in health equity. We hope to encourage more ACOs to partner with community-based organizations whether they provide items and services reimbursed by Medicare or not. We recognize that Federal and other sources of grant funding for social services may be insufficient to fully address the demand for services within a community or broader geography. To meet this demand, contractual arrangements between the health care sector and community-based organizations providing social services have increased in recent years.

Comment: One commenter recommended that CMS clarify that AIP funds could be used to invest in partnerships with community-based providers, including community pharmacies, and support beneficiary access to pharmacy settings where they may be connected with additional services. The commenter contended that 90 percent of Americans live within 5 miles of a pharmacy and pharmacists are viewed as one of the most trusted providers. The commenter asserted that partnerships between ACOs and pharmacies/pharmacists can strengthen access to the delivery of patient-centered care.

Response: The comment did not specifically describe the nature of the ''investments'' for which AIP funds might be used. We do not believe that it is appropriate or necessary to use AIPs—an advance payment of shared savings with Trust Fund dollars that should be repaid—to obtain an ownership or investment interest in a provider, supplier, or pharmacy. Depending on the circumstances, an ACO may use AIP funds to enable a community-based provider, supplier, or pharmacy to improve the quality and efficiency of care furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries. We note that any such arrangement must comply with all applicable laws and regulations, including the fraud and abuse laws.

Comment: Many commenters encouraged CMS to revise the beneficiary incentive provision at § 425.304(a)(2) to expressly state that nothing in § 425.304 shall be construed as prohibiting an ACO from using AIPs to cover the cost of a beneficiary incentive furnished pursuant to § 425.304(b) or (c). Section 425.304(a)(2) currently states that nothing in § 425.304 shall be construed as prohibiting an ACO from using shared savings to cover the cost of a beneficiary incentive furnished pursuant to § 425.304(b) or (c).

Response: We recognize that beneficiary incentives can be used to provide accountable care for underserved beneficiaries and may thereby constitute an allowable use of AIPs, provided that the incentive is furnished in a manner that complies with the beneficiary incentive provision at § 425.304 and other applicable laws and regulations. Because AIPs are advance payments of shared savings, we do not see any need to modify § 425.304(a)(2) in the manner suggested by the commenter.

Comment: Several commenters supported CMS proposals to include infrastructure as an appropriate use of AIPs, noting that independent provider practices serve rural areas and often do not have the infrastructure or technology needed to financially support transitioning to electronic health records (EHRs), and the reporting and sharing of health data. These commenters noted that this type of investment would encourage smaller practices to participate in value-based contracting. One commenter expressed concern about how much funding would trickle down to the individual participating practices and suggested that CMS have guidelines in place to make certain funds are allocated properly across ACO administration, as well as individual practice clinical functions. One commenter contended that AIPs would improve health technology and standardized utilization of patient-facing technology, and healthcare organizations and technology vendors would have an incentive to invest in mechanisms to track performance and improve over time. One commenter noted that AIPs could be leveraged to develop infrastructure that would enhance sociodemographic data collection, develop targeted interventions to reduce health disparities, and develop relationships with community-based organizations to address social needs.

Response: We appreciate the commenters' support. We believe that the use of AIPs to foster connections and integration between primary care practices, facilities, clinical data registries will likely improve case management and care coordination across the continuum of care, and thereby improve quality care and improved health outcomes for beneficiaries. We decline to mandate a particular allocation of funds between ACO administration and individual practice clinical functions because we believe ACOs should have discretion to decide how the funds can be best for allowable purposes consistent with the parameters set forth in this final rule. Regarding investments in networks that support health information exchange, as discussed in the CY 2023 PFS proposed rule, we encourage ACOs to review the request for information in the CY 2023 PFS proposed rule regarding the recently released Trusted Exchange Framework and Common Agreement or TEFCA,[255] which included discussion about how connecting to entities exchanging information under TEFCA could help to support health information exchange for a variety of use cases that may be relevant to ACOs.

Comment: Many commenters noted that the AIPs would not provide enough resources to help FQHC-led ACOs acquire the necessary health IT to build analytics and care coordination infrastructure at the ACO and individual health center level. The commenters noted that FQHCs experience different challenges from other safety-net providers when transitioning into value-based care models based on FQHC statutory reimbursement requirements under the Prospective Payment System (PPS). Commenters contended that health centers need flexible funding to build capacity at the provider level for care coordination, chronic disease management, and screening for social determinants of health. Commenters requested permitting ACOs to transfer AIPs to FQHC participants to support building the appropriate infrastructure and workforce to support sustainability.

Response: We believe that the proposed allowable uses criteria provides enough flexibility for ACOs to determine the best way to support the needs of their beneficiaries seeking care at facilities participating in the ACO, which may include contributing towards health IT used by FQHCs if such support is structured to comply with the fraud and abuse laws and all other applicable laws and regulations.

Comment: A few commenters noted that rural health centers (RHCs) are well-suited to lead care coordination and address social determinants of health on behalf of their ACOs. Commenters requested CMS to allow AIPs to flow into RHCs and provide essential funding for them to grow with the ACO. Specifically, the commenters advocated that CMS amend the allowable uses for AIPs to explicitly permit ACOs to use AIPs for costs that may be incurred by an RHC's employees, contractors, and participating providers.

Response: This final rule does not prohibit ACOs from using AIP funds to improve care coordination for beneficiaries who receive care at an RHC or to enhance IT infrastructure used by RHCs. We do not believe it is necessary to finalize any changes to the proposed allowable uses provision at § 425.630(e)(1). We note that any financial relationship between an ACO and an ACO participant that involves AIP funding must be structured to comply with all applicable laws and regulations, including the fraud and abuse laws.

Comment: We received several supportive comments on CMS' proposal on the use of AIP funds to improve care for beneficiaries residing in underserved communities and to encourage participation from new ACOs by defraying the start-up costs of forming an ACO. Generally, commenters found that AIPs support ACOs in partnering with community healthcare providers and in meeting the needs of historically underserved beneficiaries. Commenters noted that improving provider infrastructure, increasing staffing, and addressing beneficiaries' social and other health needs would improve care quality and beneficiary outcomes.

[255] For more information, see *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement-tefca.*

Some commenters explained that AIPs would mitigate and reduce many barriers to participation and encourage improvements in care delivery redesign, including infrastructure, staffing and social supports, to better address beneficiary needs. One commenter was supportive that AIPs may be used to cover costs associated with building new local networks that involve community-based-organizations and recommended employing a broad definition of allowable costs devoted to building those networks, including the transaction costs inherent in building new partnerships. Another commenter encouraged CMS to consider requiring ACOs that obtain such incentives to apply a portion of such incentives to help build the nursing facility health-information technology infrastructure interoperability capabilities.

Response: As we stated in our CY 2023 PFS proposed rule, it is our intent to offer flexibility in how ACOs use AIPs to meet the greatest needs of their patients. We agree with commenters that investing in infrastructure is an appropriate use of AIPs, and any such investments directed to a community-based organization or a nursing facility operating under an ACO participant agreement would need to comply with all applicable laws and regulations, including the fraud and abuse laws.

Comment: One commenter requested that CMS clarify the specific examples of allowable AIP uses and provide detailed guidance and additional examples of what would constitute a prohibited use of AIP.

Response: We have provided some additional guidance on the proper use of AIP funds in response to other comments. We are committed to furnishing additional subregulatory program guidance on the allowable and prohibited uses of AIP, which may be informed by the experience we gain in reviewing and monitoring ACO spend plans and ACO use of AIP funds.

After considering the public comments, we are finalizing without change at § 425.630(e) our proposed policies for the use and management of AIPs. Specifically, we are finalizing as proposed new § 425.630(e)(1), which requires an ACO to use AIPs to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing SDOH. Section 425.630(e)(1) further provides that an ACO's expenditures of AIPs must comply with the beneficiary incentive provision at § 425.304 and all other applicable laws and regulations, including the provision at § 425.630(e)(2) regarding prohibited uses of AIPs. Under § 425.630(e)(2), AIPs may not be used for any expense other than an allowable use under § 425.630(e)(1), and in the case of an ACO participating in Level E of the BASIC track, AIPs may not be used for the repayment of shared losses by ACOs participating in Level E of the BASIC track. We are also finalizing at § 425.630(e)(4) the requirement that ACOs segregate AIPs from all other revenues by establishing and maintaining a separate account for these funds.

(5) Advance Investment Payment Methodology

In AIM, prepaid shared savings included an upfront payment of $250,000 and a one-time payment of $36 per beneficiary, followed by a monthly payment of $8 per beneficiary per month for the first 2 performance years of an AIM ACO's agreement period. According to the AIM evaluation, AIM ACO leadership conveyed through interviews and the ACO Web survey that they wanted to join the Shared Savings Program to gain experience in delivering value-based care and remain independent, and that AIM funds were critical to building the infrastructure needed to implement their ACOs.[256] The evaluation also found that these new AIM ACOs consistently demonstrated greater reductions in key Medicare spending categories and related utilization compared to similar non-AIM Shared Savings Program ACOs.[257] Furthermore, there were greater reductions in all components of Medicare spending examined, including acute inpatient hospitalizations, outpatient visits, skilled nursing facility care, and home health use. The evaluation did not find reductions in Medicare spending and utilization to be offset by reductions in the quality of care provided or patient and caregiver experiences.

We proposed to provide an ACO that CMS determines meets the eligibility criteria described in section III.G.2.a.(2) of the CY 2023 PFS proposed rule (87 FR 46099 and 46100) with AIPs during the first 2 performance years of the ACO's participation agreement. We proposed that AIPs are comprised of two types of payments: a one-time payment of $250,000 and eight quarterly payments based on the number of assigned beneficiaries, capped at 10,000 beneficiaries.

The proposed $250,000 one-time payment is informed by the AIM payment structure, which offered a $250,000 upfront fixed payment to new AIM ACO participants starting in the Shared Savings Program in 2015 and 2016. Under the model, the upfront fixed payment reflected the estimated upfront investment requirements to establish ACOs. We proposed a $250,000 one-time AIP because, as explained in the CY 2023 PFS proposed rule (87 FR 46103), we believe that such a payment would similarly support an ACO in addressing the upfront investment requirements for a new, low revenue and inexperienced ACO to join the Shared Savings Program. We noted that we have experience with a fixed $250,000 upfront payment from AIM, which served ACOs that are similar in many ways to ACOs that would be served by the proposed AIPs. Furthermore, we believe that initial ACO start-up costs do not vary significantly by the size of an ACO or by the underlying level of risk of an assigned beneficiary population. However, we noted that we are considering alternative values of the one-time payment, such as allowing the one-time payment to vary by ACO based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both. We sought comment on the proposal to provide ACOs with a one-time payment of $250,000, as well as these alternatives.

The quarterly payments are informed by our experience in AIM where ACO participants had variable costs for clinical care management activities, such as clinical staff, which were supported by the per beneficiary per month payments offered to them in the model.

We proposed to make payments on a quarterly basis to balance providing ACOs with predictable cash flow to participate in the Shared Savings Program and simplifying operations for CMS. We noted that we considered other options for the frequency of the payments, such as monthly payments as were tested in AIM, or annual payments. Making more frequent payments, such as on a monthly basis, would result in additional operational burden for CMS because we would need to calculate the payments more frequently. Because the Shared Savings Program operates on a larger scale than AIM did, the burden of administering monthly advance payments is not feasible. Moreover, we believe that monthly payments offer little additional

[256] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (Sep. 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

[257] Ibid.

benefit to ACOs relative to quarterly payments. We did not propose a single annual payment as we believe the benefit to ACOs of consistent payments on a quarterly basis outweighs the administrative costs of calculating quarterly payments. We sought comment on the proposed schedule of the AIPs to ACOs.

We proposed to determine the value of an ACO's upcoming quarterly payment amount prior to the start of the quarter based on the latest available assignment list for the performance year (see Table 51). We noted that we believe it is important to use the latest available assignment list because under current regulation the individual beneficiaries assigned to the ACO may change between annual and quarterly assignment runs. For ACOs under preliminary prospective assignment with retrospective reconciliation as described at § 425.400(a)(2), the assignment list is updated quarterly based on the most recent 12 months of data. For ACOs under prospective assignment as described at § 425.400(a)(3), the assignment list is updated quarterly to exclude beneficiaries that meet any of the exclusion criteria during the performance year. Therefore, we noted that we believe that using the latest available assignment list to determine the upcoming quarterly payment will best reflect the attributes of the ACO's assigned population.

TABLE 51: Advance Investment Payment Schedule

	January; Performance Year (PY) 1	April; PY 1	July; PY 1	October; PY 1	January; PY 2	April; PY 2	July; PY 2	October; PY 2
Payment type	One-Time Payment; Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment

We also noted that we considered an alternative proposal for the timing of the quarterly payments calculation. Under this alternative, we would determine the ACO's quarterly payment at the start of the performance year based on the beneficiaries assigned to the ACO at the beginning of a performance year. The quarterly payment amount determined at the beginning of a performance year could remain fixed for the duration of that performance year. The total payments ACOs would receive over the course of a performance year would be known by the ACO at the start of that performance year. However, this alternative would also carry the risk that CMS would underpay or overpay an ACO relative to an approach of redetermining the quarterly payment amount prior to the start of each quarter. We sought comment on this alternative proposal.

We proposed that the quarterly payments made to ACOs would be equal to the sum of per beneficiary payments for up to 10,000 beneficiaries. The per beneficiary payment amount would vary for each beneficiary based on a risk factors-based score that we would calculate for the beneficiary. The risk factors-based score would be informed by the beneficiary's dual eligibility status and the ADI national percentile ranking of the census block group of the beneficiary's primary address, described in further detail later in this section. The quarterly payments reflect expected variable ongoing operating costs that are related to the number and risk factors of the ACO's assigned beneficiaries.

We proposed to add a new § 425.630(f) to establish the frequency and payment methodology for AIPs (87 FR 46104). Specifically, we proposed a one-time payment for ACOs at or near the beginning of PY 1 of the ACO's agreement period. Quarterly payments would be made each quarter for the first 2 performance years of the ACO's agreement period. As discussed in the CY 2023 PFS proposed rule, we would complete the following steps to calculate the ACO's quarterly payment amount:

- *Step 1:* Determine the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the quarterly payment amount would be the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for ACOs under prospective assignment), based on the certified ACO participant list for the relevant performance year.
- *Step 2:* Assign each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified in Step 1, CMS would do the following:

+ + If the beneficiary is dually eligible for Medicare and Medicaid, assign a risk factors-based score of 100.[258]

+ + If the beneficiary is not dually eligible, assign a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address.

+ + If the beneficiary is not dually eligible but cannot be matched with an ADI national percentile rank due to insufficient data, impute a risk factors-based score of 50.[259]

- *Step 3:* Determine a beneficiary's payment amount. For each beneficiary in the assigned population, CMS would determine the payment amount that corresponds to the beneficiary's risk factors-based score according to the per beneficiary payment amounts specified by CMS elsewhere in this section (refer to Table 53).
- *Step 4:* Calculate the ACO's total quarterly payment amount. The ACO's quarterly payment amount would be the sum of the payment amounts corresponding to each assigned beneficiary's risk factors-based score, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries, CMS would calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores.

As described earlier, a goal of AIPs is to reduce financial barriers for new, low revenue and inexperienced ACOs to join the Shared Savings Program. In addition to bringing ACOs into the program, as part of the Agency's goals to advance health equity, we are interested in using

[258] A beneficiary is considered dually eligible if they were dually eligible for Medicare and Medicaid in any of the 12 months that correspond with the window used for assigning beneficiaries under the preliminary prospective assignment methodology. The 12-month window is described in further detail elsewhere in this section.

[259] The imputed score of 50 is described in further detail elsewhere in this section.

the AIPs to support ACOs in improving the care received by underserved beneficiaries. We believe that we will further the Agency's goal to advance health equity by basing the ACO's quarterly payment amount on the sum of per beneficiary payments that vary by a beneficiary's risk factors-based score, as informed by the ADI national percentile rank of the beneficiary's census block group and the beneficiary's dual eligibility status. We believe the ADI national percentile rank of the beneficiary's census block group and dual eligibility are good indicators of beneficiaries with high needs. The ADI measure is intended to capture local socioeconomic factors correlated with medical disparities and underservice, while the beneficiary level measure of dual eligibility is intended to capture socioeconomic challenges that could affect a beneficiary's ability to access care.

The ADI was developed by researchers at the National Institutes of Health with the goal of quantifying and comparing social disadvantage across geographic neighborhoods. It is a composite measure derived through a combination of 17 input variables from census data. For the 2019 ADI, the 17 input variables across four domains are shown in Table 52.

TABLE 52: 17 Input Variables from Census Data for the 2019 ADI

Domain	Variable
Education	% Population aged 25 years or older with less than 9 years of education
	% Population aged 25 years or older with at least a high school diploma
	% Employed population aged 16 years or older in white-collar occupations
Income/Employment	Median family income in US dollars
	Income disparity
	% Families below Federal poverty level
	% Population below 150% of Federal poverty level
	% Civilian labor force population aged 16 years and older who are unemployed
Housing	Median home value in US dollars
	Median gross rent in US dollars
	Median monthly mortgage in US dollars
	% Owner-occupied housing units
	% Occupied housing units without complete plumbing
Household Characteristics	% Single-parent households with children younger than 18
	% Households without a motor vehicle
	% Households without a telephone
	% Households with more than 1 person per room

The ADI is calculated at the census block group level through the US Census Bureau's American Community Survey. Census blocks, the smallest geographic area for which the Bureau of the Census collects and tabulates decennial census data, are formed by streets, roads, railroads, streams and other bodies of water, other visible physical and cultural features, and the legal boundaries shown on Census Bureau maps. A census block group is the next level above census blocks in the geographic hierarchy and is a combination of census blocks that is a subdivision of a census tract or block numbering area. The census block group typically contains 600 to 3,000 people and is the smallest geographic entity for which the decennial census tabulates and publishes sample data. Files containing the ADI of U.S. census block groups is publicly available through the Neighborhood Atlas from the University of Wisconsin.[260] It is a relative measure that is reported at the individual block group level, typically reported by nationwide percentile (1–100) or Statewide decile (1–10), with a higher percentile indicating greater disadvantage. The relative measure reported at the census block group level is referred to as the ADI national percentile rank.

We proposed to use the ADI national percentile rank for the census block group in which a beneficiary resides for that beneficiary's risk factors-based score if the beneficiary is not dually eligible for Medicare and Medicaid. Specifically, we proposed to establish the ADI national percentile rank of the beneficiary's census block group derived from the beneficiary's latest mailing address in CMS data systems at the time of the calculation. Furthermore, we proposed to use the most recently available version of the ADI. At the time of issuing the CY 2023 PFS proposed rule, the latest version available was the 2019 ADI which was based on the 2015–2019 ACS Five Year Estimates. The ADI data files are publicly available for download at *https://www.neighborhoodatlas.medicine.wisc.edu/*.

We proposed to use the beneficiary's dual eligibility status to inform the risk factors-based score. Specifically, we proposed that if a beneficiary is dually eligible, the beneficiary's risk factors-based score would be 100 (87 FR 46105). A score of 100 would ensure that the ACO receives the maximum payment amount for each beneficiary dually enrolled in Medicare and Medicaid, which would further the Agency's goal to ensure beneficiaries with dual eligibility have full access to seamless, high quality health care.

To determine a beneficiary's dual eligibility status, we explained that we would consider the beneficiary's enrollment status in each month of a 12-month window (87 FR 46105). The 12-

[260] The ADI data files are publicly available for download at *https://www.neighborhoodatlas.medicine.wisc.edu/*.

month window would correspond with the assignment window used for preliminary prospective assignment with retrospective reconciliation for that particular assignment run. For example, we proposed to use PY1 Quarter 1 assignment to inform the quarterly payment we would make to the ACO in July of PY1; the preliminary prospective assignment window for that assignment run would be April 1 of the prior calendar year through March 30 of the current calendar year. We explained as a result that we would consider the beneficiary's dual eligibility status in each of those 12 months. If a beneficiary had zero months of dual enrollment, we would consider the beneficiary not dually enrolled. If the beneficiary had at least one month of dual enrollment in Medicare and Medicaid, we would consider the beneficiary dually enrolled.

We considered alternatives to assigning 100 points to the beneficiary for dual eligibility status (87 FR 46105 and 46106). One alternative we considered was to calculate a beneficiary's risk factors-based score as the sum of the ADI national percentile rank of the beneficiary's census block group and 25 points if the beneficiary is dually eligible for Medicare and Medicaid. As explained in the CY 2023 PFS proposed rule, the maximum risk factors-based score would be 125, and we would revise the payment amount ranges to account for a higher maximum score. We also explained that we considered 25 points for dual status because through preliminary analysis we observed that the median ADI score for the population that was aligned to Direct Contracting Entities in PY 2021 was 42 with a standard deviation of 25. Furthermore, given the fact that the ADI score is a variable value and the bonus points for dual eligibility status would be fixed at 25 points, we noted that the relative weight of the 25 points would be lower for beneficiaries living in a relatively highly deprived area and higher for beneficiaries in a relatively advantaged area. For example, consider one dually eligible beneficiary and one non-dually eligible beneficiary, both living in a census block group with an ADI national percentile rank of 50 (the U.S. median). The dually eligible beneficiary would receive a risk factors-based score of 75 (50 plus 25), which is 50 percent higher than the risk factors-based score of the non-dually eligible beneficiary. For a dually eligible beneficiary who lives in a census block group with an ADI national percentile rank of 70 (more deprived than the median), 25 points would increase their score by 36 percent. There are many people who do not qualify for Medicaid but still face systemic and structural barriers to care. Therefore, as discussed in the CY 2023 PFS proposed rule, we noted that we believe it would be reasonable to add a relatively moderate bonus to the beneficiary's ADI national percentile rank to calculate a combined risk factors-based score that values both dual status and other structural barriers to care that also may require upfront investments by an ACO to help their assigned beneficiaries overcome. We sought comment on an alternative proposal to calculate the beneficiary's risk factors-based score by taking the sum of the ADI national percentile rank where the beneficiary lives and 25 points if the beneficiary is dually eligible for Medicare and Medicaid.

We proposed per beneficiary payment amounts that increase as a beneficiary's risk factors-based score increases (87 FR 46106). The per beneficiary payment amounts by range are shown in Table 53. A dually eligible beneficiary would receive a risk factors-based score of 100, which corresponds to a quarterly payment amount of $45. A beneficiary not dually eligible and residing in a census block group with an ADI in the 75th percentile would receive a risk factors-based score of 75 which corresponds to a quarterly payment amount of $40.

TABLE 53: Quarterly Per Beneficiary Payment Amounts

Risk Factors-Based Score	1-24	25-34	35-44	45-54	55-64	65-74	75-84	85-100
Per beneficiary payment amount	$0	$20	$24	$28	$32	$36	$40	$45

We calibrated the per beneficiary payment amounts against the distribution of risk factors-based scores for beneficiaries assigned to ACOs in PY 2020, such that the average ACO participating in PY2020 would have received approximately the same payment value across 2 performance years as the average ACO that participated in AIM (87 FR 46106). The payments would begin at $20 and would be scaled upward by increments of 4–5 dollars as the risk factors-based score increases. We proposed that a beneficiary with a risk factors-based score of less than 25 would have a corresponding payment of $0, as a goal of the AIPs option is to encourage formation of new ACOs that serve underserved beneficiaries. A beneficiary risk factors-based score of less than 25 would indicate that the beneficiary is not dually eligible for Medicare and Medicaid and is residing in a census block group with low area deprivation. We proposed that any beneficiary with a risk factors-based score of 85 or higher would receive the maximum payment of $45. As discussed in the CY 2023 PFS proposed rule, these beneficiaries either have dual eligibility or reside in a census block group with high area deprivation; we consider beneficiaries with these factors to represent the highest need for upfront investments in care coordination interventions by ACOs. As we gain more experience with AIPs, we would reevaluate the effectiveness of the payment amounts in Table 53 and may propose modifications in future rulemaking.

We proposed to calculate the quarterly payment as the sum of the per beneficiary payment amounts corresponding to each assigned beneficiary, capped at 10,000 beneficiaries. The proposed 10,000 beneficiary cap is similar to what was tested in AIM. We noted that we believe a cap is necessary to insulate the Trust Funds from making extremely large quarterly payments to large ACOs. Also similar to AIM, we proposed that if an ACO has more than 10,000 assigned beneficiaries, we would calculate the quarterly payment based on the 10,000 assigned beneficiaries with the highest risk factors-based scores, which would maximize the quarterly payment for the ACO.

We proposed under the new § 425.630(f) that CMS would notify in writing each ACO of its determination of the amount of AIP. If CMS does not make any AIP, the notice would specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the standards

specified in subpart I of our regulations. Thus, with each quarterly payment we proposed to provide the ACO with a report that shows our calculation of the ACO's quarterly payment amount, including the risk factors-based score we assigned to each beneficiary used as part of the calculation, and the per beneficiary payment that corresponds to that score.

We noted that we considered alternative methodologies to calculating an ACO's quarterly payment (87 FR 46106 and 46107). We also noted that we considered an approach of determining an ACO's average risk factors-based score based on all of the ACO's assigned beneficiaries. That is, we would take the sum of the risk factors-based scores for each of the ACO's assigned beneficiaries and divide by the total number of the ACO's assigned beneficiaries. In this alternative, ACOs with an average risk factors-based score above the median would have their per beneficiary payment amount scaled upward and those with an average risk factors-based score below the median would have their per beneficiary payment amount scaled downward. An ACO with an average risk factors-based score of the median would have their per beneficiary payment amount set to $30. An ACO with an average risk factors-based score greater than the median would have their per beneficiary payment amount increased by the percentage difference of the score compared to the median. For example, if the median is 50, an ACO with an average risk factors-based score of 70 would have their per beneficiary payment amount increased by 20 percent to $36 and an ACO with an average risk factors-based score of 32 would have their per beneficiary payment amount reduced by 18 percent to $24.60. The quarterly payment would equal the per beneficiary per quarter payment amount multiplied by the number of assigned beneficiaries, capped at 10,000 beneficiaries. This alternative approach would allow us to consider the risk factors-based scores of all of an ACO's assigned beneficiaries, not only the 10,000 assigned beneficiaries with the highest risk factors-based scores, in determining the ACO's quarterly payment. We sought comment on this alternative methodology.

We also noted that we considered an alternative proposal to identify underserved beneficiaries based on whether their mailing address is located in a Health Professional Shortage Area (HPSA) for primary care instead of the beneficiary's mailing address' ADI percentile rank (87 FR 46107). As part of the Health Resources and Services Administration's (HRSA) cooperative agreement with the State Primary Care Offices, the State Primary Care Offices conduct needs assessment in their States, determine what areas are eligible for designations, and submit designation applications to HRSA. HRSA reviews the HPSA applications submitted by the State Primary Care Offices, and—if they meet the designation eligibility criteria for the type of HPSA the application is for—designates a HPSA. HPSAs are defined under section 332(a) of the Public Health Service Act. HPSA designations identify geographic areas, population groups, or facilities within the United States that are experiencing a shortage of health care professionals. Geographic HPSAs are defined as having a shortage of provider services for the entire population within an established geographic area; population HPSAs, in which there is a shortage of providers services for a specific population subset within an established geographic area; and facility HPSAs, that include certain categories of facilities. HRSA is responsible for making these HPSA designations in accordance with section 332(a) of the Public Health Service Act. Under this alternative, the risk factor-based score would be based on the sum of points assigned based on whether an assigned beneficiary is residing in an area designated as a geographic HPSA, as determined by the beneficiary's mailing address, and whether a beneficiary is dually eligible for Medicare and Medicaid. As a result, there would be three different per beneficiary payment amounts based on whether an assigned beneficiary is: (1) both residing in a geographic HPSA and dually eligible for Medicare and Medicaid; (2) residing in a geographic HPSA only; or (3) dually eligible for Medicare and Medicaid only. Under this alternative, we discussed that we would not provide a per beneficiary payment amount if the assigned beneficiary is not in a geographic HPSA and not dually eligible for Medicare and Medicaid. As noted in the CY 2023 PFS proposed rule, we believe the ADI metric can support identification of beneficiaries who face a variety of social determinants to health, not only health provider shortages, we proposed to use ADI. We sought comment on an alternative methodology of using HPSA scores.

We also discussed that we considered an alternative methodology that additionally considers whether a beneficiary is enrolled in the Medicare Part D low-income subsidy (LIS) when CMS calculates the quarterly payment amount.[261] In this alternative, the risk factors-based score would be equal to the assigned beneficiary's ADI national percentile or 100 points if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid. We sought comment on this alternative methodology.

As explained in the CY 2023 PFS proposed rule (87 FR 46107), there are circumstances where a beneficiary may not have an ADI national percentile rank. In the cases where Medicare beneficiaries have a missing or partial address in our database, we would not be able to match them with a census block group. In a preliminary review of Medicare beneficiary information, less than 2 percent of beneficiaries could not be matched to a census block group due to missing or insufficient mailing address data. Additionally, under the ADI methodology approximately 2 percent of U.S. census block groups do not receive an ADI national percentile rank due to data suppression criteria. These suppression criteria include: fewer than 100 people, fewer than 30 housing units, or more than 33 percent of the population living in group quarters or missing core component variables. In our preliminary review of Medicare beneficiary information, approximately 1 percent of Medicare beneficiaries had sufficient address data, but were in a U.S. census block group without a national percentile rank due to data suppression criteria. For beneficiaries with no ADI national percentile rank due to missing or insufficient mailing address data or data suppression criteria, and are not automatically receiving a score of 100 for being a beneficiary who is dually eligible for Medicare and Medicaid, we proposed to impute a value of 50 in place of the ADI national percentile rank for the purposes of determining an assigned beneficiary's risk factors-based score and per beneficiary payment amount. As discussed in the CY 2023 PFS proposed rule, an imputed ADI ranking of 50 corresponds to the average national ADI ranking and would be the most neutral imputed value. This would avoid biasing an ACO's payments in either direction due to missing information. We sought comment on the proposal to impute a value in place of the ADI national percentile rank to

[261] The low-income subsidy helps people with Medicare pay for prescription drugs, and lowers the costs of Medicare prescription drug coverage. For more information about the LIS, refer to *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources.*

address missing beneficiary information when calculating the risk factors-based score.

To summarize, we proposed to provide an ACO with a one-time payment of $250,000 prior to the start of the ACO's first performance year. We also proposed to calculate an ACO's upcoming quarterly payment prior to the start of the quarter, using the latest available assignment list. We noted that we would calculate an ACO's quarterly payment amount based on risk factors-based scores of up to 10,000 beneficiaries assigned to the ACO prior to the start of the performance year, and ACOs with more than 10,000 beneficiaries would have a quarterly payment calculated based on the 10,000 beneficiaries assigned to the ACO with the highest risk factors-based scores. We proposed to assign a risk factors-based score for each beneficiary using the ADI national percentile rank of the beneficiary's census block group or assigning 100 points if the beneficiary is dually eligible for Medicare and Medicaid. We proposed to impute a value of 50 in place of an ADI national percentile rank if the beneficiary is not dually eligible for Medicare and Medicaid and cannot be matched with an ADI national percentile rank due to insufficient data. Finally, we proposed dollar value amounts that vary by risk factors-based score, in that the amounts gradually increase as the risk factors-based score increases. We sought comment on each of these proposals.

The following is a summary of the public comments received on the proposed advance investment payment methodology and our responses:

Comment: Most commenters expressed general support for and appreciation of the advance investment payment option.

Response: We thank the commenters for their support.

Comment: A number of commenters weighed in on the amount of the $250,000 upfront payment proposed, the amount of proposed quarterly payments, or total amount of advance investment payments generally. One commenter stated they support the proposed payment amounts for calculating the ACO's quarterly payment, stating the amount appropriately provide additional funding for ACOs treating beneficiaries with greater levels of need. Another commenter suggested that if CMS were to expand eligibility for the advance investment payments option to high revenue ACOs, payment rates that make up the ACO's quarterly payment could be halved for high revenue ACOs. MedPAC urged CMS to adopt CMS' alternative to calculate an ACO's average risk factors-based score and make the ACO's upfront $250,000 payment contingent upon the ACO reaching a minimum average risk factors-based score (such as 25). In such a scenario, an ACO with an average risk factors-based score of less than 25 across all its assigned beneficiaries would not receive upfront or quarterly payments.

Several commenters disagreed with the amount of advance investment payments proposed by CMS. One commenter stated that they question the adequacy of the initial and quarterly payments, suggesting they may not be enough to meaningfully encourage participation while meeting the various resource needs of beneficiaries, and that the payments' benefit would be limited when spread over the size of the entire ACO. Several expressed concern that the amount is the same as the upfront payment made under AIM and does not account for inflation or increased health care costs.

Commenters offered various suggestions for increasing the total amount of advance investment payments. One commenter encouraged CMS to increase the quarterly payments to account for at least the highest risk 20,000 beneficiaries rather than the proposed 10,000. A few commenters suggested increasing the value of the upfront payment for ACOs in certain areas, by using a health equity factor based on the ADI to determine if the ACO would be eligible for a higher upfront payment. One commenter suggested doubling the upfront payment amount and extending the duration of upfront payments to yearly for 3 to 5 years, indicating that this would result in a more sustainable model. Another commenter suggested increasing the quarterly payment per-beneficiary amounts by modeling the payment amounts off Innovation Center models that provide monthly per-beneficiary payments, such as the Primary Care First Model or the Maryland Total Cost of Care Model. A number of commenters suggested that CMS increase the amount of the upfront payment, with many arguing it would be a means of attracting safety net providers and supporting infrastructure investments. Several other commenters suggested that $250,000 should be the minimum upfront payment and CMS should increase the upfront payment amount based on the size and risk profile of the ACO.

Response: We do not agree with the commenter's suggestion to provide half of the advance investment payments amount to high revenue ACOs. As we explain in III.G.2.a.(2) of this final rule, providing advance investment payments to high revenue ACOs would be counter to the purpose of advance investment payments. High revenue ACOs are likely to have more ready access to capital for the necessary upfront investments than new, low revenue ACOs.

With respect to MedPAC's suggestion to further limit payments for new, low revenue ACOs inexperienced with performance-based risk that do not reach a minimum average risk factors-based score, while we are not modifying the proposed methodology in this final rule, will continue to consider this approach and may revisit it in future rulemaking.

At this time, we disagree with commenters' requests that we increase the amount of the upfront payment or recalibrate the quarterly payments to increase the total amounts made available to ACOs over the course of the agreement period in which they are receiving advance investment payments. As we discussed in the CY 2023 PFS proposed rule (87 FR 46106), we believe it is necessary to insulate the Trust Funds from making extremely large quarterly payments to large ACOs. We also considered the ability of newly formed ACOs to spend funding in a short time period, drawing on lessons from AIM. We calibrated the payment amounts such that we expect the average ACO to receive approximately $2.5 million in advance investment payments over their first 2 performance years, an amount similar to the largest amount an ACO that participated in AIM received. Additionally, in the first 2 years of AIM, we recouped about 46 percent of the total upfront amounts paid. Based on this prior experience, we believe the $2.5 million estimated average does not overburden ACOs with an overwhelming amount that could remain outstanding for many future years and increases the likelihood CMS is able to recoup the majority of the AIP provided in a relatively short period of time.

We do not agree with the suggestion to modify our proposal to increase the value of the upfront payment for ACOs based on a health equity factor or based on size of the ACO. Under our proposal, the first payment the ACO will receive will be equal to the fixed $250,000 upfront payment plus the first quarterly payment which itself is already based on such factors. Therefore, the first payments received by the ACO will be greater than $250,000 and will vary depending on the risk factors of beneficiaries initially assigned to the ACO and the size of the ACO.

We also do not agree we should modify our proposal to align more

closely with the per beneficiary payment amounts found in other Innovation Center models such as Primary Care First and the Maryland Total Cost of Care Model. The advance investment payments option under the Shared Savings Program is designed for a different purpose. Unlike the per beneficiary amounts in those Innovation Center models, the advance investment payments are not intended to serve as care management fees for individual beneficiaries, but rather are intended to provide the ACO with upfront capital to make investments in systems, processes or interventions that are expected to yield lower cost and higher quality of care for their assigned beneficiary population. We believe that the payment amounts as proposed will serve to attract safety-net providers to the Shared Savings Program and will support infrastructure investments, however, we intend to monitor the uptake of this option and the ability of participating ACOs to spend the amount of advance investment payments availed to them through the methodology we are finalizing in this rule. We would consider modifications in future rulemaking.

Comment: We received several comments on our proposed approach to provide variable, quarterly payments, and to calculate those payments prior to the start of the upcoming quarter using the latest assignment list and latest beneficiary-level risk factors data available. Several commenters supported the proposal to provide payments to ACOs on a quarterly basis, indicating that such a cadence of payment correctly balances CMS burden and predictability of funding for ACOs. One commenter agreed with calculating quarterly payment amounts at the start of each quarter over an alternative proposal to calculate the quarterly payment amount ahead of the start of the performance year, indicating that the alternative of calculating the quarterly payment annually might result in over payment or under payment. However, another commenter suggested calculating the quarterly payment amounts prior to each quarter using the latest available data for ACOs under preliminary prospective assignment with retrospective reconciliation, while separately calculating the quarterly payment amounts for ACOs under prospective assignment prior to the first quarter of the performance year. One commenter suggested that CMS provide more flexibility to receive funds on an annual basis rather than quarterly payments. Another commenter thought that CMS should allow ACOs to opt into CMS calculating the quarterly payments once before the start of the year, or recalculating payments quarterly. The commenter indicated that the flexibility to choose between fixed or varying payments would allow ACOs to best meet the needs of their individual organization.

Response: We continue to believe that quarterly payments provide the best balance between consistent payments for ACOs and operational burden for CMS. We do not believe that allowing ACOs to have their quarterly payments calculated once at the beginning of the year, as opposed to at the beginning of each quarter, would offer significant benefit to ACOs nor substantially reduce burden for CMS. Calculating the payments at the beginning of each quarter ensures that the latest available assignment list is used and that the quarterly, variable payments to ACOs are appropriate. Fixing the quarterly payments at the beginning of a year creates unnecessary risk that quarterly payments are too high or too low relative to an ACO's assigned beneficiary population.

Comment: With respect to information available to ACOs about the quarterly payment, one commenter expressed support for CMS' proposal to notify ACOs of quarterly payment amounts via a detailed report of the calculation. Another commenter expressed concern that the existing ADI mapping tools (available through Neighborhood Atlas®) are limited and only allow users to look up addresses one at a time. The commenter believes that licensing restrictions would prevent ACOs from partnering with other entities that could assist them in developing more sophisticated tools to allow them to identify their beneficiaries' ADI scores more readily.

Response: We agree that providing ACOs with a report detailing the calculation of quarterly, variable payments will ensure both transparency of the process and also the accuracy of such payments. As explained in the CY 2023 PFS proposed rule, with each quarterly payment we will provide each ACO with a report that shows our calculation of the quarterly payment amount, including the risk factors-based score, ADI national percentile rank, dual eligibility status, and LIS status we assigned to each beneficiary used as part of the calculation and the per beneficiary payment that corresponds to their risk factors-based score. We note that such information overlaps with the information shared regarding the health equity adjustment, which we are finalizing as part of the quality performance standard. For a discussion of our reporting of this information to ACOs please see section III.G.4.b.(7).(g) of this final rule. We believe this information will be sufficient for ACOs to identify their beneficiaries' ADI rankings and that ACOs would not need to additionally identify their beneficiaries' rankings on their own using the mapping tools or the publicly available files from the Neighborhood Atlas®.

Comment: Several commenters expressed general support of the use of a risk factors-based score in calculating the advanced payments or support for particular elements of CMS' proposed methodology for determining beneficiaries' risk factors-based scores. A couple commenters expressed their preference for the use of ADI over the alternative proposal of using health provider shortage area (HPSA) data, with one such commenter citing that the ADI better represents the health-related social needs a beneficiary may face and leverages pre-existing data which lowers burden on practices, and the other citing that living in a health provider shortage area is only one of many socioeconomic factors impacting health, and therefore, it is appropriate for CMS to use more comprehensive measures of disadvantage (such as the ADI) in the effort to incorporate health equity as a consideration in APM designs. One commenter expressed support for CMS' proposal to determine a beneficiary's dual eligibility status based on whether the beneficiary had at least one month of dual enrollment within the 12-month window corresponding with the assignment window used for preliminary prospective assignment with retrospective reconciliation for that particular assignment run. The commenter also supported CMS' proposal to impute a score of 50 out of 100 for those beneficiaries for which CMS does not have sufficient data to calculate a risk factors-based score and provide the median payment amount. One commenter preferred CMS' proposal to assign a score of 100 to dually eligible beneficiaries over the alternative considered to calculate a score based on the combination of the national ADI percentile rank and an additional 25 points for dually eligible beneficiaries, indicating that the alternative was overly complicated for program participants.

Response: We appreciate the commenters' support for risk factors-based scores and for particular elements of the proposed methodology to calculate those scores.

Comment: We also received comments expressing concern with CMS' proposed methodology to

calculate beneficiary risk factors-based scores. We received a couple of comments expressing concern with the proposed use of dual eligibility status in calculation of the beneficiary's risk factors-based score. MedPAC urged CMS to consider use of the Medicare Part D LIS in the risk factors-based score rather than dual eligibility, citing recent Commission work that found using the LIS designation helped to reduce the impact of variation in State Medicaid benefits on nationally standardized Medicare policies. The other commenter expressed similar concerns with using dual eligibility, stating that dual eligibility status is not a consistent measure of economic distress across States as Medicaid eligibility varies by State. The commenter encouraged CMS to evaluate the impacts of this variation and consider whether another—more uniform—measure of economic insecurity should be used to target AIP funds to ACOs.

Response: We agree with the commenters that dual eligibility status has limitations due to variability in Medicaid eligibility across different States, and we are persuaded that LIS status is a preferable and more standardized measure of low income among the Medicare FFS population. However, we note that LIS also has certain limitations. For example, all beneficiaries with dual eligibility status or who receive Supplemental Security Income (SSI) automatically receive the LIS designation in CMS data systems. Beneficiaries who do not have dual eligibility status or SSI status but whose income is lower than 150 percent of the Federal poverty level must apply for the LIS.[262] Our analysis found that the vast majority of Medicare beneficiaries with the LIS designation are those who automatically received this designation rather than those who applied for the benefit and were approved. Nonetheless, despite this limitation, we agree that the use of the LIS designation, in addition to dual eligibility status, is preferable to using dual eligibility status alone, as doing so reduces variability across States while moderately expanding the number of beneficiaries we will identify as low income and who will automatically qualify for the maximum risk factors-based score of 100. Furthermore, we note that including LIS in the calculation provides ACOs with an incentive to support eligible beneficiaries who must apply for the benefit to make the connection.

We note that, like beneficiary dual eligibility status, beneficiary LIS enrollment is a monthly indicator. Therefore, we will use similar logic as we proposed for dual eligibility status (87 FR 46105) to determine if a beneficiary has the LIS designation. We will consider the beneficiary's enrollment status in LIS for each month of a 12-month window. The 12-month window will correspond with the assignment window used for preliminary prospective assignment with retrospective reconciliation for that particular assignment run. If a beneficiary had zero months of LIS enrollment, we will consider the beneficiary not enrolled in LIS. If the beneficiary had at least one month of LIS enrollment, we will consider the beneficiary enrolled in LIS.

Comment: Several commenters expressed concern with the use of the national ADI percentile ranks in the calculation of the risk factors-based score. A couple of these commenters suggested that the national ADI was inadequate for identifying underserved populations, as the high cost of living for certain areas masks some disadvantaged areas, particularly high cost urban areas. Another commenter warned that relying heavily on ADI national percentile rankings to inform equity initiatives may further disadvantage underserved populations in urban areas, given that the index is not adjusted for geographic differences in cost of living. Another commenter shared a similar sentiment, suggesting that the use of ADI as proposed, would direct funds primarily towards rural areas again. A couple commenters noted that the CMS cited study from the CY 2023 PFS proposed rule on the proposed health equity adjustment actually uses regionally calibrated ADI rankings instead of the national percentiles CMS proposed to use.

Commenters offered a variety of alternatives to the proposal to use the ADI national percentile rank in the risk factors-based score, including:

- Adjusting the ADI to reflect geographic price differences, as well as incorporating additional metrics such as life expectancy.
- Informing the risk factors-based scores with individual beneficiary-level social risk factors once adequate data sources become available.
- Replacing the ADI national percentile rank with the CDC's small area life expectancy measure.
- Replacing the ADI national percentile rank with a proprietary index that incorporates social determinants of health metrics as an alternative to the ADI.
- Exploring strategies for incorporating HPSA and other metrics into score calculations.
- Regionally adjust the ADI national percentile rank, or replace it with State-level ADI decile to more adequately capture geographic price differences.
- Use the ADI national percentile rank and a beneficiary's dual eligibility status unless an ACO is able to provide more granular individual social determinants of health data to adjust the scoring.

Some commenters who found the national ADI rankings unfavorable suggested that CMS take more time to recalibrate the methodology to calculate a risk factor-based score to more sensitively identify underserved areas.

Response: We thank commenters for their thoughtful input on this topic. After consideration and review of commenters suggestions, we believe that, at this time, the ADI national percentile rank remains the best available option for assigning a risk factors-based score to a beneficiary who does not have the LIS or dual eligibility status designation. One key strength we see with the ADI is that it is a comprehensive, publicly available dataset that applies a standardized score for all census block groups nationwide and can be updated periodically as new ACS Five Year Estimates become available. This also aligns with recent recommendations from the Office of the Assistant Secretary for Planning and Evaluation (ASPE). ASPE commissioned three environmental scans of: (1) area-level indices of social risk; (2) measures used in government programs that target areas, providers, or populations with social risk; and (3) existing payment models that incorporate measures of social risk. Although ASPE concluded that none of the existing area-level indices are ideal, for immediate policy development, they concluded that the ADI or the Social Deprivation Index (SDI) were the best available choices when selecting an index for addressing Health Related Social Needs or Social Determinants of Health.[263]

We agree with the commenters who stated that certain census block groups in certain areas of the U.S. may have lower ADI national percentile ranks than they would using the ADI State decile ranks. We acknowledge that census block groups in areas with

[262] Memo: ''2021 Resource and Cost-Sharing Limits for Low-Income Subsidy (LIS)''. October 30, 2020. Department of Health & Human Services. Accessed at *https://www.cms.gov/files/document/2021-lis-resource-limits-memo.pdf* on September 22, 2022.

[263] Report: ''Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments.'' Accessed at *https://aspe.hhs.gov/reports/area-level-measures-account-sdoh* on September 27, 2022.

higher cost of living (which some commenters suggest tend to be urban areas) are more likely to have this result than areas with lower cost of living. However, our analysis finds that using State decile ranks in lieu of national percentile ranks would actually reduce the quarterly payment amount for the majority of ACOs in our simulation. Additionally, our analysis suggests that including LIS and dual eligibility status in the calculation of the risk factors-based score assists ACOs in areas where beneficiaries have a higher State ADI than a national ADI. We looked at the effect of the policy to assign 100 points for dual eligibility status among the remaining ACOs that would have had higher quarterly payments if we use State deciles. We found that when we assigned 100 points for LIS and dual eligibility status (as opposed to only using the beneficiary's ADI), the payment differences between using national versus State ADI shrunk for nearly all of those ACOs. We believe that switching to a State ADI decile would dilute the effectiveness of this option to attract ACOs to form or expand into more underserved areas of the country.

We remind commenters that beneficiaries determined to be low income using LIS status or dual eligibility status will automatically receive the maximum risk factors-based score of 100 and will qualify for the maximum per beneficiary payment. Additionally, beneficiaries whose risk factors-based score instead reflects the ADI national percentile rank of the area in which they reside will still receive a per beneficiary payment amount (if the beneficiary has a score of at least 25 and is among the ACO's 10,000 assigned beneficiaries with the highest risk factors-based score). We designed the per beneficiary payment amounts to moderately decrease as a beneficiary's risk factors-based score decreases, but any beneficiary who has a risk factors-based score of 25 or higher will be included in the calculation of the ACO's quarterly payment if the beneficiary is among the ACO's 10,000 beneficiaries with the highest risk factors-based score.

We reiterate that we appreciate commenters' thoughtful input on this matter; we intend to continue exploring how we might incorporate such factors in a fair, standardized, comprehensive, and transparent manner into our future policy. We believe that the determination of a beneficiary risk factors-based score should be transparent, and that the underlying metrics should use recent data in a similar manner as the ADI.

Comment: We also received a few comments related to the proposed methodology to calculate the quarterly payment amount based on the beneficiaries with the highest risk factors-based scores for up to 10,000 beneficiaries, or an alternative to calculate an average risk factors-based score based on all the assigned beneficiaries in the ACO. A few commenters noted that the proposal to consider the 10,000 beneficiaries with the highest risk factors-based score was preferable to using an average score for all assigned beneficiaries, citing that the latter might mask variation, dilute the scores, or result in an improper distribution of funds. MedPAC supported the alternative to use an average risk factors-based score for the entire ACO's assigned population, indicating that this would encourage large ACOs to continue to include beneficiaries with high risk factors-based scores beyond the first 10,000 and inducing a greater inclusion of underserved beneficiaries.

Response: We continue to believe that the proposed policy, which determines quarterly, variable payments solely based on the 10,000 beneficiaries with the highest risk factors-based score, is the most generous to participating ACOs and will best meet their needs when establishing operations and care in underserved areas. Calculating the quarterly payments based on the average risk factors-based score across an ACO's entire assigned beneficiary population would lead to lower quarterly payments for ACOs with more than 10,000 assigned beneficiaries and thereby reduce the ability of many participating ACOs to expand care to underserved populations. Based on the profile of the low revenue ACOs participating in the Shared Savings Program in recent years, we expect that a large proportion of new, low revenue ACOs have more than 10,000 assigned beneficiaries, and would thus receive lower quarterly payments if we were to adopt the alternative to calculate it using the ACO's average risk factors-based score. We prefer an approach to determine a payment based on the 10,000 beneficiaries in the ACO with the highest risk factors-based scores, as those are the beneficiaries for whom we expect could benefit the most from the upfront investments made by the ACO.

After consideration of the public comments and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46103), we are finalizing the advance investment payment methodology at § 425.630(f) with a modification to incorporate the low-income subsidy designation in the calculation of the risk factors-based score at § 425.630(f)(ii). That is, the risk factors-based score will be set to 100 if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid. The risk factors-based score will be set to the ADI national percentile rank matched to the beneficiary's mailing address if the beneficiary is not enrolled in the Medicare Part D LIS or is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an ADI national percentile rank. The risk factors-based score will be set to 50 if the beneficiary is not enrolled in the Medicare Part D LIS or is not dually eligible for Medicare and Medicaid and sufficient data is not available to match the beneficiary to an Area Deprivation Index national percentile rank. We are finalizing our proposal as proposed to use the ADI national percentile rank, without additional modifications to that rank, to inform the beneficiary's risk factors-based score.

(6) Duration of Advance Investment Payment

In AIM, ACOs in the model participated in 3-year agreements in the Shared Savings Program, and they received prepaid shared savings for the first 2 years of their participation and were allowed to spend that funding over their entire 3-year agreement period. In AIM, we observed that many ACO model participants needed the entire agreement period to be able to spend the prepaid shared savings they received under the model. Based on our experience with AIM, we proposed at § 425.630(f)(1) that the ACOs would receive AIPs (a one-time payment of $250,000 plus quarterly payments calculated in accordance with § 425.630(f)(2)) in the first 2 years of their participation agreement. We proposed at § 425.630(e)(3) that an ACO would be permitted to spend the AIPs over its entire 5-year agreement period and must repay to CMS any unspent funds at the end of its agreement period. We stated that CMS would issue a demand letter for any such amounts. We stated that the requirement that funds be spent during the agreement period furthers our goals of supporting the establishment of ACOs and delivering care to beneficiaries in a prompt manner. We sought public comments on our proposal to provide AIPs to ACOs for the first 2 years of the ACO's performance period, to allow ACOs to spend those payments over the duration of their 5-year agreement period, and to send a demand letter for any unspent

funds at the end of the ACO's agreement period.

Comment: We received a couple comments on the duration of advance investment payments. One commenter agreed with the duration as proposed that an ACO receive quarterly payments for 2 years and that the ACO be permitted to spend the AIPs over their entire 5-year agreement period. The commenter stated it provides ample time for ACOs to use the funds and invest in sustainable initiatives while ensuring the funds are used promptly and appropriately to impact beneficiaries' care. Another commenter suggested that CMS provide quarterly payments for the full duration of a 5-year agreement period for new, low revenue ACOs, citing that the extended payments would help these ACOs acclimate to the program.

Response: We agree with the first commenter, that an ACO be permitted to spend the AIPs over their entire 5-year agreement period. We expect this to enable ACOs to make appropriate investments into quality care for underserved beneficiaries in a thoughtful manner and strategize how best to accomplish Shared Savings Program goals. We do not agree with the suggestion to extend the quarterly payments for the full 5-year agreement period. We have concerns that extending the quarterly payments would burden ACOs with larger repayment amounts. In the case of ACOs that do not achieve sufficient shared savings to repay the AIP amounts, extending the quarterly payments would increase costs to the program. We believe providing 2 years of quarterly payments appropriately balances providing sufficient start-up capital for an ACO with providing the ACO time to implement their care coordination efforts to earn shared savings in later years.

For the reasons discussed above, we are finalizing the policies as proposed. Specifically, we are finalizing § 425.630(e)(3), which permits ACOs to spend AIPs over their entire agreement period, and § 425.630(f)(1), which establishes a single upfront fixed payment and quarterly, variable payments for the first 2 years of an ACO's agreement period.

(7) Compliance and Monitoring

(a) Public Reporting and Monitoring of Spend Plan

We proposed to monitor the spending of AIPs to provide CMS with a clear indication of how ACOs intend to spend AIPs, provide adequate protection to the Medicare Trust Funds, and to prevent funds from being misdirected or appropriated for activities that do not constitute a permitted use of the funds. We explained in the CY 2023 PFS proposed rule that we would do so by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against the actual spending as reported on the ACO's public reporting web page, including any expenditures not identified in the spend plan. We proposed that the reported annual spending must include any expenditures of AIPs on items not identified in the spend plan. ACOs would be required to annually report their actual expenditures via an updated spend plan on their public reporting web page.

We noted that we believe that transparency of information in the health care sector facilitates more informed patient choice and offers incentives and feedback that help improve the quality and lower the cost of care and improve oversight with respect to program integrity. As we discussed in previous final rules, improved transparency supports a number of program requirements. In particular, increased transparency is consistent with and supports the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it.

Therefore, as discussed in the CY 2023 PFS proposed rule, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's use of AIPs to be available to the public. Making this information available will provide both Medicare beneficiaries and the general public with insight into the use of AIP funds by an ACO. Accordingly, we proposed to modify § 425.308 to require that an ACO annually report on its public reporting web page information regarding AIPs. Specifically, we proposed at § 425.308(b)(8) that, for each performance year, an ACO would be required to report (in a standardized format specified by CMS) its spend plan, the total amount of AIPs received, and an itemization of how any AIPs were actually spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan as submitted under § 425.630(d)(1), and such other information as may be specified by CMS. We proposed that this itemization would include expenditures not identified or anticipated in the ACO's submitted spend plan, and any amounts remaining unspent. As proposed, if CMS determined that an ACO had disbursed AIPs for a prohibited use under proposed § 425.630(e)(2), CMS could terminate the ACO's receipt of AIPs under proposed § 425.630(h), as discussed later in this section. Any AIPs that are unspent at the end of the ACO's agreement period must be repaid to CMS under proposed § 425.630(e)(3), as discussed above in section III.G.2.a.(6) of this final rule. Additionally, CMS could take compliance action as specified in §§ 425.216 and 425.218 if an ACO spent the funds on a prohibited use or had unspent funds at the end of the agreement period. We sought comment on all aspects of the proposal.

We noted that under existing § 425.314, ACOs would be required to retain adequate books and records to ensure that CMS has the information necessary to conduct appropriate monitoring and oversight of ACOs' use of AIPs (for example, invoices, receipts, and other supporting documentation of AIP disbursements). To protect the program and the Medicare Trust Funds, we explained that we may use our authority under §§ 425.314 and 425.316 to audit ACO compliance with Shared Savings Program requirements and to monitor the performance of ACOs, respectively. We noted that we would conduct audits as necessary to monitor and assess an ACO's use of AIPs and compliance with other requirements related to such payments.

The following is a summary of the public comments received on the policies we proposed regarding public reporting and monitoring of spend plans and our responses:

Comment: One commenter supported the proposals concerning public reporting and monitoring of ACO spend plans. A few commenters supported leveraging the public reporting web page to include ACO spend plans. Several commenters requested that CMS provide guidance on reporting requirements to minimize ACO administrative burden. The commenters suggested seeking feedback from ACOs when developing standardized reporting formats.

Response: We appreciate the support of the commenters. CMS will provide guidance for reporting AIP spend plan and usage of AIP funds on the ACO's public reporting web page, and we intend to develop guidance that will minimize administrative burden in the reporting of this information. To ensure program transparency and public accountability, CMS will require an ACO to publicly report its spend plan in a standardized format before and after the performance year. Before each

performance year, the ACO must publicly report the anticipated spend plan, including planned expenditure categories and percentages within each category. After each performance year, the ACO must publicly report the total amount of AIPs received and an itemization of the AIPs spent during the year (that is, expenditure categories and the amounts spent on the various categories), and any changes to the spend plan. CMS will also post information on the ACOs' AIP payments, spend plans, and actual expenditures on its Shared Savings Program data page. CMS's monitoring of this information will assist CMS in protecting the Medicare Trust Funds from being misdirected or misappropriated for activities that do not constitute a permitted use of AIP funds.

We are finalizing our public reporting policy as proposed. Specifically, we are finalizing new § 425.308(b)(8), which sets forth the reporting requirements for AIPs.

(b) Monitoring for Changes in ACO Experience With Risk and ACO Revenue

As described in section III.G.2.a.(2) of this final rule, under the new § 425.630(b), ACOs must meet the following basic criteria to be eligible for AIPs:

- The ACO is not a renewing or re-entering ACO, as defined under § 425.20.
- The ACO is applying to participate under any level of the BASIC track glide path as specified under § 425.600(a)(4)(i)(A).
- The ACO must be inexperienced with performance-based risk Medicare ACO initiatives, as defined by § 425.20.
- The ACO must be a low revenue ACO, as defined by § 425.20.

Based on our program experience, the inexperienced/experienced and low/high revenue ACO determination could be affected by changes in the ACO participant list that are made during the course of the agreement period, where the changes are not motivated by the ACO's desire to avoid program requirements regarding participation options. ACO participant list changes during the agreement period could affect the categorization of ACOs, particularly for ACOs close to the threshold percentage. As discussed in the CY 2023 PFS proposed rule, we considered that an ACO may change its composition of ACO participants each performance year. Any approach under which we would apply different policies to ACOs based on a determination of ACO participant prior experience under performance-based risk would need to recognize the potential for an ACO to add or remove ACO participants which could affect whether an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives. We noted our concerns about the possibility that an ACO may be eligible to receive AIPs and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding the inexperience and low revenue eligibility requirements.

To identify and address these circumstances, we proposed at § 425.316(e)(1) that CMS will monitor ACOs that receive AIPs to determine if they remain low revenue ACOs that are inexperienced with performance-based risk. We noted that we would monitor ACOs for changes in the risk experience of ACO participants that would cause an ACO to be considered experienced with performance-based risk or a high revenue ACO, and therefore, ineligible for AIPs.

We proposed at § 425.316(e)(2) to specify that if an ACO receiving AIPs becomes experienced with performance-based risk Medicare ACO initiatives or becomes a high revenue ACO during any performance year of the agreement period, CMS would cease paying the ACO AIPs starting the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO and may take compliance action as specified in §§ 425.216 and 425.218.

As proposed, § 425.316(e)(3) would require that the ACO repay spent and unspent AIPs if CMS takes pre-termination action under § 425.216 and the ACO continues to be experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to such compliance action (for example, the next deadline for updating the ACO participant list). We proposed that to retain its AIP, an ACO that CMS determines to be experienced with performance-based risk or a high revenue ACO would be required to remedy the issue by the deadline specified by CMS. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list so that the ACO could meet the definition of a low revenue ACO. If the ACO fails to respond to compliance action under § 425.216 or otherwise fails to remedy the eligibility issue by the applicable deadline, the ACO would be required to repay all AIPs it had received. We proposed that CMS would provide written notification to the ACO of the amount due, and the ACO must pay such amount no later than 90 days after the receipt of notification. We noted that CMS may recover the amount owed by reducing the amount of any shared savings.

To aid us in determining whether it would be appropriate for us to recoup AIP funds from an ACO, we further proposed to update the definitions of ''inexperienced with performance-based risk Medicare ACO initiatives'' and ''experienced with performance-based risk Medicare ACO initiatives'' under § 425.20 to allow for a rolling lookback period of the 5 most recent performance years beginning from the current performance year being monitored. This would be applicable to both ongoing compliance determinations and the assessment of an ACO's application to participate under a participation option for an agreement period under proposed § 425.600(h). We noted that we would provide ACOs with preliminary participation options reports throughout the application and ACO participant list change request cycles so ACOs can be fully informed of the impact of becoming experienced with performance-based risk or high revenue for the upcoming performance year.

The following is a summary of the public comments received on these proposals and our responses:

Comment: One commenter encouraged CMS to take a more nuanced approach when taking remedial action should an ACO become designated as high revenue ACO or an ACO experienced with performance-based risk Medicare ACO initiatives. The commenter suggested that CMS consider the ACO's specific circumstances. For example, if an ACO adds a CAH to its ACO participant list and subsequently becomes high revenue, the commenter suggested that CMS could cease future payments of AIPs but not require payback of disbursed funds to avoid penalizing the ACO for adding a safety net provider. The commenter also suggested that CMS review the spending of AIPs when determining repayment. For instance, if the spent funds were invested in patient care or infrastructure that results in an ongoing benefit for Medicare providers, suppliers, and/or beneficiaries, the commenter suggested CMS only require repayment of the unspent AIP funds.

Response: We disagree with the commenter. As outlined in the 2018 final rule, Pathways to Success, we believe that the total Medicare Parts A and B FFS revenue of the ACO

participants could be indicative of whether the ACO participants, and therefore, potentially the ACO, are more or less capitalized. We intend to limit AIP to ACOs that would not otherwise have access to funding, as some proportion of ACOs are unlikely to earn enough shared savings to repay AIP, and distributing AIP funding to ACOs that are sufficiently capitalized poses an unnecessary risk to the Trust Funds. However, we would continue to evaluate and employ a range of methods to monitor and assess the effectiveness of the eligibility requirements as AIP is implemented.

We are finalizing the provisions we proposed at § 425.316(e) regarding monitoring of ACO eligibility for AIPs, with additional language confirming that CMS may review eligibility during any performance year. This language is consistent with the preamble, but was inadvertently omitted from the regulation text.

(c) Termination of Advance Investment Payments

Under §§ 425.216 and 425.218, CMS can terminate an ACO or take pre-termination actions (such as requesting a corrective action plan) if CMS determines that an ACO is not in compliance with eligibility or other Shared Savings Program requirements. Accordingly, in the CY 2023 PFS proposed rule, we discussed that if we finalize our proposal to implement AIPs, CMS could take remedial action under those provisions if an ACO receiving such payments becomes experienced with performance-based risk Medicare ACO initiatives, becomes a high revenue ACO, spends AIPs for a prohibited use, fails to comply with other AIP requirements, or meets any of the grounds for ACO termination set forth in § 425.218(b). We noted that where appropriate, we would work with the ACO to understand why the noncompliance with AIP requirements had occurred so that we could develop an effective plan of action and monitoring technique. We also noted that our existing pre-termination actions do not include the cessation of payments to an ACO. To protect the Trust Funds, encourage speedy resolution of noncompliance, and provide an added safeguard against abuse, we proposed at § 425.630(h)(1) and (2) that CMS may terminate an ACO's receipt of AIPs if the ACO ceases to meet the eligibility requirements specified in proposed § 425.630(b)(3) and (4), fails to comply with other AIP requirements, or meets any of the grounds for termination set forth at § 425.218(b). For the same reasons, we further proposed under § 425.630(h)(3) that CMS may immediately terminate an ACO's AIPs without taking any of the pre-termination actions set forth in § 425.216. We noted that we expect that immediate termination of AIPs would be invoked only in cases of serious noncompliance or when the ACO's actions or inaction poses a risk of harm to beneficiaries or negatively affects access to care.

The following is a summary of the public comments received on this proposal and our responses:

Comment: One commenter supported the proposal because it ensures program integrity and appropriate protections for beneficiaries.

Response: We agree with the commenter. We note that we intend to work with an ACO to understand why it is not compliant with AIP requirements and to develop an effective plan of action and monitoring technique to ensure future compliance.

For the reasons discussed above, we are finalizing without change the policies we proposed at § 425.630(h). Specifically, under § 425.630(h)(1), CMS may terminate advance investment payments if the ACO fails to comply with the requirements of § 425.630, or meets the grounds for termination under § 425.218(b). Under § 425.630(h)(2), CMS will terminate an ACO's AIPs in accordance with § 425.316(e) if the no longer meets the AIP eligibility requirements set forth at § 425.630(b)(3) and (b)(4). Under § 425.630(h)(3), CMS may immediately terminate distribution of an ACO's advanced investment payments without taking any pre-termination actions under § 425.216.

(8) Recoupment

In AIM, we recouped prepaid shared savings from any shared savings earned by an ACO in its current agreement period, and if necessary, future agreement periods. If the ACO did not achieve shared savings, then the prepaid shared savings were not recouped. Additionally, the balance of funding was not recouped if the ACO completed the agreement period and decided not to reenroll in a second agreement period. If the ACO terminated prior to the end of its 3-year agreement period, the remaining balance was required to be repaid in full. During the model, we observed that offering new small ACOs prepaid shared savings that they were not at risk of being forced to repay if they did not achieve savings was a critical incentive for small providers and suppliers to form ACOs to join AIM and the Shared Savings Program. Based on our experience in AIM, we proposed at § 425.630(g) a policy for recoupment of AIPs from an ACO. The Shared Savings Program now has 5-year agreement periods instead of the 3-year agreement periods that were in effect during AIM, so some timing adjustments to the recoupment policy are necessary, but the majority of the proposed policy aligned with AIM recoupment policy.

We proposed at § 425.630(g)(1) to recoup AIPs from any shared savings, as defined in § 425.20, earned by the ACO in any performance year until CMS has recouped all AIPs. We further proposed that if there are insufficient shared savings to recoup the AIPs made to an ACO for a performance year. We further proposed that for both renewing and re-entering ACOs, we would carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including any performance year(s) in a subsequent agreement period.

At § 425.630(g)(2), we proposed that in circumstances where the amount of shared savings earned by the ACO is revised upward by CMS for any reason, we would reduce the redetermined amount of shared savings by the amount of AIPs made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, we proposed that the ACO would not receive a refund of any portion of the AIPs previously recouped or otherwise repaid.

We proposed under § 425.630(g)(3) that for each performance year, we would not recoup an amount of AIPs greater than the shared savings earned by an ACO for that performance year (except as provided in § 425.630(g)(4) and § 425.316(e)(3)). Thus, if an ACO does not earn shared savings in its agreement period or a subsequent agreement period, we would not recoup any of the AIPs from the ACO.

For example, if an ACO received $300,000 in AIPs and achieved shared savings of $500,000 for the first performance year, we would recoup $300,000 and pay $200,000 in shared savings to the ACO. Alternatively, if an ACO received $300,000 in AIPs and achieved shared savings of $200,000 for the first performance year, we would recoup only $200,000 and not pay any shared savings to the ACO. The outstanding balance of $100,000 would be carried forward, to be recouped in a future performance year in which the ACO achieves shared savings. Under a third scenario, if the ACO does not achieve shared savings in all 5 performance years of its agreement period and does not renew for another agreement period in the Shared Savings

Program, we would not recoup any AIPs made to the ACO. However, to protect the program from abuse, CMS would recoup any outstanding balance from a re-entering ACO determined to be experienced with performance-based risk Medicare ACO initiatives. We noted that a ''re-entering ACO,'' as defined at § 425.20, includes an ACO that is a new legal entity that is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years.

At § 425.630(g)(4), we proposed that if an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received. In such a case, CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. As explained in the CY 2023 PFS proposed rule, we noted that this proposal would ensure that AIPs are used by ACOs that complete their agreement period and reduces the risk of ACOs using termination to avoid repayment of the AIPs.

As described in section III.G.2.a.(2) of the CY 2023 PFS proposed rule, we proposed that an ACO would not be eligible for AIPs unless it is a low revenue ACO, as defined at § 425.20, and inexperienced with performance-based risk Medicare ACO initiatives, as defined at § 425.20. A goal of the AIPs is to encourage the formation of ACOs, and based on our experience with AIM, we recognize that new, smaller ACOs need start-up funding to join the Shared Savings Program and to continue care coordination over the agreement period.

As described in section III.G.2.a.(7)(b) of the CY 2023 PFS proposed rule, we proposed to monitor and notify ACOs if they become high revenue or experienced with performance-based risk during a performance year so they may choose to modify their ACO participant lists for the next performance year to maintain their low revenue and inexperienced status. As proposed at § 425.316(e), if CMS determines that an ACO is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, CMS will cease payment of AIPs starting the quarter after the ACO became experienced with performance-based risk or became a high revenue ACO, and CMS may take compliance action as specified in §§ 425.216 and 425.218. For example, if CMS determines that an ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO during the annual change request and assignment process for the second performance year of the agreement period, CMS would not pay to the ACO additional AIPs, effective the next quarterly payment after the ACO became experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO, which would be January 1 of the second performance year. In addition, CMS could take compliance action as specified in §§ 425.216 and 425.218. If CMS determines after all AIPs have been paid (for example, during the third performance year of the agreement period) that an ACO became experienced with performance-based risk Medicare ACO initiatives, CMS may take compliance action as specified in § 425.216 and account for any inappropriate payments. For example, CMS could issue a request for a corrective action plan, and the ACO would be required to come back into compliance the following performance year. If an ACO remains noncompliant after the compliance deadline specified by CMS, we would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification. To achieve the goal of AIPs and ensure that the payments support new, smaller ACOs, we proposed at § 425.316(e) that if CMS determines during the agreement period in which an ACO received an AIP that the ACO became a high revenue ACO or became experienced with performance-based risk Medicare ACO initiatives, the ACO may be required to repay all AIPs it received during the agreement period. We proposed to provide written notification to the ACO of the amount due and to require the ACO to pay such amount no later than 90 days after the receipt of notification.

We proposed at § 425.630(g)(5) that if an ACO that received AIPs enters into proceedings relating to bankruptcy, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved. We proposed that the notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). We proposed that the notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices. We noted that our proposal was consistent with the AIM model participation agreement and ensures that CMS can recover AIPs if an ACO files for bankruptcy.

We are sought comment on all aspects of our proposals for recoupment of the AIPs made to ACOs.

The following is a summary of the public comments received on these proposals and our responses:

Comment: In general, commenters advocated for a longer recoupment period, which they believe would encourage ACO long-term participation and reinvestment of funds into ACO operations and improvements. Several commenters suggested that CMS should allow ACOs to retain some percentage of their shared savings payments during each recoupment period. Some of these commenters suggested that CMS should recoup AIPs by collecting only up to 50 percent of earned shared savings per performance year during the agreement period and in any subsequent agreement period. A few of these commenters noted that they believe longer recoupment periods would provide continuity and sustained funding for these ACOs, making them more likely to continue participation in the program and to progress to more advanced levels of risk. One commenter opined that it typically takes low revenue ACOs 2 to 3 years to achieve savings, suggesting that immediate recoupment of AIPs would disadvantage new entrant ACOs or those serving lower income or underserved populations. To increase program participation and reduce barriers to entry, a few commenters suggested CMS reduce AIP recoupment proportionally to the number of underserved beneficiaries served by the ACO. The commenters requested that CMS monitor the individual circumstances surrounding an ACO's early termination and consider unintended negative consequences it may have on the ACO's beneficiaries.

Response: We disagree with the commenters. Regarding the comment that ACOs should be permitted to repay AIPs over a longer period of time, we note that the recoupment period begins in the first performance year of the agreement period in which the ACO receives AIPs and can continue for the remainder of that agreement period and into one or more agreement periods. We believe that this policy safeguards the Medicare Trust Funds by recouping

AIPs expeditiously. We do not believe that immediately recouping these funds from earned shared savings will disadvantage any ACOs as they will be receiving quarterly payments for the first 2 years. Regarding the commenters who advocated that ACOs should be able to retain a portion of their AIPs or be liable for a reduced repayment amount, we note that the AIPs are not intended to supplement FFS payments, but rather provide start-up capital out of future shared savings to be used by new ACOs to provide sufficient resources for staffing, providing accountable care for underserved beneficiaries, and investing in healthcare delivery infrastructure.

Comment: One commenter advocated that CMS forgive the repayment requirement should an ACO complete its initial agreement period without achieving shared savings. Another commenter encouraged CMS not to recoup any remaining AIP balance owed even if an ACO terminates during the same agreement period in which it received AIP. One commenter speculated that recoupment could discourage participation because it would be difficult for an ACO to transition smoothly out of the Shared Savings Program if AIPs must be repaid upon early termination and if recoupment continues into the next agreement period. One commenter suggested recoupment of AIP funds be limited to unspent funds at the time of termination because early termination may be the result of an ACO's inability to secure operating funds or the loss of ACO participants through competition from other ACOs. A few commenters stated that, in determining the amount of AIPs to be repaid, CMS should consider an ACO's circumstances and timing of termination, as well as investments made with the funds before recoupment. The commenter recommended that CMS revise the proposed recoupment policies to take a more equitable approach.

To encourage and support ACOs that provide care for underserved beneficiaries, one commenter suggested that CMS forgo AIP recoupment for ACOs that exceed quality and savings goals over the participation agreement period. Another commenter proposed eliminating the requirement to recoup AIPs if safety net provider-led ACOs achieve shared savings, invest in population health infrastructure and programs and select higher levels of risk. One commenter advocated that CMS should never recoup any AIPs paid to rural ACOs and that, in the alternative, AIPs should be considered an interest-free loan. By tying recoupment policies to equity goals, CMS could incentivize the expansion of ACOs into underserved communities.

MedPAC expressed concern that significant, forgivable upfront payments coupled with ACOs exiting the program would preclude program savings. MedPAC asserted that if program exit were high and significant upfront payments are not recouped, several types of corrective action would be needed. This could involve lowering upfront payments or requiring repayment upon exit of the program. Based on findings from prior advance payment models, MedPAC stated that stringent requirements may be needed in the future to deter ACOs from receiving advance investment payments and exiting the Shared Savings Program before they are paid back.

Response: We disagree with the commenters' assertions that AIP should not be recouped or that it should be recouped to a lesser degree under various circumstances. We view recoupment of AIPs as a critical measure necessary to ensure the adequate protection of the Medicare Trust Funds regardless of the characteristics of the ACO's provider composition, aligned beneficiary population, and financial or quality performance. In addition, by requiring immediate repayment of AIPs upon early termination, we reduce the risk that ACOs will voluntarily terminate their participation agreements to avoid repayment of the AIPs. We note that AIPs are interest free; CMS will not charge interest in when collecting AIPs via recoupment from shared savings. However, if an ACO terminates its agreement period early and fails to pay its AIP balance in full by the applicable due date, CMS will charge interest on the remaining unpaid AIP balance. We thank MedPAC for its concern for program oversight risks, and we will monitor the amount of AIPs that are not required to be repaid under the term of the program. We may consider addressing the issue in future rulemaking.

For the reasons discussed above, we are finalizing without change at § 425.630(g) our proposed policies regarding recoupment and recovery of AIPs and bankruptcy notices. Specifically, we are finalizing § 425.630(g)(1) which permits CMS to recoup AIPs made to an ACO from any shared savings it earns. Under § 425.630(g)(2), if the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS would reduce the redetermined amount of shared savings by the amount of AIPs made to the ACO and if the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the AIPs previously recouped or otherwise repaid. Under § 425.630(g)(3), CMS will not recover an amount of AIPs greater than the shared savings earned by an ACO in a given performance year (except as provided in § 425.630(g)(4) and § 425.316(e)(3)). Under § 425.630(g)(4), if an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs received. In § 425.630(g)(5), an ACO that declares bankruptcy must notify CMS and the U.S. Attorney's Office in the district where the bankruptcy was filed, unless all AIPs have been repaid.

b. Smoothing the Transition to Performance-Based Risk

(1) Background

Since its inception in 2012, the Shared Savings Program has included both one-sided financial models (shared savings only) and two-sided financial models (shared savings and shared losses) for ACOs to select based on the arrangement that makes the most sense for their organization. Over the years, we have modified available financial models (participation options) providing ''on-ramps'' to attract both providers and suppliers that are new to value-based purchasing, as well as more experienced entities that are ready to accept two-sided risk. We have modified these participation options to adjust the maximum level of risk that must be assumed under two-sided models and to smooth the transition to two-sided models, including modifying eligibility criteria and adding flexibility for more advanced ACOs to transition to risk-based arrangements more quickly. These participation option modifications have been informed by lessons learned from CMS' experience with the program, testing through other initiatives conducted by the CMS Innovation Center under section 1115A of the Act (the Pioneer ACO Model, the Next Generation ACO Model and the Medicare ACO Track 1+ Model), and feedback from interested parties.

In the November 2011 final rule (76 FR 67904), we stated our belief that a one-sided model would have the potential to attract a large number of participants to the program and broadly introduce value-based purchasing to providers and suppliers, many of whom may not have participated in a value-based purchasing initiative before. Another reason we included the option for a one-sided track with no downside risk was that this model would be

accessible to and likely to attract small, rural, safety net, and physician-only ACOs. However, we also noted that while a one-sided model could provide incentives for participants to improve quality, it might not be sufficient incentive for participants to improve the efficiency and cost of healthcare delivery (76 FR 67904). Thus, in the November 2011 final rule, we created two tracks in which ACOs could choose to participate. The one-sided model (Track 1) incorporated the statutory payment methodology under section 1899(d) of the Act, and the two-sided model (Track 2) was also based on the payment methodology under section 1899(d) of the Act but incorporated performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models. Track 1 was available for an ACO's initial agreement period, and all ACOs were required to transition to Track 2 to continue participating in subsequent agreement periods. (76 FR 67904 through 670909).

In the June 2015 final rule (80 FR 32759), we reiterated our intent to continue to encourage ACOs' forward movement up the ramp from the one-sided model to performance-based risk. The June 2015 final rule discussed policy changes that would allow ACOs not yet ready to transition to performance-based risk a second agreement period under the one-sided model, while also encouraging ACOs to enter performance-based risk models by lowering the risk under the existing Track 2 and offering an additional two-sided model (Track 3) that was based on the payment methodology under Track 2 but incorporated different elements intended to make it more attractive for entities to accept increased performance-based risk. (80 FR 32759 through 32780).

In 2017, the Innovation Center designed an additional option for eligible Track 1 ACOs, referred to as the Track 1+ ACO Model, to facilitate ACOs' transition to performance-based risk. The Track 1+ ACO Model was a time-limited model that began on January 1, 2018; it was based on Shared Savings Program Track 1 but tested a payment design that incorporated more limited downside risk, as compared to Track 2 and Track 3. Our early experience with the design of the Track 1+ ACO Model demonstrated that the availability of a lower-risk, two-sided model is an effective way to encourage ACOs in one-sided models (including ACOs within a current agreement period, initial program entrants (that is, new ACO legal entities), and renewing ACOs to progress more rapidly to performance-based risk.

Most recently, in the December 2018 final rule (83 FR 67822), CMS redesigned the participation options available under the program to encourage ACOs to transition more rapidly to two-sided models under two tracks, a BASIC track and an ENHANCED track. Both tracks are designed for 5-year agreement periods. The BASIC track includes a glide path with 5 Levels (A through E) that allows eligible ACOs to begin under a one-sided model for 2 years (each year of which is identified as a separate level (Levels A and B)) and advance to a two-sided model that includes incrementally higher levels of risk and reward (Levels C, D, and E) for the remaining 3 years of the agreement period.[264] We allowed additional flexibility for new ACO legal entities that qualify as low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives to participate for up to 3 performance years under a one-sided model (4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) of the BASIC track's glide path before transitioning to the highest level of risk and potential reward under the BASIC track (Level E) for the final 2 years of the agreement period.

Based on a combination of factors, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track along with the number of agreement periods that the ACO may participate in the BASIC track. These factors include the degree to which the ACO's ACO participants control total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries (low revenue ACOs versus high revenue ACOs), and the ACO's experience and its ACO participants' experience with the Shared Savings Program and other performance-based risk Medicare ACO initiatives. As noted in the December 2018 final rule (83 FR 67826), these policies were designed to increase savings for the Medicare Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles.

An ACO's ability to participate in the BASIC track is limited, and all ACOs eventually must transition to participation in the ENHANCED track to continue in the program. High revenue ACOs are limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. Low revenue ACOs are limited to, at most, 2 agreement periods for a total of 10 performance years under the BASIC track (or 11 performance years in the case of an ACO that participates in an agreement period that began on July 1, 2019, and spans a total of 6 performance years). These agreement periods do not need to be sequential. The regulations at § 425.600(e) also require that should a low revenue ACO, identified as experienced with performance-based risk Medicare ACO initiatives, have changes in the revenue of its ACO participants that would cause the ACO to be considered a high revenue ACO (as these terms are defined in § 425.20) for a given performance year, the ACO must take corrective action or terminate its participation under the BASIC track by the end of the current performance year (83 FR 67877 and 67878).

As discussed in the December 2018 final rule (83 FR 67881), many commenters who addressed the proposed changes to the participation options disagreed with the more aggressive transition of ACOs to performance-based risk under the proposed program redesign. Some commenters cautioned that although the proposed requirement that all ACOs undertake two-sided risk at some point during their first agreement period might improve the performance of the ACOs that continue to participate in the Shared Savings Program, it might also reduce ACO participation in the program. Several commenters expressed concern that the change in program requirements might cause ACOs to end their participation in the Shared Savings Program and create a barrier to entry for ACOs to join the program. One commenter recommended that CMS carefully monitor Shared Savings Program participation and change course if participation falls precipitously. As discussed in the Regulatory Impact Analysis section below, AIM participants—a subset of Track 1 ACOs that meaningfully outperformed peer ACOs in reducing spending and earning shared savings over the period from 2016 through 2018—dropped out at an elevated frequency before even attempting to enter the one-sided model (upside-only) portion of the BASIC track glide path, where spending reductions were found to be similar regardless of an AIM

[264] For more information on shared savings and shared losses for each level, see Centers for Medicare & Medicaid Services, Shared Savings Program Participation Options for Performance Year 2022, version 4, April 2021, available at *https://web.archive.org/web/20220401033547/* and *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ssp-aco-participation-options.pdf.*

ACO's decision to continue or exit the program.[265] This suggests both that, while an upside-only participation option with a lower shared savings rate can be a highly effective incentive for smaller, low revenue ACOs targeted by AIM, such ACOs also likely experience a correspondingly-magnified disincentive to accept exposure to even the limited downside risk presented by the current BASIC track glide path, and not even superior performance under Track 1 appears to provide enough confidence for such ACOs to consistently move into participation options leading to assumption of two-sided risk.

Several commenters expressed concern that requiring the rapid assumption of significant levels of risk by ACOs would discourage new participants and impede current ACOs' ability to make patient-centered infrastructure investments that are necessary for successful participation. Another commenter believed that reducing the amount of time permitted under the one-sided model was ill-advised and would jeopardize ACOs' continued participation. Our response to these comments included our commitment to continue to monitor program participation and consider further refinements to the program's participation options as we gained experience with implementing the redesigned program (83 FR 67835).

Most commenters on the proposed participation options that were finalized in the December 2018 final rule recommended that CMS extend the time any ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years proposed for ACOs eligible to participate under the BASIC track with participation agreements beginning on or after January 1, 2020 that do not qualify for a third year under the one-sided model under the exception in § 425.600(a)(4)(i)(B)(*2*)(*ii*), stating that it takes longer than 2 performance years to implement meaningful changes in a healthcare delivery model and among healthcare provider and patient populations. Other commenters believed that the progression to two-sided risk that we proposed and ultimately finalized was far too aggressive and would deter participation. These commenters generally suggested allowing for 4 or 5 performance years (or a full agreement period) under a one-sided model. Some commenters suggested that rural ACOs should be allowed at least two, 5-year agreement periods under a one-sided model (83 FR 67847). At the time of the December 2018 final rule, we disagreed with suggestions to allow ACOs to remain under the one-sided model for an extended time because our experience suggested that the availability of 6 performance years of no risk under Track 1 and the ability to benefit from significant waivers available in the program could be leading to the formation of one-sided ACOs that were not making serious efforts to improve quality and reduce spending, potentially crowding out the formation of more effective ACOs.

The design of the current Shared Savings Program participation options, including a BASIC track glide path incorporating more limited downside risk as compared to the ENHANCED track, demonstrates that the availability of a lower-risk, two-sided model is an effective way to encourage ACOs (including ACOs within a current agreement period, initial program entrants, re-entering ACOs, and renewing ACOs) to progress more rapidly to performance-based risk. For PY 2022, a majority of the 483 ACOs (284 (59 percent)) that currently participate in the Shared Savings Program, selected a two-sided model. Refer to Table 54.

TABLE 54: 2022 Shared Savings Program ACO Track Information

ACO Track	ACOs	Percent
One Sided (41% of ACOs)		
BASIC Track Levels A&B	199	41%
Two Sided (59% of ACOs)		
BASIC Track Levels C&D	40	8%
BASIC Track Level E*	98	21%
ENHANCED Track*	146	30%
TOTAL ACOs PY 2022	483	100%

*Qualifies as an Advanced Alternative Payment Model (APM).

Note: Tracks 1, 2, 3 and the Track 1+ ACO Model are no longer applicable as of PY 2022.

While many ACOs have agreed to participate under a two-sided model, not all ACOs appear to be ready to take on performance-based risk. In 2020 and 2021, due to the PHE for COVID–19, as defined in § 400.200, we provided additional participation option flexibilities, allowing ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement and ''freeze'' their participation for PY 2021 and PY 2022 at their PY 2020 and 2021 levels, respectively. (See May 2020 Interim Final Rule with comment period (IFC) (85 FR 27575 and 27576), CY 2021 PFS final rule (85 FR 84767 through 84769), and fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment Systems (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45502 through 45506)). Thus, eligible ACOs may have elected to remain in the same level of the BASIC track's glide path in which they participated during PY 2020 and PY 2021 once again, for PY 2022. As specified in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45503 through 45506), for PY 2023, an ACO that elected one or both of these advancement deferral options will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if the ACO had advanced automatically to the required level of the BASIC track's glide path for PY 2021 and PY 2022, as applicable (unless the ACO elects to advance more quickly before the start of PY 2023). For ACOs that continued their participation in the

[265] Trombley, MJ, et al. ACO Investment Model Produced Savings, But the Majority of Participants Exited when Faced with Downside Risk. *Health Affairs.* 2022; 138–146. doi:10.1377/hlthaff.2020.01819, available at *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2020.01819.*

Shared Savings Program into the next performance year, when given the opportunity to freeze at the ACO's current BASIC track level on the glide path, most eligible ACOs under a one-side model (Level A or Level B) chose to remain in a one-sided model:

- 140/157 (89 percent) currently participating ACOs chose to maintain their participation in a one-sided model rather than move to risk for PY 2021.
- 103/140 (74 percent) chose to maintain their participation in a one-sided model rather than move to risk for PY 2022.

As we have addressed several times through previous rulemakings, an ongoing consideration for CMS is how long ACOs should be allowed to participate under a one-sided model. We have to balance our goal of driving the greatest possible shift to high-value care delivery, which we believe may be incentivized most effectively under a two-sided model, with concern that requiring ACOs to take on too much downside risk too quickly will disincentivize program participation and reduce the program's potential to positively affect the quality and cost of care furnished to beneficiaries. Although we continue to believe there are stronger incentives for increased efficiency when ACOs are in a two-sided risk track, ACOs continue to report that they are constrained by the current participation options and need more time to invest in infrastructure and redesigned care processes for high quality and efficient health care service delivery before transitioning to performance-based risk. Additionally, some ACOs have reported that the ENHANCED track is too risky, and therefore, requiring ACOs to eventually move to ENHANCED may hinder continued participation. Therefore, we believe it would be prudent to provide greater flexibility for ACOs to join the program under the one-sided model and to remain in the program under lower levels of performance-based risk in order to balance our desire to see more ACOs participate under performance-based risk while also working towards our goal of increasing overall Shared Savings Program participation and improving outcomes for beneficiaries, including high need beneficiaries with complex health and social needs who may most benefit from ACOs' linked networks of clinicians with incentives to close inequitable gaps in care associated with poorer health outcomes.[266] [267]

We note that the Shared Savings Program was established as, and remains, a voluntary program for providers and suppliers that choose to participate in an ACO and to become accountable for the quality and cost of care for an assigned population of Medicare FFS beneficiaries. Thus, to promote the program's goal of ACO accountability for the quality and cost of care furnished to assigned beneficiaries, we believe it would be appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model (with a lower sharing rate) for a longer period of time, rather than risk having those ACOs leave the program altogether to avoid transitioning to two-sided risk before the ACO is confident it has been able to implement the systemic changes necessary to deliver high quality, value-based care. Even if an ACO does not earn shared savings, ACOs have demonstrated that they are likely saving Trust Fund dollars by modifying their ACO participants' behavior to coordinate care and carry out other interventions to improve quality and financial performance. In particular, ACOs with average to above-average baseline spending may decide that a benchmark with a neutral or negative regional adjustment presents too much exposure to performance-based risk if they are also required to participate under a two-sided model, but they may otherwise elect to participate and begin to reduce spending if permitted to join and remain under a one-sided model.

In light of these considerations, we are concerned that our current policy of considering an ACO's status as a high- or low revenue ACO (as these terms are defined in § 425.20) in determining the participation options available to the ACO may disincentivize certain providers and suppliers from forming ACOs or joining existing ACOs. At the start of July 1, 2019, 52 percent of the participating ACOs met the definition of ''high revenue ACO.'' For PY 2020, 48 percent of participating ACOs were high revenue ACOs, for PY 2021, 46 percent of participating ACOs were high revenue ACOs, and for PY 2022, 44 percent of participating ACOs are high revenue. In all, the share of participating ACOs that meet the definition of high revenue ACO has decreased by 8 percentage points over 3 participation years in a consistent downward trajectory.

It is not our intent to incentivize ACOs to exclude high cost providers and suppliers from their ACO participant lists to avoid meeting the definition of high revenue ACO. We believe participation in the Shared Savings Program encourages providers and suppliers to provide better coordinated, more efficient care for beneficiaries and results in savings for the Trust Funds. High revenue ACOs, which typically include hospitals as ACO participants, have a greater opportunity to control assigned beneficiaries' total Medicare Parts A and B FFS expenditures, as they coordinate a larger portion of the assigned beneficiaries' care across care settings (83 FR 41916 through 41918). As a result, we believe it is important to provide participation options that will encourage more providers and suppliers, including those with high revenues, to participate in the Shared Savings Program.

In addition, given the feedback we have received from ACOs and other interested parties, as well as our observation of trends in ACO participation, we believe ACOs inexperienced with performance-based risk Medicare ACO initiatives, regardless of their status as a high or low revenue ACO, may be more likely to participate in the program if they are allowed more time under a one-sided model than is currently allowed under the available participation options. As discussed in the December 2018 final rule, some commenters opposed limiting high revenue ACOs to one agreement period in the BASIC track. Given that high revenue ACOs are responsible for a greater share of Medicare Part A and Part B FFS spending than low revenue ACOs, one commenter agreed that it is reasonable to ask high revenue ACOs to assume greater levels of risk and/or at a faster pace than low revenue ACOs. But this commenter also suggested that CMS should take into account that larger health systems must invest in change across a much broader delivery ''footprint'' and so may require additional investments over multiple years to make transformative system changes, and also need a longer time to recoup investments (such as in the form of shared savings). Similarly, we heard from at least one interested party that high revenue ACOs need more of an on-ramp to meaningful levels of two-sided risk because there are bigger systemic policies in place that take time to modify in order to create changes within

[266] McWilliams JM, Landon BE, Chernew ME, Zaslavsky AM. Changes in patients' experiences in Medicare accountable care organizations. *N Engl J Med*. 2014;371(18):1715–1724. doi:10.1056/NEJMsa1406552.

[267] Seshamani M, Jacobs DB. Leveraging Medicare to Advance Health Equity. *JAMA*. 2022;327(18):1757–1758. doi:10.1001/jama.2022.6613.

the organization that focus on providing value-based care.

As noted above in section III.G.2.a.(2), CMS has outlined a renewed vision and strategy for how the Innovation Center will drive health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries. Further, in a January 2022 article, CMS stated our goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[268] The Shared Savings Program is the largest Medicare alternative payment model with 483 ACOs participating in PY 2022 and 11 million assigned beneficiaries.[269] As a result, the Shared Savings Program will play an important role in achieving the goal of creating care relationships with accountability for quality and costs for all Medicare FFS beneficiaries.

We believe APMs are well positioned to close gaps in health equity. Under the Shared Savings Program, ACOs are incentivized to provide high quality care while reducing unnecessary duplication of services and preventing medical errors. We believe it is important to encourage providers and suppliers who are providing care to high needs beneficiaries to join and/or form ACOs to help close gaps in health equity. We also believe flexibility with respect to the timeline for progression to two-sided risk is important in the Shared Savings Program to encourage small, rural, safety-net providers to form ACOs or to join larger, more urban practices to share resources. Both of these strategies can be utilized to help provide high need beneficiaries served by small, rural, safety-net providers with the resources to better coordinate their care and improve outcomes.

(2) 5-Year Agreement Period Under a One-Sided Model for Eligible ACOs

In the CY 2023 PFS proposed rule, we proposed to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Shared Savings Program. As discussed in the CY 2023 PFS proposed rule, while the proposal for currently participating ACOs to elect to maintain their participation at Level A or Level B for the remainder of their current agreement period would apply beginning January 1, 2023, we proposed to make all other policies outlined in this section effective for agreement periods starting on or after January 1, 2024, rather than January 1, 2023, because the majority of the application cycle for the 2023 performance year will occur before this rule is finalized. Establishing a January 1, 2024 start date for these changes would allow ACOs time to understand the scope of the proposed changes more fully before making decisions related to their participation, and would allow CMS adequate time to update its processes and application-related guidance documents for the new participation options, if finalized.

First, we proposed to add § 425.600(a)(4)(i)(C)(*3*) to allow an ACO that enters the BASIC track's glide path at Level A under § 425.600(a)(4)(i)(A)(*1*) and is currently at Level A to elect to remain in Level A under § 425.600(a)(4)(i)(A)(*1*) for all subsequent performance years of the agreement period, for agreement periods beginning on or after January 1, 2024. Per proposed § 425.600(a)(4)(i)(C)(*3*)(*i*), in order to be eligible to participate under Level A of the BASIC track for subsequent years of the agreement period as described in § 425.600(a)(4)(i)(C)(*3*), an ACO must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track under § 425.600(a)(4), and is not participating in an agreement period under the BASIC track as a renewing ACO (as defined in § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under § 425.600(a)(4); and the ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20). We proposed to extend this participation option to re-entering former Track 1 ACOs, because they have not previously participated in the BASIC track glide path and we explained our desire to encourage them to begin participating in the program again. Eligibility for this participation option would not consider the ACO's revenue status.

For eligible ACOs, prior to the automatic advancement of the ACO to Level B, the ACO could elect to remain in Level A for all subsequent performance years of the agreement period. At § 425.600(a)(4)(i)(C)(*3*)(*ii*), we proposed to require that this voluntary election by an ACO to remain in Level A for the entirety of its first agreement period be made in the form and manner and by a deadline established by CMS. In the case of an ACO that elects to remain in Level A for the entirety of its first agreement period, the ACO generally would be eligible to enter into a subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years of no risk under the one-sided model. If an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have 7 years under the one-sided model, whereas a new ACO entering under the BASIC track's glide path may be eligible for as few as 2 performance years under the one-sided model under the current participation options. We noted our belief that that allowing a maximum of 7 years under the one-sided model would strike a more appropriate balance within the current structure of 5 performance year agreement periods and the BASIC track glide path, which provides for 2 years under the one-sided model. Currently, ACOs inexperienced with performance-based risk Medicare ACO initiatives generally are limited to 2 years under a one-sided model, which ACOs have informed us is not enough time before transitioning to risk. We noted our belief that giving ACOs longer than the proposed 7 years or potentially unlimited time under a one-sided model would dilute the program's ability to meaningfully influence expenditures and quality through the incentives provided by ACO risk assumption. As proposed, the change to extend the time eligible ACOs may remain under a one-sided model would allow ACOs more time to make investments in care improvement and to capitalize on those investments, while still working to lower costs and improve care quality for their assigned beneficiaries.

Although we proposed to increase the potential time certain ACOs may spend in the one-sided model, the proposal included a pathway to transition these ACOs into two-sided risk. We noted that we continue to recognize that ACOs are best able to select their participation options to meet the needs of their organizations, including when to time their transition to performance-based risk, including within an agreement period. We proposed to add a new § 425.600(g)(1)(i) to provide that an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 performance years and a second time in

[268] Seshamani, M, Fowler E, Brooks-LaSure C. et al. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.22 January*. doi:10.1377/forefront.20220110.198444.

[269] See Medicare Shared Savings Program Fast Facts (January 2022), available at *https://www.cms.gov/files/document/2022-shared-savings-program-fast-facts.pdf*.

progression on the glide path). Furthermore, we noted that the ability to enter a second agreement period in the BASIC track's glide path would be limited by proposed § 425.600(g)(1)(ii), which would provide that an ACO that enters an agreement at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and would only be eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfied either of the following: The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time. At paragraph (g)(1)(iii), we proposed that an ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track. For example, an ACO that voluntarily terminates its participation agreement during its first agreement under Level A of the BASIC track's glide path and chooses to re-enter the BASIC track under proposed § 425.600(g)(1)(ii) would be re-entering a second agreement and, if continuing to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives, could progress along the BASIC track glide path for this second agreement period. For its third agreement, the ACO would be required to enter the BASIC track at Level E for all years of the agreement period, or the ENHANCED track. As proposed, the provisions would prevent ACOs from terminating their participation agreement before transitioning to two-sided risk in order to stay under the one-sided model, potentially indefinitely.

We also proposed to add § 425.600(a)(4)(i)(B)(*2*)(*vi*) to allow currently participating ACOs that are participating in the BASIC track at Level A or Level B for PY 2022 to elect to continue in their current level of the BASIC track glide path for PY 2023 and continuing for the remainder of the agreement period. If the ACO does not elect to remain under Level A or Level B, for PY 2023, the ACO would be automatically advanced to the next level of the BASIC track's glide path to which the ACO would have automatically advanced absent any election to maintain its participation level for PY 2022 and, if applicable, the election to maintain its participation level for PY 2021 under § 425.600(a)(4)(i)(B)(*2*)(*iii*), unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). We proposed to modify § 425.600(a)(4)(i)(B)(*2*)(*iv*) to account for the proposed new election option under paragraph (*vi*). We also proposed to add § 425.600(a)(4)(i)(B)(*2*)(*vii*) to extend this participation option to eligible ACOs that begin an agreement period in Level A or Level B on January 1, 2023.

We recognized we proposed to implement participation option changes in the middle of an agreement period for currently participating ACOs in the BASIC track Level A or Level B. However, we proposed to allow these ACOs to elect to remain at the level in which they are currently participating for PY 2022 for the remainder of their current agreement period, and to offer a similar option to ACOs that enter an agreement period starting under Level A or Level B of the BASIC track glide path beginning on January 1, 2023, because we noted that we wished to encourage continuity of participation in the program and did not see any advantage to excluding currently participating ACOs and ACOs with participation agreements beginning on January 1, 2023, from the same participation option that we proposed to make available to newly participating ACOs inexperienced with performance-based risk Medicare ACO initiatives that begin a new agreement period on or after January 1, 2024. We proposed that, in the case of a currently participating ACO that elects to remain in Level A or Level B under proposed § 425.600(a)(4)(i)(B)(*2*)(*vi*) or (*vii*) for the remainder of its current agreement period, the ACO would be eligible to enter into a subsequent agreement period under the BASIC track's glide path pursuant to § 425.600(g)(1)(ii), giving the ACO an opportunity to participate for up to 2 additional years under the one-sided model. For performance year 3 of this subsequent agreement period, the ACO would be automatically advanced to Level C and to each successive level of risk and potential reward for each performance year thereafter, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). We proposed to require that this voluntary election by an ACO to remain in the one-sided model in Level A or Level B for the remainder of its current agreement period be made in the form and manner and by a deadline established by CMS.

Consistent with the proposal to expand the participation options for renewing and re-entering ACOs, we proposed to make changes to the definition of *Performance-based risk Medicare ACO initiative* in § 425.20 and to the regulation at § 425.224(a)(4) to allow a renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path (Level A or B) to reapply for participation in the BASIC track's glide path, provided the ACO is not identified as having also participated previously under a two-sided model. We explained that the proposed change to the definition of *Performance-based risk Medicare ACO initiative* in § 425.20 would be effective for performance years beginning on January 1, 2023 and for subsequent years. Specifically, we proposed to amend the definition of *Performance-based risk Medicare ACO initiative* in § 425.20, including to add a new paragraph (1)(ii) to apply to performance years beginning January 1, 2023 and in subsequent years, to include only Levels C through E of the BASIC track, and to remove the one-sided Levels A and B from the definition. Similarly, in § 425.224(a)(4), we proposed to remove the reference to ''a one-sided model of the BASIC track's glide path (Level A or Level B),'' so that renewing and re-entering ACOs that previously participated in a one-sided model of the BASIC track's glide path but that are not identified as having participated in a two-sided model, are not limited to reapplying for participation in a two-sided model.

Because the annual application and change request cycle began before the CY 2023 PFS final rule is issued, we noted that we would give ACOs currently participating in Level A or B of the BASIC track glide path the opportunity during the change request cycle to indicate whether they are interested in maintaining their participation at Level A or Level B under this proposed policy, should it be finalized. ACOs expressing such an interest would not be required to submit a repayment mechanism at that time. In the event this proposed policy were not finalized in the CY 2023 PFS final rule, we noted that ACOs that are required under § 425.600(a)(4)(i)(B)(*2*) to advance from Level A or Level B to a two-sided risk model for PY 2023 would have a

limited opportunity to submit a repayment mechanism, resolve any deficiencies, and have it approved in time for the start of the performance year. ACOs that failed to establish a repayment mechanism that complies with the requirements of § 425.204(f) by the deadline specified by CMS would be terminated as required under § 425.600(a)(4)(i)(B)(*3*).

In order to determine an ACO's eligibility to participate under the proposed new participation options, we proposed to consider an ACO's experience with performance-based Medicare ACO initiatives only, rather than also considering the ACO's status as a high or low revenue ACO. Our proposal would make the ENHANCED track optional for all ACOs, regardless of experience with performance-based risk Medicare ACO initiatives. As discussed in the CY 2023 PFS proposed rule, because we do not wish to disincentivize the formation of ACOs that include high-cost providers (that is, high revenue ACOs), we proposed to no longer use revenue status for determining ACO participation options. As proposed, the provision also would simplify the determination of which participation options are available to a particular ACO and would reduce burden on ACOs (in terms of ascertaining likely available participation options) and CMS (in terms of determining ACO eligibility for its selected participation option). We proposed to modify the regulations in § 425.600(a)(4)(i)(B) and § 425.600(d) to apply only to agreement periods beginning on or after July 1, 2019, and before January 1, 2024, and § 425.600(e) to apply only to performance years beginning on or after July 1, 2019, and before January 1, 2024, because these complex provisions depend on the ACO's status as a high or low revenue ACO. The distinction that § 425.600(e) would apply to performance years, rather than to agreement periods, aligns with our proposal to make the ENHANCED track optional. With that change, it no longer would be necessary to monitor low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO, and therefore, ineligible for participation in the BASIC track. For agreement periods beginning on or after January 1, 2024, we proposed to streamline the specification of the BASIC track glide path in § 425.600(a)(4)(i)(C) and eligibility for participation options in § 425.600(g), which would define an ACO's participation options based solely on the ACO's level of experience with performance-based risk Medicare ACO initiatives.

We noted our belief that the determination of whether an ACO is inexperienced or experienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20) could be affected by changes made by an ACO to its ACO participant list during the course of an agreement period, particularly for ACOs that are determined to be inexperienced when their agreement period begins but are close to the threshold percentage of 40 percent of ACO participants having participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the agreement start date. Any approach under which we would apply different policies to ACOs based on the prior experience of an ACO's ACO participants with performance-based risk Medicare ACO initiatives would need to recognize the potential for an ACO to add or remove ACO participants during the course of the agreement period, which could affect whether the ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives. We noted our concerns about the possibility that an ACO may begin participating under a one-sided, shared savings-only level of the BASIC track based on a determination that the ACO is inexperienced with performance-based risk Medicare ACO initiatives, and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding the limitations under our proposed participation options regarding the availability of the one-sided model for experienced ACOs.

To protect against this circumstance, we proposed to add § 425.600(h) to provide that for performance years beginning on or after January 1, 2024, CMS would monitor ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to a voluntary election under § 425.600(a)(4)(i)(B)(*2*)(*vi*), (a)(4)(i)(B)(*2*)(*vii*), or (a)(4)(i)(C)(*3*) for changes to their ACO participant list that would cause an ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

We further proposed to update the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives under § 425.20 to allow for a rolling lookback period (applicable to both the assessment of an ACO's application to participate under a participation option for an agreement period and to ongoing compliance determinations as proposed at § 425.600(h)) of the 5 most recent performance years beginning from the current performance year being monitored. If an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (as specified in § 425.20), we proposed under the new provision at § 425.600(h)(2)(i) that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year. As specified under proposed § 425.600(h)(2)(ii), the ACO would be required to meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b), in accordance with § 425.600(a)(4)(i)(B)(*2*)(*v*) or (a)(4)(i)(C)(*4*), as applicable. If the ACO fails to meet the requirements to participate under performance-based risk, its agreement would be terminated in accordance with § 425.600(a)(4)(i)(B)(*3*) or § 425.600(a)(4)(i)(C)(*5*), as applicable.

An eligible ACO that enters a new agreement period beginning on or after January 1, 2024, at Level A of the BASIC track would be permitted to elect to remain in Level A for the next performance year and remain at Level A for all subsequent performance years of the agreement period under proposed § 425.600(a)(4)(i)(C)(*3*). We would review the ACO's proposed ACO participant list for each subsequent performance year and provide feedback to allow the ACO to assess if the proposed changes to its ACO participant list (if any) would yield a determination that the ACO qualifies as experienced with performance-based risk Medicare ACO initiatives based on the 5 most recent performance years prior to the performance year under review (for example, PY 2020 through PY 2024, if

PY 2025 were under review). CMS would perform the same monitoring activity ahead of all subsequent performance years of the agreement period in which the ACO elected to remain in Level A under proposed § 425.600(a)(4)(i)(C)(*3*).

If the ACO were to meet the definition of experienced with performance-based risk Medicare ACO initiatives based on the proposed ACO participant list for the performance year under review, the ACO would still be permitted to complete that performance year in Level A of the BASIC track. CMS would then reassess the proposed ACO participant list for the subsequent performance year. If at that point the ACO has made changes to its ACO participant list such that it no longer meets the definition of experienced with performance-based risk Medicare ACO initiatives, the ACO would be permitted to complete that subsequent performance year in Level A of the BASIC track. But if the ACO continues to meet the definition of performance-based risk Medicare ACO initiatives based on its proposed ACO participant list for the subsequent performance year, the ACO would be automatically advanced to Level E of the BASIC track for that performance year, provided the ACO met all requirements to participate under performance-based risk. If the ACO did not meet all requirements to participate under performance-based risk, including establishment of an adequate repayment mechanism and selection of an available MSR/MLR, the ACO's participation agreement would be terminated.

Our proposed approach to monitoring of risk experience for agreement periods under Level A of the BASIC track was illustrated in a table in the CY 2023 PFS proposed rule, which we duplicate in Table 55. As shown, hypothetical ACOs A and B begin a Shared Savings Program agreement period on January 1, 2024, and for that performance year, are determined to be inexperienced with performance-based risk Medicare ACO initiatives. Both ACOs are monitored ahead of PY 2025 as proposed, and both continue to meet the definition of inexperience with performance-based risk Medicare ACO initiatives based on their proposed ACO participant lists for PY 2025. Consistent with their status as inexperienced with performance-based risk Medicare ACO initiatives, both ACO A and ACO B elect to maintain their participation at level A of the BASIC track for all years of the agreement period, as proposed in § 425.600(a)(4)(i)(C)(*3*). Ahead of PY 2026, both ACOs are determined to be experienced with performance-based risk Medicare ACO initiatives based on their proposed ACO participant lists for PY 2026. Both ACOs are permitted to remain at Level A of the BASIC track for PY 2026, but will continue to be monitored by CMS. Ahead of PY 2027, the proposed ACO participant list for ACO A for PY 2027 is reviewed and the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, and ACO A is thus permitted to continue its agreement under Level A of the BASIC track for PY 2027. However, ACO B is determined to continue to meet the definition of experienced with performance-based risk Medicare ACO initiatives based on its proposed ACO participant list for PY 2027, and therefore, is advanced to Level E of the BASIC track for PY 2027 and must remain there for the remainder of its agreement period.

TABLE 55: Monitoring of Risk Experience for Agreement Periods under Level A of the BASIC Track

Performance Year for which ACO Participant List is Monitored	ACO A		ACO B	
	Risk Experience Determination	Level of the BASIC Track	Risk Experience Determination	Level of the BASIC Track
PY 2024	Inexperienced	A	Inexperienced	A
PY 2025	Inexperienced	A	Inexperienced	A
PY 2026	Experienced	A	Experienced	A
PY 2027	Inexperienced	A	Experienced	E
PY 2028	Inexperienced	A	Experienced	E

Our intention in proposing these policies was to provide ACOs with a more gradual on-ramp to taking on two-sided risk and to allow them the flexibility they need to best ensure their readiness to take on two-sided risk. In the CY 2023 PFS proposed rule, we noted our belief that the proposals would encourage more ACOs to form and join the program, as well as encourage currently participating ACOs to remain in the program. Additionally, we noted our belief that the proposals would help to increase our participation options so that an ACO has more flexibility to select the option that best fits its circumstances when applying to participate in the Shared Savings Program.

Increasing the participation options in the program by expanding the flexibilities for participation in the one-sided model would also be expected to promote health equity for underserved and vulnerable beneficiaries by providing ACOs and their ACO participants with an additional opportunity to close gaps in care for underserved populations before they are required to transition to performance-based risk. These additional flexibilities would also afford ACOs that serve high-need beneficiaries or face greater start-up costs with more time to prepare to take on two-sided risk, as well as allowing ACOs to balance their response to the COVID–19 pandemic, while also managing normal operations, implementing care redesigns and improving the quality of care provided to beneficiaries.

The following is a summary of the public comments received on the proposal for a 5-year agreement period under a one-sided model for eligible ACOs and our responses:

Comment: Most commenters were supportive of CMS' proposal to allow ACOs inexperienced with performance-based risk to remain in Level A of the BASIC track during their first agreement period. These commenters emphasized that the transition to performance-based risk under the current glide path often proves challenging and can deter participation by driving ACOs out of the program if they are forced to assume risk too quickly. Many commenters expressed that ACOs generate increased shared savings over the duration of program participation, and thus, these gains could be hindered by a

requirement to quickly transition to risk that resulted in ACOs leaving the program rather than taking on risk. Commenters also noted that ACOs that include as ACO participants FQHCs providing care in medically underserved areas are often more hesitant to take on risk, as these health centers incur unique financial risks due to their location in medically underserved areas and by providing care to all patients, regardless of ability to pay. Commenters noted that they believe that this proposal would encourage Shared Savings Program participation and emphasized that the extended on-ramp to two-sided risk, as proposed, would allow sufficient time for ACOs to build infrastructure and the processes necessary to be successful in the program by gathering data and funding, refining programs, designing care delivery and practice patterns, and developing physician leader experience.

Many commenters praised the potential equity implications of the proposed change, saying it would aid ACOs that incur higher costs when serving vulnerable populations and enable them to allocate funds to address social determinants of health. Other commenters maintained that it would encourage diverse participation in the Shared Savings Program, with one commenter saying it would encourage community clinic ACO participation, another highlighting that the flexibility and stability would provide an incentive for providers and suppliers serving complex patients and for small non-profit organizations to form or join ACOs, and another pointing to how it would assist providers and suppliers in rural areas and safety-net organizations. Another commenter stated that the proposed policy would be especially beneficial for new ACOs that are inexperienced with performance-based risk and low revenue ACOs, especially when paired with the advance investment payment proposals, and would attract ACOs to participate in the Shared Savings Program that, absent these policies, would have been unable to consider participation. Commenters highlighted that participation in the one-sided model can yield meaningful outcomes and savings. Multiple stakeholders urged CMS to place less emphasis on revenue status, which was reflected in our proposed shift to only using performance-based risk experience (not revenue status) as a determinant for participation options.

Response: We agree with commenters who emphasized that the extended on-ramp to two-sided risk will allow ACOs more time to develop the healthcare delivery infrastructure to successfully manage the patient experience across the continuum of care and to be able to gather data, educate staff, and refine practice patterns that improve quality of care and reduce the costs of care. We appreciate the insight from commenters that these new flexibilities will encourage participation among rural area providers, safety-net providers, and providers serving high-need populations, which will in turn help increase the diversity of beneficiaries receiving accountable care.

Comment: Several commenters argued that two-sided risk is necessary to drive reduction in spending and invest in transforming care delivery.

Response: We agree that two-sided risk has proven to be effective in encouraging many ACOs to reduce spending; however, we also believe that allowing more time under a one-sided model will provide more ACOs with the time that they need to make the needed preparations, such as adopting new technologies and processes that will allow them to successfully take on two-sided risk while also achieving meaningful cost and quality improvements. Data have shown that ACOs can take between 1–3 years to become accustomed to the Shared Savings Program [270] and that ACOs are more likely to leave the program when they are unprepared to take on two-sided risk.[271] We note that the rapid progression to two-sided risk is a barrier to entry and continued participation by some ACOs, as noted by several ACO and provider group commenters in response to the CY 2023 PFS proposed rule. We acknowledge that two-sided risk is an effective tool to drive investment in cost-saving measures and quality of care improvements, but we have observed that providers and suppliers that participate in a one-sided model are also able to realize shared savings while improving quality of care for patients. We also believe that ACOs that successfully earn shared savings under two-sided risk generally made the transition to risk when the ACO was confident that its care coordination strategies were sufficiently mature and well-implemented to successfully reduce spending. Recognizing that this point of readiness may arrive sooner for some ACOs than for others, we would like to provide more ACOs the time they need to gain that same confidence to succeed. Furthermore, we have received comments from many ACOs and practitioner groups that allowing ACOs to remain in a one-sided model would allow them to make the investments needed to improve quality of care and develop processes to manage total cost of care in anticipation of assuming two-sided risk. As such, it is our belief that finalizing the ability for some ACOs to remain in a one-sided model for an extended period of time as proposed will encourage new and continued participation by ACOs, resulting in the continued success of the Shared Savings Program.

Comment: One commenter stated that the proposed changes may result in well-resourced providers and suppliers that are capable of moving to two-sided risk remaining in a one-sided model longer than necessary. Other commenters noted that there are financial incentives for ACOs ready to assume two-sided risk to continue forward along the BASIC track glide path and to the ENHANCED track, since the higher levels of risk are accompanied by higher levels of potential reward through higher available sharing rates.

Response: We agree with the commenters that noted the significant financial incentives that encourage high-performing ACOs to continue forward along the glide path to risk, since the current and the proposed participation options compensate the assumption of risk (and higher levels of risk) with the corresponding opportunity for greater reward. Further, we believe that one-sided model participation provides incentives for providers and suppliers to manage total cost of care and make improvements in care quality while also providing stability, sustainability, and flexibility to providers and suppliers serving rural areas, safety-net providers, and providers and suppliers in underserved areas. We acknowledge that moving to two-sided risk further increases these incentives, and by allowing these ACOs more time in a one-sided model, they will have time to mature the infrastructure needed to confidently move into two-sided risk.

Comment: MedPAC suggested an ACO should not be able to benefit from both 7 years under a one-sided model and a positive regional adjustment to its benchmark, as this could result in an ACO earning shared savings without making any demonstrable improvements in care delivery or cost reduction. They suggested that CMS also consider implementing criteria that would assess if an ACO received a positive regional adjustment to its

[270] ''The Medicare Shared Savings Program In 2020: Positive Movement (And Uncertainty) During A Pandemic'', Health Affairs Blog, October 14, 2021. DOI: 10.1377/hblog20211008.785640.

[271] ''Why Do Accountable Care Organizations Leave The Medicare Shared Savings Program?'', Health Affairs Blog, May 6, 2019. DOI: 10.1377/hlthaff.2018.05097.

baseline expenditures when determining if an ACO is eligible for additional years in BASIC track Level A or Level B.

Response: We acknowledge MedPAC's concern that ACOs with a positive regional adjustment could elect to participate for an extended time in the one-sided model. We note that in recent years around 90 percent of ACOs participating in the Shared Savings Program have received a positive regional adjustment, and thus implementing a restriction such as the one suggested by MedPAC would largely moot the proposal to allow ACOs inexperienced with performance-based risk Medicare ACO initiatives to participate for a full agreement period under Level A of the BASIC track, followed by a second agreement period in the BASIC track's glide path. We appreciate MedPAC's concerns around potential ACO behavior during an extended period under a one-sided model and will continue to analyze ACO trends and may take this suggestion into consideration in future rulemaking.

Further, we acknowledge that ACOs that would benefit from a positive regional adjustment are incentivized to participate in the Shared Savings Program as their spending is already low compared to the region, and that selective participation by these ACOs may help to explain why the large majority of current ACOs receive a positive regional adjustment. Because we believe that the proposal to allow extended participation in the one-sided model will appeal especially to ACOs and potential ACOs that are currently reluctant to join or remain in the Shared Savings Program, such as those that would receive a negative regional adjustment, we believe that finalizing this extended participation in the one-sided model as proposed will increase Shared Savings Program participation, including by ACOs that will not receive a positive regional adjustment.

We also note that there are existing guardrails on positive regional adjustments in place, as discussed in III.G.5.c.(5) of the CY 2023 PFS proposed rule. For an ACO that has lower spending compared to its regional service area (that is, an ACO that would receive a positive regional adjustment), the weight applied to the regional adjustment is 35 percent for the first agreement period in which the ACO is subject to a regional adjustment and 50 percent in the ACO's second and subsequent agreement periods subject to a regional adjustment. Perhaps more importantly, we cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (sometimes referred to as the ''symmetrical cap'' on the regional adjustment). The current schedule of weights described in § 425.601(f)) and the symmetrical cap on the regional adjustment described in § 425.601(a)(8)(ii)(C)) were designed to address a dynamic where the regional adjustment could provide overly inflated benchmarks for ACOs that are relatively low spending compared to their region (that is, ACOs that receive a positive regional adjustment), while ACOs with higher spending compared to their region (that is, ACOs that receive a negative regional adjustment) may find little value in remaining in the program when faced with a significantly reduced benchmark. As we have previously explained, these policies are designed to prevent windfall shared savings payments for ACOs that have relatively low spending levels relative to their region (83 FR 67822).

Comment: Some commenters were supportive of allowing more time in a one-sided model, but suggested that CMS should provide more scrutiny and/or requirements to demonstrate improvements in care delivery when determining which ACOs would be allowed to continue to participate in a one-sided model for an extended time.

Response: We believe that the requirements governing which ACOs may participate in a one-sided model for up to 7 years are sufficient to ensure inexperienced ACOs that will best benefit from these arrangements are encouraged to participate in the program, while also excluding from this participation option experienced ACOs that do not need the additional time in a one-sided model to develop the processes and infrastructure needed for success in the Shared Savings Program. Additionally, we note that ACOs are subject to measuring and reporting metrics relative to their performance in the Shared Savings Program, such as quality reporting, and that CMS routinely conducts compliance monitoring of ACOs. We believe that the systems and processes already established provide sufficient oversight into how ACOs are using the additional time in a one-sided model.

Comment: Many commenters supported the proposed policy to allow new ACOs inexperienced with performance-based risk Medicare ACO initiatives up to seven years in a one-sided model of the Shared Savings Program and several included requests for CMS about its implementation. One commenter urged CMS to provide data for glide path level selection, such as information about our expected determination of the ACO's experience with performance-based risk Medicare ACO initiatives, with ample time before a decision on glide path level needs to be made, ensuring the election process is not burdensome and allows for transparency and sufficient information for educated decision making by ACOs.

Response: We appreciate the commenters suggestion, and we plan to inform ACOs of these participation option changes using education and outreach to ACOs on the available participation options through various methods, including ACO coordinators, guidance documents, tip sheets, FAQs, and a biweekly newsletter to assist ACOs as they navigate to higher levels of risk and potential reward throughout their participation in the program. Information about an ACO's experience with performance-based risk Medicare ACO initiatives is also communicated at standardized intervals during each application/change request cycle.

Comment: One commenter urged CMS to address potential gaming around this policy so that its implementation encourages new entity participation in the Shared Savings Program and does not allow inexperienced ACOs to enter a one-sided model, terminate its participation before moving to two-sided risk, and reenter another agreement in a one-sided model.

Response: We note that we proposed a number of safeguards to prevent the situation described in the comment, including in § 425.600(g)(1)(ii) and (h), to limit ACO gaming opportunities to continue to enter into one-sided model agreements after terminating a participation agreement and to engage in ACO participant churn. Under § 425.600(g)(1)(ii), an ACO that enters an agreement at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and would only be eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfied either of the following: The ACO is the same legal entity as a current or previous ACO that previously entered into a

participation agreement for participation in the BASIC track's glide path only one time; or for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time. Under § 425.600(h), for performance years beginning on or after January 1, 2024, CMS will monitor ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to a voluntary election under §§§ 425.600(a)(4)(i)(B)(*2*)(*vi*), (a)(4)(i)(B)(*2*)(*vii*), or (a)(4)(i)(C)(*3*) for changes to their ACO participant list that cause an ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

Comment: Several commenters suggested adjustments to proposals outlined in the CY 2023 PFS proposed rule. In terms of monitoring ACOs for experience with performance-based risk and the proposal to move an ACO previously determined to be inexperienced with performance-based risk to Level E if its ACO participant list later causes it to qualify as experienced with performance-based risk, several commenters suggested allowing those ACOs to choose between advancing to Level C, Level D, or Level E. A couple commenters urged CMS to eliminate categorization as experienced or inexperienced with performance-based risk Medicare ACO initiatives for individual practitioners, as the commenter suggested that experience with risk does not correlate to greater success in lowering cost or improving quality by individual physician practices, and rather has more to do with leadership and management of the ACO. Several commenters suggested CMS should tie transition timelines for moving from a one-sided model to two-sided risk to metrics that evaluate an ACO's performance and progress.

Response: We believe our proposals strike an appropriate balance between allowing additional time in one-sided models and moving ACOs that begin to qualify as experienced with performance-based risk Medicare ACO initiatives to an appropriate level of two-sided risk. Our performance-based risk experience monitoring proposal allows ACOs one full performance year to make adjustments to their ACO participant lists once a formerly inexperienced ACO that is participating in Level A of the BASIC track for the entire agreement period starts to qualify as experienced with performance-based risk Medicare ACO initiatives. If after that period, the ACO is still found to be experienced with performance-based risk, we believe it is reasonable for that ACO to move to Level E of the BASIC track in line with the participation options available to other ACOs that are experienced with performance-based risk. We believe our proposal appropriately addresses how an ACO and/or ACO participants are determined to be experienced with performance-based risk Medicare ACO initiatives. Our proposal includes an updated definition of performance-based risk Medicare ACO initiatives in § 425.20, including only Levels C through E of the BASIC track, and removing the one-sided Levels A and B from the definition. This change will help prevent inexperienced ACOs from beginning to qualify as experienced during the ACO's agreement period, because ACO participants (including newly added ACO participants) with only prior BASIC track Level A or Level B experience will not cause the ACO to become experienced with performance-based risk Medicare ACO initiatives.

We continue to believe that risk experience and prior participation are relevant. The definition for experienced with performance-based risk Medicare ACO initiatives states that it is either the same legal entity or 40 percent or more of the ACO's ACO participants participated under performance-based risk (§ 425.20). A single independent practice is unlikely to deem an entire ACO as experienced with performance-based risk. However, a collection of independent practices that have all participated together under the same ACO, could if they make up at least 40 percent of the ACO participants on the ACO participant list. As the entities have participated together under performance-based risk, we do believe that experience does correlate to working together to lower costs and provide high quality care to beneficiaries.

We do not want to force ACOs to take on two-sided risk before they are ready and would like ACOs to successfully participate in the Shared Savings Program. However, we have observed that ACOs in performance-based risk tracks have better financial performance than ACOs in shared savings-only tracks, so we would like to provide ACOs adequate time to move towards performance-based risk and to continue under risk once they have move to a two-sided model. While we appreciate commenters' suggestion to require ACOs to meet certain performance metrics in order to remain in the one-sided model for an extended period of time, we note that we currently monitor ACOs for their compliance with quality performance standards under § 425.316(c) and financial performance under § 425.316(d) and we can take pre-termination actions identified under § 425.216 if CMS concludes that termination of an ACO from the Shared Savings Program is warranted. We will continue to monitor and, if necessary, refine our approach to performance monitoring and determining available participation options in future rulemaking. We hope to find the right balance between providing strong incentives to deliver high quality care, while reducing spending and giving ACOs adequate time to implement changes that allow for successful participation.

Comment: One commenter suggested shortening the lookback period in the definition of ''experienced with performance-based risk Medicare ACO initiatives'' under § 425.20 to 2 years (from 5) to encourage continued growth of the Shared Savings Program.

Response: We appreciate the commenter's suggestion to shorten the lookback period for determining whether an ACO qualifies as inexperienced or experienced with performance-based risk Medicare ACO initiatives. At this time, we are not considering making a change to the lookback period. We believe the longer lookback period mitigates the chances providers and suppliers will sit out from the Shared Savings Program for a relatively short time in order not to be considered experienced with performance-based risk Medicare ACO initiatives. We believe 5 years provides less incentive for entities to join the program, leave, and rejoin under a one-sided model after a relatively short time. We believe these policies balance providing incentives for providers and suppliers to form ACOs and limit opportunities for gaming.

Comment: A few commenters suggested CMS provide additional technical assistance and resources to help ACOs successfully transition to two-sided risk.

Response: We appreciate the commenters' suggestion that CMS provide additional technical assistance and resources to transition to two-sided risk, and we will continue to develop appropriate materials and resources to support ACOs. We also encourage ACOs to participate in our learning system events to learn about successes and pitfalls other ACOs have experienced.

Comment: While supportive of the overall policy changes proposed for the Shared Savings Program participation options, some commenters suggested that ACOs that have already transitioned to two-sided risk should also have additional flexibilities, including the option to modify existing participation agreements. For example, a few commenters suggested CMS consider allowing ACOs currently participating at Level C or Level D of the BASIC track to elect to maintain at that level for the remainder of their current agreement period, similar to the proposal for qualifying ACOs in Levels A and B of the BASIC track, suggesting that this option would allow ACOs that are ready to move to two-sided risk but not ready to go to Level E additional time to grow more comfortable with risk while continuing to build their infrastructure.

Response: We note that some of the proposed changes would be available to ACOs already participating in the program, such as the ability for currently participating ACOs in Level A or Level B of the BASIC track to elect to maintain at that level for the remainder of their agreement period, and continue to believe that the BASIC track's glide path offers a gradual on-ramp to higher levels of risk and potential reward for ACOs when they begin to take on two-sided risk. Many currently participating ACOs have had the opportunity to benefit from the election to maintain their participation level in PYs 2021 and 2022, allowing many to have extended time in a one-sided model, or in Level C or Level D of the BASIC track. Additionally, all ACOs would benefit from the proposal to make the ENHANCED track optional, with ACOs in the ENHANCED track having the new option to move back to Level E of the BASIC track. Therefore, we do not believe it is necessary to offer an option for ACOs currently participating in Level C or Level D of the BASIC track glide path to elect to freeze their participation at one of those levels for more than one performance year.

Comment: One commenter encouraged CMS to consider the tradeoffs of having a program with fewer ACOs that requires ACOs to take on higher levels of two-sided risk, which therefore acts as a more powerful incentive to decrease costs while maintaining or improving quality of care, versus a program with more ACOs that does not require them to take on such high levels of risk, which therefore does not drive as meaningful results for the Medicare Trust Funds and quality of care. The commenter also suggested that CMS consider transitioning the Shared Savings Program to a mandatory model. This commenter suggested that increasing participation in models with downside risk will require shifting to a mandatory model, and without a mandatory model, CMS will need to accept lower levels of participation in two-sided risk models.

Response: As we stated in the CY 2023 PFS proposed rule, the Shared Savings Program was established by statute as, and remains, a voluntary program for providers and suppliers that choose to participate in an ACO. For that reason, it is important that we implement the Shared Savings Program in a manner sufficiently attractive to ACOs and potential ACOs to encourage their participation and achievement of positive results for the Trust Funds and for the ACOs' assigned beneficiaries. Thus, we believe it is appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model for a longer period of time, rather than risk having those ACOs leave the program altogether.

Comment: One commenter suggested CMS create a payment model for FQHCs and Critical Access/Rural Hospitals, that would remove unspecified barriers to participation by providers in cost-based reimbursement models and would allow such entities to participate for 7 years under a one-sided model. The commenter suggested the creation of a new model in order to allow FQHCs, RHCs, and CAHs to remain independent and not consolidate or join a convener organization. Another commenter suggested CMS establish a track where ACOs participate at full risk and could be eligible for 100 percent shared savings and shared losses. Another suggested a permanent upside-only model for physician-owned ACOs. Another commenter requested CMS reassess the cap on shared savings that cannot exceed 10 percent of updated benchmark for the BASIC track, but did not provide detail on how the cap should be adjusted.

Response: We appreciate the feedback; however, these suggestions are out of scope of the proposed rule. We will consider these suggestions for possible future rulemaking and have shared them with the Innovation Center.

Comment: Some commenters supported the policy for ACOs currently participating in Level A or Level B of the BASIC track to elect to maintain their participation for the remainder of the agreement period, but expressed concerns about the timing between the release of this final rule and the deadline for ACOs to select a Shared Savings Program track, especially if the proposals were not finalized. The commenters recommended that CMS allow for a renewal extension period for currently participating ACOs when making changes to the program's participation options to avoid wasting program resources if a policy change necessitates an ACO change their desired participation options, but did not elaborate on how that renewal extension period should operate. Another commenter shared similar sentiments about timing of this policy, and in the event CMS does not finalize the proposal to allow BASIC Track Level A or Level B ACOs to remain in their current level, urged CMS to allow ACOs moving to two-sided risk an opportunity to prepare their SNF 3-day rule waiver applications.

Response: We proposed to allow currently participating BASIC track ACOs to maintain participation under the one-sided model for the remainder of their current agreement period to allow these ACOs an opportunity for one full agreement period under a one-sided model, which we proposed to be available for qualifying ACOs entering new agreement periods beginning on or after January 1, 2024. However, for new applicants and re-entering ACOs, we proposed for this policy to become effective beginning in 2024 to provide applicants and CMS adequate time to consider and implement the changes, as finalized, before the start of the application cycle to which they will apply.

After reviewing the comments received, we are finalizing, without modification, the proposal to offer a 5-year agreement period under a one-sided model of the BASIC track for eligible ACOs. Specifically, we are finalizing the proposal to amend paragraph (1)(i), redesignate paragraphs (1)(ii) and (1)(iii) as paragraphs (1)(iii) and (1)(iv), and add new paragraph (1)(ii) of the definition of Performance-based risk Medicare ACO initiative in § 425.20. We are amending paragraph (1)(i) to apply to performance years beginning prior to January 1, 2023, and we are adding paragraph (1)(ii) to apply for performance years beginning January 1, 2023, and in subsequent years, to include only Levels C through E of the BASIC track, and to remove the one-sided Levels A and B from the definition. We are also finalizing as proposed, changes to the definition of ''Experienced with performance-based risk Medicare ACO initiatives'' and ''Inexperienced with performance-based risk Medicare ACO initiatives'' in § 425.20 by removing the phrase ''prior to the agreement start date''. This

change allows for a rolling lookback period (applicable to both the assessment of an ACO's application to participate under a participation option for an agreement period and to ongoing compliance determinations under proposed § 425.600(h)) of the 5 most recent performance years beginning from the current performance year being. We are also finalizing the amendatory instructions for § 425.20, to include corrections to typographical errors in punctuation. In § 425.224(a)(4), we are finalizing the proposal to remove the reference to ''a one-sided model of the BASIC track's glide path (Level A or Level B),'' so that renewing and re-entering ACOs that previously participated in a one-sided model of the BASIC track's glide path but that are not identified as having participated in a two-sided model are not limited to reapplying for participation in a two-sided model.

We are also finalizing as proposed our revisions to § 425.600. We are amending paragraph (a)(4)(i)(B) to apply to agreement periods beginning on or after July 1, 2019 and before January 1, 2024. We are finalizing as proposed the new § 425.600(a)(4)(i)(B)(*2*)(*vi)* and *(vii)* to allow an ACO currently participating in Level A or Level B of the BASIC track to elect to remain at that level for the remainder of their agreement period for both performance year 2023 and performance year 2024, respectively, and corresponding changes to § 425.600(a)(4)(i)(B)(*2*)(*ii*) and (*iv*). Additionally, we are finalizing as proposed the streamlining of the specification of the BASIC track glide path in § 425.600(a)(4)(i)(C) for agreement periods beginning on or after January 1, 2024, which includes paragraphs related to the following: (1) glide path entry; (2) automatic advancement; (3) the option for eligible ACOs to elect to remain under a one-sided model; (4) requirements to be met before entering performance-based risk; (5) agreement termination for failure to meet certain requirements; and (6) automatic advancement along the BASIC track's glide path in performance years following an ACO's election to transition to a higher level of risk and reward.

Additionally, we are finalizing as proposed our revision to limit the monitoring of BASIC track ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period, for changes in revenue, as specified under § 425.600(e) to apply to performance years beginning on or after July 1, 2019, and before January 1, 2024. We are finalizing as proposed the new paragraph (h) of § 425.600 applicable for performance years beginning on or after January 1, 2024, to specify our approach for monitoring ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model.

After consideration of the public comments, we are finalizing without modification the new § 425.600(g) which defines an ACO's participation options based solely on the ACO's level of experience with performance-based risk Medicare ACO initiatives for agreement periods beginning on or after January 1, 2024. Therefore, we are also finalizing as proposed the change at § 425.600(d) to limit it to agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

We also sought comment on whether to extend the proposed option for certain ACOs inexperienced with performance-based risk Medicare ACO initiatives to spend an entire 5-year agreement period under the one-sided model of the BASIC track for an additional agreement period for low revenue ACOs that enter the BASIC track as a new legal entity (that has never before participated in the Shared Savings Program and is not identified as a renewing or re-entering ACO), so that these ACOs would be eligible for a second one-sided only agreement period followed by a third agreement period in the BASIC track glide path, which would include an additional 2 years under the one-sided model (for a total of 12 years under the one-sided model) before progressing to two-sided risk. We noted that we considered extending this participation option only to low revenue ACOs that enter the BASIC track as a new legal entity because other ACOs have already had time under the one-sided model, and therefore, do not need a second agreement period in one-sided only. Although, as we noted previously, using revenue status in determining the participation options available to ACOs may disincentivize certain providers and suppliers from forming ACOs or joining existing ACOs, we also noted that we have observed that there are differences in financial performance outcomes based on revenue status. An independent study found the first three entry cohorts of physician-group ACOs (ACOs whose core medical groups for beneficiary attribution were not associated with hospitals, which are generally low revenue) consistently reduced spending as their first agreement periods progressed such that average per beneficiary benefit spending was reduced by $300 in 2015 compared to only $37 lower for hospital-integrated ACOs (ACOs whose core medical groups for beneficiary attribution were part of larger organizations or health systems that included hospitals).[272] Therefore, we discussed that we estimated that this alternative could increase program retention for the type of ACO that, as a group, has demonstrated greater program savings under an upside-only incentive in the past (that is, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives) and increase program savings (net of shared savings payments) by at least $1 billion.

As discussed in the CY 2023 PFS proposed rule, under this alternative, a voluntary election by a qualifying ACO to remain in Level A for the entirety of its second agreement period in the BASIC track would be made in the form and manner and by a deadline established by CMS. In the case of a qualifying ACO that elects to remain in Level A for the entirety of its second agreement period in the BASIC track that is determined to be low revenue at the time of application for renewal to a third agreement period in the BASIC track, the ACO generally would be eligible to enter into this subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years under the one-sided model. If an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have a total of 12 years under the one-sided model in the BASIC track.

As discussed in the CY 2023 PFS proposed rule, if we were to adopt this alternative, we noted our concern about the possibility that an ACO may be found eligible to continue for a full second agreement period under a one-sided model of the BASIC track because of a determination that it is an inexperienced, low revenue ACO at the time of application, and then quickly thereafter seek to add experienced and/or higher revenue ACO participants, thereby avoiding the requirement under our proposed participation options to move to the glide path for the second agreement period under the BASIC track if it did not meet the eligibility requirements to continue under the one-sided model for the entire agreement period. To protect against these circumstances, we noted we would continue monitoring for experience with performance-based risk Medicare ACO initiatives. Furthermore, we discussed

[272] McWilliams JM, et al. Medicare Spending After 3 Years of the Medicare Shared Savings Program. *New England Journal of Medicine.* Sept. 2018. 379:1139–1149. DOI: 10.1056/NEJMsa1803388.

that we would establish a monitoring policy to monitor for changes to revenue status during the ACO's second agreement period in the one-sided model of the BASIC track, to ensure that the ACO continues to meet the definition of a low revenue ACO (as well as an ACO inexperienced with performance-based risk Medicare ACO initiatives). We discussed that we would take the following approach to ensuring continued compliance of ACOs with the eligibility requirements for this alternative participation option. When an ACO applies for a second agreement period entirely under the one-sided model of the BASIC track, we would determine whether the ACO would be a high- or low revenue ACO (and an ACO inexperienced or experienced with performance-based risk Medicare ACO initiatives) as defined under § 425.20, using the ACO's ACO participant list for the first performance year of the new agreement period. Only low revenue ACOs would be eligible to elect this participation option to remain in Level A for the entirety of their second agreement period under the BASIC track, and we would continue to monitor for revenue status (as well as experience with performance-based risk Medicare ACO initiatives) during the second agreement period. If, during the second agreement period, the ACO began to meet the definition of a high revenue ACO (or an ACO experienced with performance-based risk Medicare ACO initiatives), we proposed that the ACO would be permitted to complete the remainder of its current performance year under Level A, but the ACO would be ineligible to continue participation in Level A after the end of that performance year unless it took corrective action. For example, if the ACO participants' total Medicare Parts A and B FFS revenue increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list, so that the ACO could continue to meet the definition of low revenue ACO. In the event the ACO did not take steps to maintain its status as a low revenue ACO, we would take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, to ensure the ACO did not continue in Level A for subsequent performance years of the agreement period. For example, we would send the ACO a request for a corrective action plan to resolve their change in revenue status, which would allow the ACO time to modify its ACO participant list or PECOS enrollment data such that the ACO could continue to meet the definition of a low revenue ACO. If the ACO continued to meet the definition of a high revenue ACO at the end of the next performance year (that is, based on the ACO's proposed ACO participant list for the following performance year), we proposed that the ACO would be required to move to the level of the BASIC track's glide path in which the ACO would be participating for the following performance year if it had begun the agreement period in the BASIC track's glide path instead of under the one-sided model-only path. This includes meeting the applicable requirements prior to entering performance-based risk, such as establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting an MSR/MLR from the options specified under § 425.605(b). Under this alternative, if an ACO remained either high revenue or experienced with performance-based risk Medicare ACO initiatives based on the ACO's proposed ACO participant list for the following performance year, the ACO would be required to move to Level E, as discussed in the CY 2023 PFS proposed rule for monitoring for changes in risk experience.

As discussed in the CY 2023 PFS proposed rule, when the ACO applied for a third agreement period under the BASIC track, we would determine revenue status at the time of application. Only low revenue ACOs that continued to be inexperienced with performance-based risk Medicare ACO initiatives and had entered into a participation agreement under the BASIC track only twice would be eligible to enter the BASIC track glide path. If at time of application CMS determined the ACO was a high revenue ACO as defined under § 425.20 (or if the ACO met the definition of experienced with performance-based risk Medicare ACO initiatives), then it would be required to participate in Level E of the BASIC track (or the ENHANCED track) for the agreement period, rather than entering the BASIC track glide path. If at any time during the ACO's third agreement period CMS determined the ACO had begun to meet the definition of a high revenue ACO (or of an ACO experienced with performance-based risk Medicare ACO initiatives), the ACO would be permitted to complete the remainder of the current performance year under the ACO's current level of the glide path, but would be ineligible to continue participation in the glide path after the end of that performance year and would be moved to Level E of the BASIC track unless the ACO took corrective action to modify its ACO participant list as described above.

The following is a summary of the public comments received on the request for comments on the alternative policy of offering new legal entity, low revenue, inexperienced ACOs an additional agreement period in Level A of the BASIC track.

Comment: We received three comments in response to our request for comments on offering new legal entity, low revenue, inexperienced ACOs an additional agreement period in Level A, for a potential total of 12 years in a one-sided model, prior to progressing to performance-based risk. One commenter expressed support, citing experience in risk-sharing arrangements as one of the most critical variables explaining the success of rural ACOs. Another believed that 7 years in the one-sided model is enough and did not believe such an extension was necessary. This commenter also expressed that limiting participation options to only one agreement period entirely in the one-sided model is in the best interest of the Medicare Trust Funds. A third commenter suggested that CMS should consider allowing all inexperienced ACOs—regardless of revenue status—to remain in Level A of the BASIC Track for two full agreement periods.

Response: We appreciate the commenters' input on offering this cohort of ACOs an additional agreement period in Level A, and for their emphasis on providing ACOs with needed flexibility while also protecting the Medicare Trust Funds. At this time, we are not taking further action on this alternative policy discussed in the CY 2023 PFS proposed rule, but we may consider pursuing this in future rulemaking.

(3) Remove the Limitation on the Number of Agreement Periods an ACO Can Participate in Level E of the BASIC Track

We proposed to make the ENHANCED track optional by adding § 425.600(g)(2) to specify that if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter Level E of the BASIC track under § 425.600(a)(4)(i)(A)(*5*) for all performance years of the agreement period, or the ENHANCED track under § 425.600(a)(3). These options would be available without regard to the ACO's status as a high- or low revenue ACO. We also proposed that all ACOs would be permitted to participate indefinitely under the Level E of the BASIC track. This would include ACOs currently in the ENHANCED track or that participate

under the ENHANCED track in the future. These ACOs would be permitted to enter a new participation agreement under Level E of the BASIC track. As explained in the CY 2023 PFS proposed rule, there are current limitations on how long ACOs may participate in Level E of the BASIC track, and some ACOs have reported that they would rather leave the program than be required to move to the ENHANCED track. We explained that in our implementation of the Shared Savings Program, we intend to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for Medicare FFS beneficiaries. We continuously seek to balance creating sufficient incentives for participation in a voluntary program with ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds. Accordingly, in the CY 2023 PFS proposed rule, we discussed our belief that it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under Level E of the BASIC track, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track. Our experience shows that ACOs in Level E of the BASIC track and ACOs in the ENHANCED track have similar performance results. We noted that our belief that it is important to offer this option to encourage ACOs that may be ready to take on the higher level of risk and potential reward under the ENHANCED track to progress to that participation option, secure in the knowledge that the more moderate level of risk and potential reward under Level E of the BASIC track would be available to the ACO in the future if the ACO concludes based on experience that that participation option is more appropriate for the ACO than the ENHANCED track. We anticipated providing education and offering outreach to ACOs on the available participation options through various methods available, including ACO Coordinators, guidance documents, tip sheets, FAQs, and a biweekly newsletter to assist ACOs as they navigate to higher levels of risk and potential reward throughout their participation in the program. Table 56 summarizes the proposed participation option policies on which we sought comment.

In conjunction with the proposed changes to the participation options available under the program, we proposed making several technical and conforming changes to the existing regulations. We proposed to modify § 425.600(a)(4)(ii) to reference paragraph § 425.600(g)(2) in addition to the currently identified paragraph (d). We proposed to add § 425.605(b)(2)(ii)(E) to include a provision for an ACO to select its MSR/MLR if it automatically transitions from Level A to Level E of the BASIC track's glide path under the new § 425.600(h)(2). Lastly, we proposed to modify § 425.605(d)(1) and (d)(2) to reference paragraph (g) in addition to the current reference to paragraph (d). We sought comment on these proposals, as well as all proposals in the relevant section of the CY 2023 PFS proposed rule, and related issues.

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TABLE 56: Participation Options

ACO type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation Options		
		First Agreement Period (or Subsequent for Renewing/Re-entering ACOs, or Current for Currently Participating ACOs)	Next Agreement Period	Future Agreement Periods
New legal entity (An ACO that has never participated in the Shared Savings Program and is not identified as a re-entering ACO or a renewing ACO)	Inexperienced*	A, A, A, A, A via one-time election prior to the start of the second performance year	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
New legal entity (An ACO that has never participated in the Shared Savings Program and is not identified as a re-entering ACO or a renewing ACO)	Experienced	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Inexperienced– former BASIC track Level A or B	A, B, C, D, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Inexperienced* – former Track 1	A, A, A, A, A via one-time election prior to the start of the second performance year	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Experienced – participated under Track 2, 3, BASIC track Level C, D, or E, ENHANCED track, the Track 1+ ACO Model, or another performance-based risk ACO initiative	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Currently participating ACO in Level A or B for PY 2022	Inexperienced* – BASIC track Level A or B	Current level (remain at A or B for remainder of current agreement period)	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
ACOs in Level A or B with agreement periods beginning on January 1, 2023	Inexperienced* – BASIC track Level A or B	Current level (remain at A or B for remainder of current agreement period)	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
Renewing ACO	Inexperienced	A, B, C, D, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Renewing ACO	Experienced – participated under Track 2, 3, BASIC track Level C, D, or E, or ENHANCED track, the Track 1+ ACO Model, or another performance-based risk ACO initiative	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track

Any ACO, regardless of type or experience level, may elect to progress more quickly along the BASIC track glide path or to apply to enter a new agreement period under the ENHANCED track at any time.

*Under § 425.600(h), if an inexperienced ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (as specified in § 425.20), that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year.

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The following is a summary of the public comments received on the proposed revisions to remove the limitation on the number of agreement periods an ACO can participate in Level E of the BASIC track and our responses:

Comment: All comments received which included mention of CMS' proposal to allow ACOs to remain in Level E of the BASIC track indefinitely and elect to not move to the ENHANCED track were supportive. Commenters noted that the flexibility provided by the proposal would encourage continued participation in the Shared Savings Program. Commenters mentioned that this change would help ensure the long-term success of the Shared Savings Program as ACOs in Level E would still be assuming substantial levels of risk and contributing greatly to protecting the Trust Funds.

Response: We appreciate the commenters for their support of this proposal.

Comment: Multiple commenters, while supportive of the proposal as written, offered an alternative (if the proposal were not finalized as proposed) for CMS to perform the check for high-revenue ACO status 60 days

before the Shared Savings Program application period opens. The stakeholders noted this change would enable existing ACOs that move from low revenue to high revenue status adequate time to apply for the ENHANCED track when the application period opens.

Response: We thank these commenters for their suggestion in the event we did not finalize this policy as proposed. As we are finalizing the policy as proposed, we will not incorporate these suggestions, but may consider them as may be relevant in future rulemaking.

After consideration of the public comments, we are finalizing without modification the new § 425.600(g), and the conforming changes to § 425.600(a)(4)(ii), § 425.605(b)(2)(ii)(E), and § 425.605(d)(1) and (d)(2).

3. Determining Beneficiary Assignment Under the Shared Savings Program

a. Proposed Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

For the performance year beginning on January 1, 2022, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(vi) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

(A) *CPT codes:*

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(9) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(10) 99439 (code for non-complex chronic care management).

(11) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(12) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(13) 99495 and 99496 (codes for transitional care management services).

(14) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) *HCPCS codes:*

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in ETA hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 and G2252 (codes for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(13) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) Revisions

(a) HCPCS and CPT Codes Used in Assignment

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we proposed to recognize for payment starting in CY 2023, we discussed in the proposed rule our belief that it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years in order to remain consistent with billing and coding guidance under the PFS.

We proposed to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Prolonged services HCPCS codes GXXX2 and

GXXX3, if finalized; and (2) Chronic Pain Management HCPCS codes GYYY1 and GYYY2, if finalized. The following provides additional information about the HCPCS codes that we proposed to add to the definition of primary care services used in assignment:

• *Prolonged Services Codes GXXX2 and GXXX3:* In section II.F of the proposed rule, we proposed that prolonged nursing facility services furnished by a physician or non-physician practitioner (NPP) would be reportable under GXXX2, which would be used when the total time for the primary service is exceeded by 15 or more minutes to account for the additional time spent. The long descriptor would be GXXX2 (*Prolonged nursing facility* evaluation and management *service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility* evaluation and management *services). (Do not report GXXX2 on* the same *date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report GXXX2 for any time unit less than 15 minutes*)). Prolonged physician or NPP nursing facility (NF) services would be reportable once 95 minutes are spent for initial NF visits, and once 85 minutes are spent for subsequent NF visits, and for each additional 15 minutes furnished thereafter. Because GXXX2 would be reportable for each additional 15-minute increment of time beyond the total time for CPT codes 99306 and 99310, which are included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we noted our belief that GXXX2 should also be included in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for the code is made permanent through the CY 2023 PFS rulemaking, since this code would represent the provision of services that are already included in the definition of primary care services for a longer period of time.

Additionally, we proposed that prolonged home or residence services by a physician or NPP would be reportable under GXXX3 (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately* in *addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report GXXX3 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report GXXX3 for any time unit less than 15 minutes*)). Because code GXXX3 would be reportable as an add-on code to CPT codes 99345 or 99350 once the practitioner spends 15+ minutes beyond the total time finalized for the primary service, and CPT codes 99345 and 99350 are included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we expressed our belief that GXXX3 should also be included in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for the code is made permanent through the CY 2023 PFS rulemaking, since this code would represent the provision of services that are already included in the definition of primary care services for a longer period of time.

• *Chronic Pain Management (CPM) HCPCS codes GYYY1 and GYYY2:* In section II.E of the proposed rule, we proposed two new HCPCS codes for CPM services, beginning January 1, 2023. We recognized that there is no existing code that specifically describes the work of the clinician involved in performing the tasks necessary to perform holistic, CPM under current Medicare payment policy. These new HCPCS codes would be analogous to Chronic Care Management (CCM) services and Principal Care Management (PCM) services because GYYY1 would include similar care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional, as described in CPT code 99424; and GYYY2 would include similar activities as described in CPT code 99425, both of which already are included in the Shared Savings Program definition of primary care services used in assignment. Additionally, we discussed in the proposed rule our expectation that most of these services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain and we expect the billing practitioner to demonstrate in the Medicare patient's record when there is coordination or continuity of care between a specialist or other relevant practitioner, such as a physical therapist or occupational therapist, which, we indicated, supports the inclusion of the services described by these HCPCS codes in our definition of primary care services for purposes of beneficiary assignment under the Shared Savings Program. Under the Shared Savings Program, CCM services reported using CPT codes 99437, 99439, 99487, 99489, 99490 and 99491 and HCPCS code G2058 and PCM services reported using CPT Codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065 currently are included in the definition of primary care services for purposes of beneficiary assignment (refer to 85 FR 84749 and 86 FR 65274 through 65275) and as such, to remain consistent with updates to the scope of care management services payable under the PFS, we proposed to include these CPM services codes, if finalized, in the definition of primary care services used for beneficiary assignment. Accordingly, we proposed to include HCPCS code GYYY1 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g., physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1 30 minutes must be met or exceeded.))* and GYYY2 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). When using GYYY2 15 minutes must be met or exceeded.)* because GYYY2 is similar in scope as

GYYY1, just for additional duration, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for these codes is made permanent through the CY 2023 PFS rulemaking.

(b) Technical Update to the Description of CPT Codes 99341 Through 99350

In the CY 2019 PFS final rule (83 FR 60093), we updated our regulations at § 400(c)(1)(iv)(A)(*4*) by adding the descriptor ''codes for evaluation and management services furnished in a patients' [sic] home for claims identified by place of service modifier 12'' to CPT codes 99341 through 99350, as used in the definition of primary care services used in assignment for performance years (or a performance period) starting during 2019 and PY 2020. This descriptor, slightly modified to correct a typographical error, also applied for the performance year starting on January 1, 2021, under § 425.400(c)(1)(v)(A)(*5*) and continues to apply for the performance year starting on January 1, 2022, and subsequent performance years, under § 425.400(c)(1)(vi)(A)(*5*).

On March 17, 2021, the AMA updated the CPT® Editorial summary of Panel Actions for February 2021 (*https://www.ama-assn.org/system/files/2021-03/february-2021-summary-panel-actions.pdf*). This summary describes revisions made to Home and Residence Services to revise the guidelines for CPT codes 99341 through 99350 to include services provided in assisted living facilities, group homes, custodial care facilities, and residential substance use treatment facilities. As discussed in section II.C of the proposed rule, we proposed to adopt these changes under Medicare FFS payment policies and as such, we proposed conforming changes to omit the reference to ''for claims identified by place of service modifier 12'' from the description for CPT codes 99341 through 99350. We proposed that the modification would be reflected in the definition of primary care services used in assignment for the performance year starting on January 1, 2023, and subsequent performance years at § 425.400(c)(1)(vii)(A)(*5*).

As proposed, CPT codes 99341 through 99350 would be described as codes for evaluation and management services furnished in a patient's home, without the place of service 12 identifier. The place of service logic is included in claims processing algorithms, and therefore, accounted for in paid claims used by the Shared Savings Program in determining beneficiary assignment. As described in Medicare Claims Processing Manual, Publication 100–04, Chapter 26, place of service codes are two-digit codes placed on health care professional claims to indicate the setting in which a service was provided. Claims submitted for services that are allowable when provided in certain settings will process only when the appropriate place of service is included on the claim. Place of service 12 is defined as ''location, other than a hospital or other facility, where the patient receives care in a private residence.'' In previous rulemaking, we updated the reference to CPT codes 99341 through 99350 in the definition of primary care services at § 425.400(c) to include place of service 12 for clarity; however, as discussed in the proposed rule, we now believe it is no longer accurate as these codes have been revised to include multiple places of service, any of which we would consider to be the patient's home.

(c) Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA) of 2021, was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals that were CAHs or rural hospitals with not more than 50 beds, participating in Medicare, as of the date of enactment of the CAA, are eligible to seek conversion to an REH. REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas. Section 1861(kkk)(1)(A) of the Act defines the term ''REH services'' as emergency department and observation services, as well as other medical and health services furnished on an outpatient basis as specified by the Secretary.

Under section 1861(k)(10) of the Act, payments will be made for REH services furnished on or after January 1, 2023. We expect that REHs will submit claims in a similar manner to hospital outpatient departments paid under the OPPS. As a result, we explained in the proposed rule our belief that we did not need to propose special policies regarding the treatment of services furnished in REHs for purposes of beneficiary assignment under the Shared Savings Program. Rather, we would consider services furnished in REHs in the same manner that we currently consider services furnished in hospital outpatient departments for purposes of conducting assignment under the Shared Savings Program. However, we noted that we would continue to monitor the development of payment policy for REHs to determine whether any adjustments to our assignment policies may be necessary to account for services furnished in REHs and would consider whether any findings may warrant changes through future notice and comment rulemaking. In addition, we noted that in section III.G.3.b. of the proposed rule, we proposed to include on an ACO's ACO provider/supplier list any CCNs that may be deactivated and then reactivated, or disenrolled as one facility type but re-enrolled as another facility type, which would include any CAHs that elect to re-enroll as rural emergency hospitals.

We proposed to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vii) to include the list of HCPCS and CPT codes specified in § 25.400(c)(1)(vi) along with the proposed additional HCPCS codes GXXX2 and GXXX3, and GYYY1 and GYYY2, if these additional codes were finalized through the CY 2023 PFS rulemaking. We further proposed to omit from the description for CPT codes 99341 through 99350, the reference to ''for claims identified by place of service modifier 12.'' We proposed that the new provision at § 425.400(c)(1)(vii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years. Further, we proposed technical modifications to the introductory text in § 425.400(c)(1)(vi) to limit the applicability of this provision to the performance year starting on January 1, 2022.

We sought comment on the proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2023, and subsequent performance years. We also welcomed comments on any other existing HCPCS or CPT codes and proposed HCPCS or CPT codes, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

The following is a summary of the public comments received on the proposed revisions to the HCPCS and

CPT codes used in assignment and our responses:

Comment: Many commenters supported the inclusion of the CPM HCPCS codes GXXX2 and GXXX3 and new prolonged services codes GYYY1 and GYYY2 in the definition of primary care services used in assignment. Some commenters agreed with our statement that the new prolonged services HCPCS codes reflect the provision of services beyond the total time for codes currently included in the Shared Savings Program definition of primary care services used in assignment. An additional commenter stated their belief that these additional beneficiary assignment codes will positively impact beneficiary assignment for ACOs providing care to the most serious and chronically ill patients.

A couple of commenters did not support the addition of chronic pain management codes, suggesting that the management of chronic pain does ''not routinely follow the overall health of the patient; it is often managed by a very specialized set of skills that are focused on treating a specific condition'' and that chronic pain seems to fall outside the definition of ''primary care services'' as intended in the original design of the model. Another commenter stated that they oppose inclusion of the proposed codes due to unspecified potential unintended consequences that could result in assignment of beneficiaries to ACOs based on care that is provided outside of the ACO's control.

A couple of commenters recommended that CMS monitor the utilization of both the CPM and prolonged services codes to ensure that they are being furnished as primary care services. One of these commenters supported the inclusion of the codes with monitoring to ensure that they adequately reflect beneficiaries' receipt of primary care services, while the other did not support the use of the codes until after monitoring for the same. The commenters stated that if the codes are primarily being billed by non-primary care physicians, it would not be appropriate to use them in assignment.

Response: We agree with commenters who stated that our proposal to revise the definition of primary care services used for assignment will positively impact beneficiary assignment for ACOs providing care to the most serious and chronically ill patients. While the commenters did not provide additional rationale for how beneficiary assignment would be positively impacted, we interpret this comment to mean that beneficiary assignment would be more inclusive of serious and chronically ill patients which could increase assigned beneficiaries for certain ACOs. We further agree, as explained earlier in this section of this final rule, that CPM services are analogous to CCM and PCM services already included in the definition of primary care services used in assignment, and that the new prolonged services HCPCS codes reflect the provision of services beyond the total time for codes currently included in the Shared Savings Program definition of primary care services used in assignment.

We acknowledge the commenters that opposed or expressed concerns about the inclusion of these HCPCS codes in the definition of primary care services used in assignment and recognize that these are newly developed codes without historical utilization patterns. As described in our proposal, we expect that most of these services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain. Commenters were not specific in discussing unintended consequences that could occur, should these services be added to the definition of primary care services used in beneficiary assignment, so we are not persuaded by these comments.

Additionally, we continue to believe that CPM services are analogous to PCM and CCM services which are already included in the definition of primary care services used for beneficiary assignment, and we are not persuaded by commenters' feedback that chronic pain falls outside a reasonable definition of ''primary care services'' for purposes of beneficiary assignment in the Shared Savings Program. In section II.F of this final rule, which finalizes the payment policies for the new CPM codes, we reiterate our belief that most CPM services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain. As calls for improved pain management have increased in recent years, this has resulted in better education and training of primary care practitioners and heightened awareness of the need for pain care nationally. We believe the codes being finalized for CPM services will create appropriate payment for physicians and other practitioners (including but not limited to primary care practitioners) that reflects the time and resources involved in attending comprehensively to the needs of beneficiaries with chronic pain.

As a ''pre-step'' in the claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations specified in § 425.402(c). Under claims-based assignment, CMS assigns beneficiaries to ACOs through either one of two steps. Under Step 1, CMS assigns a beneficiary to a Shared Savings Program ACO when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by primary care physicians, nurse practitioners, physician assistants and clinical nurse specialists in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CCN, or non-ACO individual or group TIN. Step 2 only applies to assignable beneficiaries who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO and were therefore not assigned in assignment Step 1. CMS assigns a beneficiary to a Shared Savings Program ACO in this step when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by physicians who are ACO professionals with specialty designations as specified in § 425.402(c) in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CCN, or non-ACO individual or group TIN. We expect that the assignment algorithm will ensure appropriate assignment to an ACO when using these CPM and prolonged services HCPCS codes and we will monitor the billing and utilization of these codes to ensure that their inclusion in the definition of primary care services used for beneficiary assignment is appropriate, including by monitoring and evaluating place of service and provider specialty associated with billed claims for these CPM and prolonged services HCPCS codes. If monitoring shows that the inclusion of these services in the definition of primary care services used for beneficiary assignment is not appropriate, we will address that concern in future notice and comment rulemaking.

Comment: A few comments provided general support of our proposal to make conforming changes to omit the reference to ''for claims identified by place of service modifier 12'' from the description for CPT codes 99341 through 99350. One commenter indicated strong support because these coding changes will help bring transparency to the services provided in

those settings. These commenters believe that under current coding and billing conventions, ''home'' services are all lumped together and thus difficult to untangle and analyze productively.

Response: We agree that our proposal to adopt technical updates to the Shared Savings Program beneficiary assignment regulations is important for determining where patients receive most of their primary care while also ensuring that the definition of primary care services used for purposes of assignment remains in alignment with HCPCS/CPT coding changes made under the PFS. As discussed in Section II.C of this final rule, for CY 2023, the home and domiciliary E/M code family will be revised by the CPT to include services provided in assisted living facilities, group homes, custodial care facilities, and residential substance abuse treatment facilities, as well as a patient's home. These changes include combining the domiciliary and rest home CPT codes with the home visit CPT codes, resulting in a single family of CPT codes that describe these types of services.

In consideration of the public comments, we are finalizing as proposed a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vi) along with the following additions: (1) Prolonged services HCPCS codes GXXX2 and GXXX3, which are being finalized as G0317 *((Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report G0317 for any time unit less than 15 minutes))* and G0318 *((Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report G0318 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report G0318 for any time unit less than 15 minutes)),* respectively, as discussed in section II.F of this final rule; and (2) Chronic Pain Management HCPCS codes GYYY1 and GYYY2, which are being finalized with modifications to the descriptions as discussed in section II.E of this final rule as G3002 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g., physical therapy and occupational therapy, and complementary and integrative approaches, and community-based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.))* and G3003 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for G3002). (When using G3003, 15 minutes must be met or exceeded.)),* respectively.

We are also finalizing as proposed the conforming changes to omit the reference to ''for claims identified by place of service modifier 12'' from the description for CPT codes 99341 through 99350.

We are additionally finalizing as proposed that the new provision at § 425.400(c)(1)(vii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years. Further, we are finalizing as proposed technical modifications to the introductory text in § 425.400(c)(1)(vi) to limit the applicability of this previous provision to the performance year starting on January 1, 2022.

We did not receive any feedback on the discussion of how REHs would be treated for purposes of beneficiary assignment. We affirm that we will continue to monitor the development of payment policy for REHs to determine whether any adjustments to our assignment policies may be necessary to account for services furnished in REHs and will consider whether any findings may warrant changes through future notice and comment rulemaking.

b. Identifying How CMS Certification Numbers Will Be Included and Used in Beneficiary Assignment

(1) Background

Under the Shared Savings Program, ACOs are accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries that are assigned to the ACO (§ 425.100(a)). ACOs are formed by one or more ''ACO participants,'' which are responsible for managing and coordinating care for the assigned beneficiary population. The Shared Savings Program regulations define ''ACO participant'' at § 425.20 as an entity identified by a Medicare-enrolled billing Taxpayer Identification Number (TIN) through which one or more ''ACO providers/suppliers'' bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118 (herein ''ACO participant list''). An ''ACO provider/supplier'' is an individual or entity that: (1) is a provider (as defined at § 400.202) or supplier (as defined at § 400.202); (2) is enrolled in Medicare; (3) bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers that is required under § 425.118 (herein ''ACO provider/supplier list''). CMS requires each ACO to execute contractual agreements with each of its ACO participants (''ACO participant agreements''), to ensure that the ACO participant and each ACO provider/supplier billing through the TIN of the ACO participant agree to the requirements of the Shared Savings Program.

Under § 425.118(a), an ACO must maintain, update, and submit to CMS an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its

National Provider Identifier (NPI), CCN, or other identifier). All Medicare-enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of an ACO participant must be included on the ACO provider/supplier list (§ 425.118(a)(4)).

(a) Development and Maintenance of the ACO Participant List

An ACO must submit a draft ACO participant list before the start of an agreement period and before each performance year thereafter. CMS reviews the draft list, conducts a program integrity screening on the individuals and entities identified on the list, approves or rejects each entry on the list, and informs the ACO of the contents of the resulting ACO participant list. In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO participant list before the start of its agreement period and before each performance year thereafter.

An ACO must maintain and periodically update its ACO participant list. An ACO is required to notify CMS no later than 30 days after an entity ceases to be an ACO participant. The entity is deleted from the ACO participant list as of the termination date of the entity's ACO participant agreement. Absent unusual circumstances, the ACO participant's data will continue to be utilized for certain operational purposes. CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, or the obligation of the ACO to report on behalf of eligible clinicians who bill under the TIN of an ACO participant for certain CMS quality initiatives, to reflect the deletion of entities from the ACO participant list that become effective during the performance year.

If the ACO wishes to add an entity to its ACO participant list, it must submit a request to CMS. If CMS approves the request, the addition becomes effective on January 1 of the next performance year. ACO participants may not be added during a performance year.

The ACO participant list is critical to Shared Savings Program operations. CMS uses the ACO participant list to identify which entities are in the ACO, generate the ACO provider/supplier list, determine which Medicare FFS beneficiaries will be assigned to an ACO, establish the historical benchmark, perform financial calculations, and coordinate among CMS quality reporting initiatives.

(b) Development and Maintenance of the ACO Provider/Supplier List

In accordance with § 425.118, ACOs must submit to CMS before the start of an agreement period and before each performance year thereafter an accurate and complete list identifying each ACO provider/supplier (including its NPI, CCN, or other identifier). In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO provider/supplier list. In addition, ACOs are required to notify CMS of any changes in their ACO provider/supplier list in accordance with § 425.118(c). Specifically, an ACO must notify CMS within 30 days after an individual or entity becomes or ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare FFS beneficiaries under a billing number assigned to the TIN of an ACO participant (§ 425.118(c)).

For performance years starting on January 1, 2019, and subsequent performance years, CMS creates the initial ACO provider/supplier list for a performance year by using the Provider Enrollment, Chain, and Ownership System (PECOS) to identify by CCN and NPI all of the providers and suppliers, respectively, that have reassigned their right to receive Medicare payment to the TIN of an ACO participant. As with its ACO participant list, each ACO must review that initial list, make any necessary corrections, and certify the resulting ACO provider/supplier list prior to the start of a performance year and at such other times as specified by CMS.

(c) Use of Lists in Beneficiary Assignment

For PYs 2012 through 2018, ACOs were required to identify on their ACO participant list the CCNs for certain provider types (FQHCs, RHCs, Electing Teaching Amendment (ETA) hospitals, and Method II Critical Access Hospitals (CAHs)), as well as the ACO participant TIN under which the CCN was enrolled in Medicare. CMS required ACOs to identify CCNs and their associated TIN information because otherwise it would not be possible to identify the institutional claims billed by those providers for purposes of beneficiary assignment since TINs are not retained in the CMS Integrated Data Repository (IDR) for the claims submitted by FQHCs, RHCs, ETA hospitals, and Method II CAHs.

Additionally, ACOs that included FQHCs and/or RHCs on their ACO participant list were also required to identify, through an attestation, a list of physicians who directly provided primary care services in each FQHC or RHC (herein ''attestation list'') in accordance with § 425.404(a). The linkage of the physicians to the FQHCs and RHCs provided via the attestation list was necessary because physicians and other individual practitioners cannot reassign their Medicare billing rights to an FQHC or RHC CCN. Therefore, although FQHCs, RHCs, physicians, and other individual practitioners are all listed in PECOS, the PECOS reassignment data used to generate the ACO provider/supplier list could not have linked the NPI of a physician or other practitioner to the CCN of an FQHC or RHC and, in turn, to an ACO participant TIN. This attestation list was collected through the ACO's application to the Shared Savings Program and could be updated annually with changes, if any, which would take effect January 1 of the next performance year.

In accordance with § 425.404(b), for performance years starting on January 1, 2019, and subsequent years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim, identified using the CCN as a unique identifier for an individual FQHC/RHC, as a primary care service performed by a primary care physician. For performance years starting on January 1, 2019, and subsequent performance years, CMS uses PECOS to identify the CCN or NPI of each ACO provider/supplier enrolled under an ACO participant TIN. Specifically, CMS uses PECOS data to identify the following: (i) all Medicare enrolled entities (as identified by a CCN) that have enrolled under the TIN of an ACO participant; and (ii) all individual practitioners (as identified by an NPI) who have reassigned their right to receive Medicare payment to the TIN of an ACO participant. The resulting initial ACO provider/supplier list reflects PECOS enrollment information at a single point in time. An ACO may need to add or remove a provider or supplier who has reassigned his or her right to receive Medicare payment to the TIN of an ACO participant after the ACO certified its ACO provider/supplier list for the performance year. An ACO that needs to make a change to its certified ACO provider/supplier list must notify CMS within 30 days of the change.

For purposes of beneficiary assignment, we identify claims for services furnished by Method II CAHs, ETA hospitals, FQHCs, and RHCs using the CCN assigned to the facility. In general, ACO participants are identified by TINs. However, the TINs for Method

II CAHs, FQHCs, RHCs, and ETA hospitals are not included in the National Claims History and IDR claims files, so we use the CCN as the unique identifier to identify services furnished by these entities. Thus, for these providers, we use TINs from the certified ACO participant list and the associated CCNs sourced from PECOS as the basis for beneficiary assignment. We also use claims from participant TINs on the certified ACO participant list and the CCNs from the initial ACO provider/supplier list in the determination of whether an ACO is a high revenue ACO or low revenue ACO, as defined at § 425.20, and in the determination of beneficiary assignment upon which benchmark and performance year expenditure calculations are determined.

This approach allows CMS to identify ACO participant TINs and associated CCNs for the downstream operations necessary to prepare for the start of the performance year on January 1, including producing the ACO's list of prospectively assigned or preliminarily prospectively assigned beneficiaries, as applicable, at the start of each performance year.

Although the CCNs enrolled under a TIN may change during the course of an ACO's performance year, CMS' current operational process identifies any related CCN changes, through use of PECOS, only during the application process or the annual change request cycle. As with the certified ACO participant list, the CCNs used for purposes of beneficiary assignment and other operations are those that appear on the initial ACO provider/supplier list that is developed before the start of a performance year, and those CCNs remain applicable for the duration of the performance year. Any new CCNs that are established during a performance year are not used for purposes of beneficiary assignment and other operations until the start of the next performance year. The same applies to CCNs that become deactivated or change their TIN affiliation (that is, enroll under a different TIN) in PECOS during a performance year; those changes are not reflected in beneficiary assignment and other operations until the start of the next performance year. In PECOS, a ''deactivated'' enrollment status includes providers or suppliers whose Medicare billing privileges have been deactivated under § 424.540, as well as providers and suppliers that have voluntarily terminated their enrollment.

(2) Revisions

As discussed in the proposed rule, in order to administer the Shared Savings Program, we need to accurately identify all ACO participant TINs and ACO providers/suppliers that participate in the program. An accurate identification of the ACO participants and the CCNs that are ACO providers/suppliers in an ACO is critical for assignment of beneficiaries to the ACO, as well as for assessing the quality of care provided by the ACO to its assigned beneficiaries. An accurate identification of the individuals and entities participating in the ACO is also critical for ensuring compliance with program rules and equally important for the ACO and its own operational and compliance purposes. Thus, both CMS and the ACO need to have a common understanding of the individuals and entities that compose the ACO. We obtain this common understanding by requiring per § 425.118 that the ACO certify the accuracy of its ACO participant and ACO provider/supplier lists prior to the start of each performance year. In addition, we require the ACO to notify CMS of any changes to its ACO participant list and ACO provider/supplier list throughout the performance year. Because we rely on these lists for operational purposes, we must have a transparent process that results in the accurate identification of all ACO participants and ACO providers/suppliers, including CCNs, that compose each ACO in the Shared Savings Program.

Based on our operational experience, we have determined that our current process, wherein we use an ACO's certified ACO participant list and data from PECOS to generate the initial ACO provider/supplier list prior to the start of the performance year and to identify the CCNs used for purposes of beneficiary assignment and other operations, may not capture all changes to providers and suppliers that participate in an ACO during the performance year. Specifically, our current processes do not capture: (a) new CCNs that are enrolled in Medicare under ACO participant TINs after the initial ACO provider/supplier list for a performance year is generated; or (b) CCNs that are in a deactivated status as listed in PECOS at the time the initial ACO provider/supplier list for a performance year is generated.

A CCN enrollment can become active or be deactivated in PECOS at any time, and a CCN can change TIN affiliations over time, including during the course of an ACO's performance year. Developing the initial ACO provider/supplier list, including the CCNs used for purposes of beneficiary assignment and other operations, before the start of a new performance year, and having that list remain applicable for the duration of the performance year, prevents us from later capturing during the performance year any newly-enrolled CCNs affiliated with ACO participant TINs.

Not recognizing new CCNs that enroll under an ACO participant TIN after the initial ACO provider/supplier list is generated impacts the determination of beneficiary assignment, expenditure and revenue calculations, and coordination among CMS quality reporting initiatives. Analysis based on PY 2019, 2019A, 2020, and 2021 data has shown that considering only the CCNs on the ACO provider/supplier list that is established prior to the start of the performance year, has a significant impact on assignment for some ACOs that include FQHCs, RHCs, ETA hospitals, and Method II CAHs. We found that 555 CCNs newly enrolled or re-enrolled during the course of PY 2020. CCNs were added across 143 (28 percent) of the 517 participating ACOs. Among the 344 ACOs under preliminary prospective assignment with retrospective reconciliation, 96 ACOs (28 percent) would have been impacted if the newly-enrolled CCNs were added to the ACO's ACO provider/supplier list during the 2020 performance year. An estimated 42,000 additional beneficiaries could have been assigned based on primary care services provided by CCNs enrolled during the performance year. Over 80 percent (that is, approximately 28,000) of these additional beneficiaries would have been concentrated among 12 ACOs under preliminary prospective assignment with retrospective reconciliation.

Accordingly, we proposed in the CY 2023 PFS proposed rule to add a new provision at § 425.402(f) to reflect how CCNs are used in assignment. As proposed § 425.402(f)(1), prior to the start of the performance year and periodically during the performance year, CMS would determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status. Under proposed § 425.402(f)(2), we would use those CCNs in determining assignment for the performance year.

Under proposed § 425.402(f)(3), we set forth how we would account for changes in CCN enrollment status during a performance year. Under the proposal, CCNs that enroll under an ACO participant TIN during the performance year would be reflected in program operations, including but not

limited to: beneficiary assignment and revenue and expenditure calculations performed quarterly and during financial reconciliation for ACOs under preliminary prospective assignment with retrospective reconciliation. Specifically, if a new CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), we would consider services furnished by that CCN in determining assignment to the ACO for the applicable performance year if the ACO has selected preliminary prospective assignment with retrospective reconciliation. As discussed in the proposed rule, we believe it would be important to limit these updates to newly-enrolled CCNs during the performance year in order to ensure equivalency between historical benchmark expenditures and performance year expenditures. We proposed to codify this change in the regulations at § 425.402(f)(3)(i).

We further proposed that services furnished by a CCN with a deactivated enrollment status prior to that CCN becoming deactivated that is enrolled under the TIN of an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year. For purposes of this policy, we noted that we would use PECOS data to determine whether a CCN has a deactivated enrollment status. In the case of a CCN with a deactivated enrollment status that had multiple TIN affiliations prior to its deactivation, we proposed to use the TIN with which the CCN was most recently enrolled to identify the appropriate ACO participant, if any, to which services furnished by the CCN should be attributed. We believe that the inclusion of CCNs with a deactivated enrollment status in PECOS is consistent with our policy on the consideration of claims billed by merged/acquired TINs as discussed in the June 2015 final rule (80 FR 32715). We noted in the proposed rule that we believe that our rationale for the merged/acquired TIN policy also applies to CCNs with a deactivated enrollment status—namely, that (a) it is likely that the physicians and other practitioners furnishing primary care services billed via the CCN will continue to serve the same patient population that they served before the CCN deactivated its enrollment and (b) their patients may appear on the ACO's list of assigned beneficiaries at the end of the performance year. We discussed that we believe the proposed change would be important to maintain accuracy and comparability with regard to historical benchmark and performance year expenditure calculations. We proposed to codify this change in the regulations at § 425.402(f)(3)(ii).

The policy under proposed § 425.402(f)(3)(ii) would apply to CCNs that are deactivated but later reactivated, or that are disenrolled as one facility type but later re-enrolled as another type of ACO provider/supplier. For example, if a CCN for a Method II CAH was deactivated during PY 2022 and later re-enrolled as another facility type during PY2023, the services furnished by the deactivated CCN would be considered in determining the ACO's assigned beneficiary population and historical benchmark expenditures for PY 2023, which is not the case under current policy. Similarly, if a CCN for a Method II CAH was deactivated during PY 2022 and later re-enrolled as an REH with a new CCN in CY 2023, the services furnished by the deactivated CCN would be considered in determining the ACO's assigned beneficiary population and historical benchmark expenditures for PY 2023, which is not the case under current policy. By considering both the deactivated CCN and the new REH CCN in determining the ACO's assigned beneficiary population, we would ensure parity between historical benchmark expenditures and performance year expenditures.

We noted in the proposed rule that while we proposed a specific policy to include deactivated CCNs in assignment, a similar policy is not needed for deactivated NPIs. During the performance and benchmark years, deactivated NPIs are included in assignment by default if they are included on a claim during the applicable assignment window.

As discussed in the proposed rule, we believe it is necessary to continue our current operational process, to not allow CCNs to switch between ACOs during the performance year. That is, if a CCN that was enrolled under the TIN of one ACO participant enrolls under a different TIN during a performance year, we would continue to treat services billed by the CCN as services furnished by the original ACO participant TIN under which the CCN was enrolled. We believe it is most appropriate to continue our current process and operationally treat CCNs in a similar fashion to ACO participant TINs and not allow a CCN to switch between ACOs during the performance year, rather than treating them in a similar fashion to an NPI that would be allowed to switch between ACOs during a performance year due to the relative magnitude of services provided by and assignment associated with a CCN, as compared to a much smaller amount of services and assignment associated with a single NPI, as described above. This operational approach would limit the potential for large impacts on performance year expenditure calculations and reduce the potential for gaming opportunities. Including services billed by the CCN as services furnished by the ACO participant is consistent with our policy on the treatment of ACO participant TINs included on the ACO participant list, wherein an entity is deleted from the ACO participant list as of the termination of its ACO participant agreement but claims billed under the ACO participant TIN continue to be included in program operations until the end of the performance year. We proposed to codify this approach for CCNs in the regulations at § 425.402(f)(3)(iii).

We proposed to identify all CCNs associated with ACO participant TINs as determined by the methodology described in the preceding paragraphs for use in assignment and other operations prior to determining historical benchmarks, running quarterly assignment, and financial reconciliation. We noted that we also intend to develop a mechanism for reporting to ACOs all CCNs used in assignment and for purposes of program operations to provide for a transparent process. This CCN information would be provided to ACOs on a periodic basis for informational purposes, and this information will not need to be certified by the ACO.

We proposed that this revised approach to the treatment of CCNs would be applicable for purposes of all program operations for the performance year starting on January 1, 2023, and subsequent performance years. We sought comment on all aspects of this proposal.

The following is a summary of the public comments received on the proposed revisions to identifying how CMS certification numbers will be included and used in beneficiary assignment and our responses:

Comment: We received a few comments on this proposal and all were supportive of our proposed approach.

A couple of commenters stated that this approach would create a more accurate assignment list for ACOs that have participant providers that are FQHCs, RHCs, ETA hospitals, and CAHs. These commenters also

encouraged CMS to monitor the impacts of this new policy for unintended consequences, such as penalizing ACOs for bringing more safety net providers into the program. Other input included recommendations that CMS solicit feedback from ACOs on the reporting mechanism to ensure that ACOs affected by these policies have a clear understanding of assignment list changes during the performance year and how those changes affect program operations.

Response: We agree that finalizing this proposal will create a more accurate assignment list for ACOs that have FQHCs, RHCs, ETA hospitals and CAHs on their participant list as it will capture changes to CCN enrollment status that occur during the performance year. With regard to the suggestion to monitor the impacts of the use of CCNs in assignment for unintended consequences, such as penalizing ACOs for bringing more safety net providers into the Shared Savings Program, we will include analysis of this as part of our on-going monitoring. We appreciate the recommendation that CMS solicit feedback to ensure that ACOs affected by these policies have a clear understanding of assignment list changes during the performance year and how these changes impact program operations. As stated in our proposal, we intend to develop a mechanism for reporting to ACOs all CCNs used in assignment for the purposes of program operations to provide for a transparent process. This information will be provided to ACOs on a periodic basis throughout the performance year and will be in addition to the feedback provided on beneficiary and provider overlaps that is provided before the participant lists are finalized.

As a result of the public comments, we are finalizing our proposal to add a new provision at § 425.402(f) to reflect how CCNs will be used in assignment for PY 2023 and subsequent performance years. Under § 425.402(f)(1), prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status. Under § 425.402(f)(2), we will use those CCNs in determining assignment for the performance year. Finally, under § 425.402(f)(3), we specify how changes in CCN enrollment status during the performance year will be reflected in program operations, including but not limited to beneficiary assignment and revenue and expenditure calculations performed quarterly and during financial reconciliation for ACOs under preliminary prospective assignment with retrospective reconciliation. Specifically, under § 425.402(f)(3)(i), if a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS will consider services furnished by that CCN in determining beneficiary assignment to the ACO for the applicable performance year for ACOs under preliminary prospective assignment with retrospective reconciliation. Under § 425.402(f)(3)(ii), services furnished by a CCN with a deactivated enrollment status that is enrolled under an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year. Finally, under § 425.402(f)(3)(iii), if a CCN enrolled under the TIN of an ACO participant at the start of the performance year enrolls under a different TIN during a performance year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

These provisions are being finalized as applicable for purposes of all program operations for the performance year starting on January 1, 2023, and subsequent performance years.

4. Quality Performance Standard and Reporting

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59707 through 59715 respectively).

b. Revising the Shared Savings Program Quality Performance Standard

In the CY 2023 PFS proposed rule (87 FR 46127), we proposed to further refine the quality performance standard for PY 2023 and subsequent performance years through a combination of modifications. Specifically, we noted that we have concerns that the current structure of the quality performance standard creates a cliff of ''all-or-nothing'' scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum sharing rate for the applicable performance year. We proposed to adopt an alternative quality performance standard that incorporates a sliding scale to avoid this cliff. This flexibility would be even more important as ACOs transition to eCQM/MIPS CQM reporting and when the quality performance standard under the Shared Savings Program increases to the 40th percentile across all MIPS Quality performance category scores starting in PY 2024. Additionally, we proposed to modify our approach for determining shared losses for ACOs in the ENHANCED track that would allow more ACOs to receive a shared loss rate based on a sliding scale rather than automatically being subject to the maximum loss rate of 75 percent. We did not propose to change the current requirements for ACOs to be eligible to share in savings at the maximum sharing rate.

Second, we proposed to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the sunsetting of the CMS Web Interface reporting option.

Third, we proposed to establish a health equity adjustment that would upwardly adjust an ACO's quality performance score when it delivers high quality care to underserved populations in order to support those ACOs serving a high proportion of underserved individuals, while also encouraging all ACOs to treat underserved populations.

(1) Current Policy

In the CY 2021 PFS final rule, we finalized new Shared Savings Program quality reporting requirements that align with the Alternative Payment Model (APM) Performance Pathway (APP) under the Quality Payment Program and revised the quality performance standard under the Shared Savings Program for performance years beginning on or after January 1, 2021, to reduce reporting burden and focus on patient outcomes. We also finalized a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. Specifically, for PYs 2021 and 2022, an ACO would be required to achieve a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores to be eligible to share in any savings generated, and for 2023 and subsequent performance years, an ACO would be required to achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores to be eligible to share in savings (85 FR 84719 through 84736).

We also finalized modifications to the Shared Savings Program regulations on the use of ACO quality performance in determining shared savings and shared losses (85 FR 84736 through 84740). We explained that section 1899(d)(1)(A) of the Act specifies that an ACO is eligible to receive a shared savings payment for a portion of the savings generated for Medicare, provided that the ACO meets both the quality performance standards established by the Secretary and achieves the required level of savings against its historical benchmark. Section 1899(d)(2) of the Act authorizes payments of shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary (according to section 1899(b)(3) of the Act) and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO, may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. Section 1899(d)(2) of the Act also requires the Secretary to establish limits on the total amount of shared savings paid to an ACO. We have also incorporated performance-based risk in the form of shared losses into certain financial models under the Shared Savings Program using the authority under section 1899(i)(3) of the Act to use other payment models.

In the CY 2021 PFS final rule, we finalized an approach to incorporating ACO quality performance in determining shared savings that would allow ACOs to maximize the potential shared savings they could earn across the Shared Savings Program's financial models. Specifically, we replaced the previous sliding scale approach with an all-or-nothing approach to determining shared savings based on quality performance (85 FR 84735).[273] Thus, under the current regulations, for performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the quality performance standard established under § 425.512, the ACO will share in any savings generated at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. If the ACO fails to meet the quality performance standard, the ACO will be ineligible to share in savings. Further, we finalized an approach that continued to allow CMS to take into consideration an ACO's quality performance score in calculating the amount of shared losses for certain two-sided models (85 FR 84740).[274] We finalized the following approach to determining the shared loss rate for ACOs participating in the ENHANCED track for performance years beginning on or after January 1, 2021, as specified under § 425.610(f)(2). If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the sharing rate of 75 percent under the ENHANCED track.
- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. The shared loss rate may not exceed 75 percent and may not be less than 40 percent.

If the ACO fails to meet the quality performance standard, the shared loss rate will be 75 percent.

In the CY 2022 PFS final rule, we finalized an extended phase-in of the modified quality performance standard under the Shared Savings Program. Specifically, we extended the phase-in of the quality performance standard for an additional performance year (30th percentile for PYs 2021, 2022, and 2023). We also finalized that, for PYs 2022 and 2023, ACOs choosing to report on the 3 eCQMs/MIPS CQMs (meeting data completeness and case minimum requirements for all 3 measures) would meet the quality performance standard if they achieve a Quality performance category score equivalent to or higher than the 10th percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP measure set and achieve a Quality performance category score equivalent to or higher than the 30th percentile of the performance benchmark on at least 1 of the remaining 5 measures in the APP measure set (86 FR 65253 through 65272).

In summary, pursuant to the policies finalized in the CY 2022 PFS final rule (86 FR 65266 through 65270), a Shared Savings Program ACO, with the exception of an ACO in the first performance year of its first agreement period, will be eligible to share in savings at the maximum sharing rate if it:

- For PY 2023:

++ Achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ If the ACO reports the three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set. Consequently, the ACO would be required to meet the

[273] We finalized modifications to the regulations to reflect this approach for Track 1 (under § 425.604), Levels A through E of the BASIC track (under § 425.605), Track 2 (under § 425.606), and the ENHANCED track (under § 425.610). The modifications to the regulations under § 425.604(d) governing the determination of the final sharing rate for Track 1 ACOs also applied to Track 1+ Model ACOs (85 FR 84763). We note that participation in Track 1, Track 2 and the Track 1+ Model concluded at the end of PY 2021.

[274] This approach continued to allow use of the ACO's quality score in determining the shared loss rate under Track 2 (§ 425.606) and the ENHANCED track (§ 425.610). ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track continued to be subject to a fixed shared loss rate of 30 percent regardless of quality performance. As noted previously, participation in Track 2 and the Track 1+ Model concluded at the end of PY 2021.

performance benchmark on either 2 outcome measures (one measure at the 10th percentile and the other at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th percentile. The outcome measures in the APP measure set are listed in Table 63.

- For PY 2024 and subsequent performance years: Achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

We noted in the CY 2022 PFS final rule that we had received several comments suggesting that we revert to the previous sliding scale methodology used prior to the alignment with the APP for determining if an ACO has met the quality performance standard (86 FR 65268 and 65269). We stated in the CY 2022 PFS final rule in response to these comments that we would consider proposing to reinstate the sliding scale methodology for determining shared savings and shared losses in the CY 2023 PFS proposed rule for ACOs that report on the three eCQMs/MIPS CQMs. We stated that under such a proposed sliding scale methodology, we would multiply the ACO's MIPS Quality performance category score, based on the ACO's performance on the three eCQMs/MIPS CQMs as reported by the ACO, the two claims-based measures calculated by CMS, and the CAHPS for MIPS survey, by the sharing rate for the ACO's track (or payment model within a track) to determine the ACO's shared savings (86 FR 65269).

(2) Scale Shared Savings Based on Quality Performance

In light of the comments received during the public comment period for the CY 2022 PFS proposed rule, we proposed in the CY 2023 PFS proposed rule to reinstate a modified sliding scale approach for determining shared savings for all ACOs regardless of how they report quality data. In particular, commenters shared their concern that ACOs are now shifting from being compared against other ACOs to broadening this comparison to include all MIPS eligible clinicians (86 FR 65260). We also continue to hear this same concern from a number of interested parties. In addition, as discussed in the proposed rule, if the proposal were limited to eCQM/MIPS CQM reporting, it would require additional complexity specific to the requirements for scaled shared savings and scaled shared losses of the ENHANCED track. We refer readers to the proposed rule (87 FR 46131) for additional rationale for the proposal to apply the sliding scale approach to all ACOs regardless of how they report quality data.

We proposed in § 425.512(a)(4)(ii) and (a)(5)(ii) that, beginning with PY 2023 and for subsequent performance years, if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate but the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set then the ACO would share in savings (if otherwise eligible) at a lower rate that reflects the ACO's quality performance score (87 FR 46129). Specifically, the ACO's final sharing rate would be a scaled rate that is calculated by multiplying the maximum sharing rate for the ACO's track (or payment model within a track) by the ACO's quality performance score. The ACO's quality performance score used in this calculation would reflect the ACO's MIPS Quality performance category score plus any health equity adjustment bonus points the ACO is eligible to receive (referred to as the health equity adjusted quality performance score) based on the proposal described in section III.G.4.b.(7) of the proposed rule (87 FR 46132).

For an example of the proposed sliding scale approach for determining shared savings, consider a hypothetical ACO in Level B of the BASIC track in PY 2023 that met the MSR to qualify for shared savings and achieved a health equity adjusted quality performance score of 45 which is less than the 30th percentile MIPS Quality performance category score based on the unweighted distribution. However, the ACO achieved a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on one of the four outcome measures in the APP measure set. In this example, the ACO would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. We would calculate the scaled final sharing rate for this ACO by multiplying the maximum sharing rate for an ACO in Level B of the BASIC track of 40 percent by the ACO's health equity adjusted quality performance score of 45 (expressed as a percentage) (that is, 40 percent x 45 percent) to obtain a final sharing rate of 18 percent. We would then multiply the final sharing rate by the ACO's total savings (measured on a first dollar basis) to calculate the ACO's shared savings amount before considering the performance payment limit.

We believe the proposed sliding scale approach meets the statutory requirements of section 1899(b)(3)(C) of the Act, which requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As proposed, ACOs would still transition to a higher quality performance standard equivalent to or higher than the 40th percentile to share in savings at the maximum savings rate for their track beginning with PY 2024. Still, the proposal to reinstate a sliding scale approach for determining shared savings for ACOs would allow for flexibility in order to avoid the all-or-nothing approach as the Shared Savings Program transitions to required reporting of eCQMs/MIPS CQMs beginning with PY 2025 after the sunsetting of the CMS Web Interface measure set. As recently as PY 2021, only 12 ACOs reported eCQMs/MIPS CQMs, indicating that most ACOs are still developing their strategy and workflows to combine data across their EHR systems in advance of the requirement to report eCQM/MIPS CQMs beginning in PY 2025. We noted that we believe that the sunsetting of the CMS Web Interface collection, the requirement to report eCQMs/MIPS CQMs beginning in PY 2025, and the increase in the quality performance standard to share in savings at the maximum savings rate starting in PY 2024 will increase the stringency of the quality performance requirements under the Shared Savings Program as contemplated under section 1899(b)(3)(C) of the Act (87 FR 46129).

We believe a scaled approach to the quality performance standard, and thus to the determination of shared savings, would be beneficial because small differences in the distribution of ACOs' MIPS Quality performance category scores and other MIPS reporters' scores for a performance year may result in a large difference in the number of ACOs that fail to meet the quality performance standard as currently defined. Moving away from an all-or-nothing approach to a sliding scale approach to determine shared savings based on ACO quality performance would help to minimize the impact of these fluctuations by allowing ACOs that are close to, but do not achieve the health equity adjusted quality performance score required to share in savings at the maximum

sharing rate under their track, to receive some shared savings.

In summary, we proposed in the CY 2023 PFS proposed rule to revise the provisions governing the quality performance standard at § 425.512(a)(4) and (5) to reflect the alternative quality performance standard (87 FR 46129). Specifically, we proposed to revise § 425.512(a)(4) and (5) to provide for a quality performance standard that an ACO must meet in order to share in savings at the maximum sharing rate under its track (or payment model within a track) and an alternative quality performance standard that an ACO would be required to meet in order to share in savings on a sliding scale. We also proposed to make conforming changes to the methodologies for calculating shared savings under the BASIC track and the ENHANCED track, as specified in § 425.605 and § 425.610, respectively to reflect the proposed sliding scale approach.

In the CY 2023 proposed rule (87 FR 46130), we reiterated our statement in the CY 2022 PFS final rule that for PYs 2022, 2023 and 2024 if an ACO: (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs; and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65261). We proposed that, for PYs 2023 and 2024, an ACO that does not meet these requirements would also not meet the proposed alternative quality performance standard. For PY 2025 and subsequent performance years, we finalized in the CY 2022 PFS final rule that if an ACO does not report any of the 3 eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65262). In the CY 2023 PFS proposed rule, we proposed that, for PY 2025 and subsequent performance years, an ACO that does not meet these requirements would also not meet the proposed alternative quality performance standard (87 FR 46129). The proposals were reflected in the proposed revisions to § 425.512(a)(4) and (5).

The following is a summary of the public comments we received on the proposal and our responses:

Comment: Many commenters supported our proposal to reinstate a modified sliding scale approach for determining shared savings for all ACOs based on quality performance. Many commenters stated that the current structure of the quality performance standard creates a cliff of ''all-or-nothing'' scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum sharing rate for the applicable performance year.

Two commenters supported the proposal and stated that the current all-or-nothing scoring is overly punitive and could cause a large portion of ACOs to miss out on shared savings. A few commenters noted that scaling shared savings based on quality performance would encourage ACOs to continue to participate in the program. Another stated that the approach is more supportive of attracting new providers to the ACO program and in helping CMS meet its goal of having all Medicare Parts A and B beneficiaries in accountable care relationships by 2030.

One commenter stated that scaling savings based on quality performance would maintain a focus on achieving quality, while ensuring that ACOs that have opportunities for improvement are not deprived of the financial resources to do so. Two commenters mentioned that scaling shared savings based on quality performance would support providers who furnish care in underserved areas to patients with high unmet health care needs. Another commenter specifically supported the use of the proposed health equity adjusted quality performance score in the sliding shared savings. Several commenters explicitly supported tying the alternative quality performance standard to individual measure benchmarks. Some commenters noted that such an approach would provide more predictability, as these benchmarks are known in advance of the performance period.

Response: We appreciate the commenters' support of our proposal. We note that in section IV.A.3.f of this final rule, we are finalizing that beginning with the CY 2023 performance period/2025 MIPS payment year, we will score administrative claims measures using benchmarks calculated using performance period benchmarks under MIPS. Due to the Shared Savings Program's adoption of the APP beginning in performance year 2021, the benchmark methodology used by MIPS would also be applicable to ACOs. Thus, the two outcome measures in the APP measure set that are administrative claims measures would have performance period benchmarks, which would not be known in advance.

Comment: One commenter noted that a high quality standard is essential to the continued success of the Shared Savings Program and suggested that the sliding scale should only apply to new ACOs for a maximum of 3 performance years as they establish their operations.

Response: We agree that meaningful quality performance standards that assess the quality of care furnished by ACOs and seek to improve such care over time are essential to the continued success of the Shared Savings Program. We refer the commenter to our prior statements regarding achieving such goals through the adoption of higher performance standards over time (see, for example, 85 FR 84734), and we note that we have historically raised the quality performance standard both through the adoption of higher percentile ranking requirements and through the transition to eCQMs/MIPS CQMs (*Id.*).

We believe that both new and existing ACOs would benefit from the application of the sliding scale approach to determining their shared savings throughout their agreement period. In the CY 2023 PFS proposed rule (87 FR 46129), we stated that our proposal to implement the sliding scale methodology would allow ACOs that otherwise would not have received any shared savings, but perform well on quality to share in a portion of the savings they achieve at a lower rate. We also stated that the sliding scale approach meets the statutory requirements of section 1899(b)(3)(C) of the Act, which requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. This policy would also avoid a cliff of ''all-or-nothing'' scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum sharing rate for the applicable performance year. Additionally, this policy would provide higher rewards for higher performance potentially allow ACOs to make a greater investment in the infrastructure necessary for transitioning to eCQM/MIPS CQM reporting in performance year 2025 or earlier by enabling certain ACOs to receive shared savings that they otherwise would not have received under the current quality performance standard policies. We believe that the opportunities to make this investment should be available to all ACOs.

Comment: One commenter requested clarification on whether the sliding scale for shared savings would apply to

ACOs reporting via the CMS Web Interface while it remains active.

Response: We proposed to apply the sliding scale approach to all ACOs regardless of how they report quality data and are finalizing this policy as proposed. Therefore, for PYs 2023 and 2024, the sliding scale will apply to ACOs reporting quality via the CMS Web Interface.

Comment: We received one comment requesting clarification on how scaling shared savings based on quality performance would operate in practice. The commenter requested that CMS confirm whether, for purposes of determining shared savings, if an ACO reaches the 40th percentile across all MIPS Quality performance category scores or above, then the ACO would receive 100 percent of savings; and below the 40 percent mark, a sliding scale would be applied.

Response: An example of the sliding scale approach for determining shared savings was included in the CY 2023 PFS proposed rule (86 FR 46129) and is restated above. We did not propose to change the current requirements for ACOs to be eligible to share in savings at the maximum sharing rate nor did this proposal modify the maximum sharing rate.[275] Therefore, an ACO that reports quality data via the APP according to the method of submission established by CMS and achieves a quality performance score that is equivalent to or higher than the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, would be eligible to share in savings at the maximum savings rate under its track (or payment model within a track) up to the performance payment limit (so long as they are not otherwise ineligible to receive shared savings) (*See* § 425.512(a)(4)(i) and (a)(5)(i); *see also* § 425.610(d)(3)). The sliding scale approach will be applied to those ACOs that do not meet the threshold for the applicable performance year.

Comment: Some commenters expressed concerns about issues that were not related to the proposals included in this section of the proposed rule. The issues were related to: sunsetting of the CMS Web Interface in PY 2024 and the requirement to report eCQMs/MIPS CQMs beginning PY 2025; use of the MIPS Quality performance category scores to determine ACO performance; use of primary care-focused measures in the APP measure set; setting the threshold at the 30th and 40th percentile across all MIPS Quality performance category score to share in savings at the maximum savings rate.

Response: We note that we did not propose any changes to these previously finalized policies in the proposed rule, and therefore, these comments are considered to be out of scope. However, we are continuing to monitor the impact of these policies as we gain more experience with ACOs reporting eCQMs/MIPS CQMs. We are exploring how to address some of the concerns related to data aggregation and the all payer requirement and may revisit these and related issues in future rulemaking based on lessons learned. We have reviewed the public comments, and for the reasons stated above and in the proposed rule, we are finalizing our proposals as proposed to scale shared savings based on quality performance and will reinstate a modified sliding scale approach for determining shared savings for all ACOs regardless of how they report quality data. Specifically, we are finalizing the proposed revisions to the quality performance standard at § 425.512(a)(4)(ii) and (a)(5)(ii) to reflect the alternative quality performance standard that an ACO will be required to meet in order to share in savings on a sliding scale. We also are finalizing proposed revisions to make conforming changes to the methodologies for calculating shared savings under the BASIC track and the ENHANCED track, as specified in § 425.605 and § 425.610, respectively to reflect the sliding scale approach.

(3) Modify Methodology for Determining Scaled Shared Losses for the ENHANCED Track Based on Quality Performance

We proposed in the CY 2023 PFS proposed rule to modify the methodology used to determine shared losses for ACOs in the ENHANCED track (87 FR 46130). Under our current regulations at § 425.610(f)(2), for performance years beginning on or after January 1, 2021, an ACO in the ENHANCED track must meet the quality performance standard in order to have its shared losses scaled based on its quality performance and avoid automatically facing the maximum shared loss rate of 75 percent. We proposed that for PY 2023, and subsequent performance years, we would determine the ACO's shared loss rate using a sliding scale approach for an ACO that has losses that exceed its minimum loss rate and either meets the existing quality performance standard applicable for the performance year (that is, an ACO that would currently be eligible for shared losses scaled based on quality performance) or that does not meet that standard but achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set (87 FR 46130). As proposed, an ACO that meets the existing quality performance standard or that meets the new alternative standard would be subject to a scaled shared loss rate equal to 1 minus the product of the maximum sharing rate for the ENHANCED track (75 percent) and the ACO's quality performance score. The ACO's quality performance score used in this calculation would reflect the ACO's MIPS Quality performance category score plus any health equity adjustment bonus points the ACO is eligible to receive (referred to as the health equity adjusted quality performance score) based on the proposal described in section III.G.4.b.(7) of the proposed rule. The scaled shared loss rate would be subject to a minimum of 40 percent and a maximum of 75 percent. An ACO that fails to achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would continue to automatically share in losses at the maximum shared loss rate of 75 percent. Likewise, as proposed, an ACO that fails to achieve the proposed alternative quality performance standard because it (1) does not report any of the ten CMS Web Interface Measures (for PY 2023 or PY 2024) or any of the three eCQMs/MIPS CQMs (for PY 2025 or subsequent performance year) and (2) does not administer a CAHPS for MIPS survey under the APP as described in section III.G.4.b.(2) of the proposed rule would also automatically share in losses at the maximum rate.

As explained in the CY 2023 PFS proposed rule (87 FR 46130), the above proposal, by itself, would not materially change the current methodology for determining shared losses for ENHANCED track ACOs that meet the existing quality performance standard (or would meet the criteria for the eCQM/MIPS CQM incentive), but would newly allow for the application of a scaled shared loss rate for ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the

[275] We note for clarity that the maximum savings rate under the ENHANCED track is 75 percent, not 100 percent (§ 425.610(d)(3)).

APP measure set, as opposed to these ACOs automatically receiving the maximum shared loss rate under the ENHANCED track of 75 percent as required under the current regulations at § 425.610(f)(2)(ii). That is, more ACOs would have the opportunity to lower their shared loss rate below the maximum rate based on their quality performance.

In practice, an ACO would need to achieve a health equity adjusted quality performance score of higher than 33 and one-third in order to have a shared loss rate below 75 percent under the proposed approach. That is, a score greater than 33⅓ is needed for the scaled shared loss rate formula to yield a value less than 75 percent. For an ACO with a score of exactly 33 and one-third, the shared loss rate calculated by the formula would equal 75 percent. For an ACO with a score below 33 and one-third, the calculated rate would be greater than 75 percent, triggering the application of the maximum shared loss rate of 75 percent.

We noted that the proposal to determine the shared loss rate using the ACO's health equity adjusted quality performance score uses language that is different from the phrasing used in the current regulation at § 425.610(f)(2), which describes the shared loss rate as being calculated using ''the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available'' (87 FR 46130). As indicated in the CY 2021 PFS final rule, this approach allowed CMS to continue to scale shared losses by the ACO's quality score under the Shared Savings Program's two-sided models with the highest levels of risk and potential reward, the ENHANCED track and the Track 2 (although PY 2021 was last year in which ACOs participated under this financial model) (85 FR 84736 through 84740). The phrasing ''the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available'' represents a mechanical description of how the score is calculated to clarify that the scaling factor represented a value between 0 and 1 which, in turn, would ensure that the shared loss rate falls between 0 and 100 percent (before the application of the minimum or maximum shared loss rate). However, upon further consideration, we noted that we believe that this phrasing may cause unnecessary confusion (87 FR 46130). For example, it does not clarify whether or how applicable MIPS bonus points or quality improvement points would be incorporated or how the calculation would be impacted if the ACO is subject to the extreme and uncontrollable circumstances policy described in § 425.512(b). Furthermore, as discussed in the proposed rule, it would not address the treatment of health equity adjustment bonus points, if the proposed health equity adjustment described in the CY 2023 PFS proposed rule (87 FR 46132) was finalized. As we have described in prior rulemaking (85 FR 84735), the ACO's MIPS Quality performance category score accounts for any MIPS bonus points and quality improvement points and the extreme and uncontrollable circumstances policy in § 425.512(b), which we proposed in the CY 2023 PFS proposed rule to redesignate as § 425.512(c), indicates how an ACO's quality performance score will be determined if the ACO is affected by an extreme and uncontrollable circumstance. Furthermore, an ACO's health equity adjusted quality performance score would always take on a value between 0 and 100 as the MIPS Quality performance category score itself will always fall between 0 and 100 and the application of the proposed health equity adjustment, if finalized, would be restricted from raising the health equity adjusted quality performance score above 100. As a result, an ACO's health equity adjusted quality performance score could be expressed as a percentage that would also ensure that the scaled shared loss rate falls between 0 and 100 percent (before the application of the minimum or maximum shared loss rate). Therefore, we explained in the CY 2023 PFS proposed rule that we favor using the phrasing ''health equity adjusted quality performance score'' in describing our proposed methodology for determining the shared loss rate for ENHANCED track ACOs for PY 2023 onward, and we also noted that this phrasing would align with the terminology used in the description of the proposed sliding scale approach for determining shared savings (87 FR 46129).

For an example of the sliding scale approach for determining shared losses, consider a hypothetical ACO participating in the ENHANCED track in PY 2023 that had total losses above its minimum loss rate and achieved a health equity adjusted quality performance score of 45, which is less than the 30th percentile MIPS Quality performance category score based on the unweighted distribution. If the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set, it would share in losses at a rate that is scaled by the ACO's quality performance score. We explained that we would calculate the scaled shared loss rate for this ACO as 1 minus the maximum shared loss rate for the ENHANCED track of 75 percent multiplied by the ACO's health equity adjusted quality performance score of 45 (expressed as a percentage) [1 − (45 percent × 75 percent)] to obtain a shared loss rate of 66.25 percent. We would then multiply this shared loss rate by the ACO's total losses (measured on a first dollar basis) to calculate the ACO's shared losses before consideration of the loss recoupment limit.

We proposed to revise § 425.610(f) to provide for this scaled approach to the determination of shared losses.

The following is a summary of the public comments we received on the proposal and our responses:

Comment: Several commenters supported the proposal to modify the methodology for calculating scaled shared losses under the ENHANCED track using the sliding scale approach. Some of the commenters stated that the proposal will provide a more balanced loss sharing rate to ACOs and prevent ACOs in the ENHANCED track from becoming automatically subject to the 75 percent loss rate.

Response: We appreciate commenters' support for our proposal.

After reviewing the comments that we received on this proposal, and for the reasons stated above and in the proposed rule, we are finalizing our proposal as proposed to revise § 425.610(f) to scale shared savings starting in CY 2023 based on quality performance consistent with our final policy described above to reinstate a modified sliding scale approach for determining shared savings and shared losses for all ACOs regardless of how they report quality data.

(4) Additional Considerations Related to Proposed Modifications to Advanced APM Criteria

Section 414.1415(b)(1) through (3) requires that to be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to Advanced APM participants. Specifically, § 414.1415(b)(1) through (3) require, in relevant part, that two quality measures, one of which is an outcome measure, be a factor when determining payment to Advanced APM participants. In the Shared Savings Program, the ENHANCED track and Level E of the BASIC track are currently Advanced APMs, and we expect them to be

Advanced APMs in the future. As part of our proposal in the CY 2023 PFS proposed rule to permit ACOs that fail to meet the existing criteria under the quality performance standard to share in savings at a lower rate (if otherwise eligible) (87 FR 46129), we proposed that an ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set. We noted that this approach would not meet the current requirements for an Advanced APM at § 414.1415(b)(2) and (b)(3). We explained that this is because the proposal permits the use of a single outcome measure as a factor when determining payment. We noted that in section IV.A.4.a of the proposed rule (87 FR 46131), we also proposed to modify the Advanced APM criteria to allow for a single quality measure to be used to meet both quality measure criteria at § 414.1415(b)(2) and (b)(3). We proposed to align the proposal with the proposed modifications to § 414.1415(b)(2) and (b)(3). As such, we proposed in § 425.512(a)(4)(ii) and (a)(5)(ii) to require that an ACO meet only one of the four outcome measures for the ACO to be eligible to share in savings at a lower rate.

As discussed in the CY 2023 PFS proposed rule (87 FR 46131), if the proposal to revise § 414.1415(b)(2) and (b)(3) were not finalized, we would consider finalizing the following alternate policy based on comments received. Beginning with PY 2023 and for subsequent performance years, if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate, but the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining measures in the APP measure set, then the ACO would share in savings (if otherwise eligible) at a lower rate that reflects the ACO's health equity adjusted quality performance score (87 FR 46131). The ACO would consequently be required to meet the performance benchmark on either 2 outcome measures (one outcome measure at the 10th percentile and another measure at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th percentile to maintain consistency with the requirements of § 414.1415(b)(1) through (3) (87 FR 46131).

We also stated that with respect to shared losses for ACOs in the ENHANCED track, we would consider finalizing a parallel approach that would allow for application of a scaled shared loss rate for ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining measures in the APP measure set (87 FR 46131).

We solicited comment on the alternative to our proposed revisions to § 425.512(a) and (b) adopted above, which would have required that, in order to meet the alternative performance standard and share in savings at a reduced rate, an ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining measures in the APP measure set.

We did not receive any comments on this alternative approach.

We note that in section IV.A.4.a of this final rule, we are also finalizing the proposal to modify the Advanced APM criteria to allow for a single quality measure to be used to meet both quality measure criteria at § 414.1415(b)(2) and (b)(3). Our final policy, described in section III.G.4.b.(2) above, aligns with the final modifications to § 414.1415(b)(2) and (b)(3). As such, we are not finalizing the alternative discussed in this section.

(5) Broad Applicability of the Final Policy To Apply the Sliding Scale Approach To Determining Shared Savings for ACOs

We proposed to apply the sliding scale approach to determine shared savings for all qualifying ACOs and to determine shared losses for ENHANCED track ACOs regardless of how they report quality data to CMS in order to maintain consistency in the treatment of quality performance across all ACOs (87 FR 46131). We noted that we believe inclusion of all qualifying ACOs in this proposal regardless of reporting method would be responsive to the concerns expressed by interested parties regarding the perceived inequality in comparing MIPS quality scores between the Shared Savings Program and the traditional MIPS program. Specifically, as discussed in the proposed rule, ACOs have indicated they are limited to reporting the measures included under the APP, whereas traditional MIPS participants have a broader range of measures to select and report (86 FR 65268). We discussed that the proposal to implement the sliding scale methodology would allow ACOs that otherwise would not have received any shared savings, but perform well on quality to share in a portion of the savings they achieve, but at a lower rate. This policy would also potentially allow ACOs to make a greater investment in the infrastructure necessary for transitioning to eCQM/MIPS CQM reporting in PY 2025 or earlier by enabling certain ACOs to receive shared savings that they otherwise would not have received under the current quality performance standard policies. Furthermore, we noted that if we were to finalize the proposal, these ACOs would have additional funds available that they could choose to invest in advancing health equity.

We sought comments on all aspects of the proposals to scale shared savings and shared losses discussed in sections III.G.4.b.(2) through (5) of the proposed rule, including the alternative approach if the proposed changes to § 414.1415(b)(2) and (b)(3) are not finalized.

Our responses to the comments received on the proposals to scale shared savings and shared losses along with a description of our final policies can be found in sections III.G.4.b.(2) through (4) of this final rule.

In summary, we are finalizing as proposed our proposals to revise § 425.512(a)(4) and (a)(5) to apply a sliding scale approach to determine shared savings for all qualifying ACOs and to determine shared losses for ENHANCED track ACOs regardless of how they report quality data to CMS in order to maintain consistency in the treatment of quality performance across all ACOs.

(6) Extension of eCQM/MIPS CQM Incentive

We separately proposed to revise § 425.512(a)(4) and (5) to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQM/MIPS CQMs before full reporting of the measures are

required beginning in PY 2025 (87 FR 46132). We originally adopted this incentive in the CY 2022 PFS final rule to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in PYs 2022 and 2023 (86 FR 65269). Under the current incentive:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- A quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

In the CY 2022 PFS final rule, we finalized our proposal to freeze the quality performance standard at the 30th percentile across all MIPS Quality performance category scores for PY 2023 (86 FR 65269). Therefore, under the current regulations, beginning with PY 2024 and subsequent performance years, an ACO must achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring (86 FR 65270). To align with the finalized policy from the CY 2022 PFS final rule, we proposed to update the eCQM/MIPS CQM incentive for PY 2024 to include this requirement. Under the proposed update to the incentive for PY 2024:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- A quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable. (87 FR 46132)

We sought comment on this proposal.

In addition, we sought comment on whether CMS should incorporate the proposed amendments to § 414.1415(b)(2) and (b)(3) described in section IV.A.4.a. of the proposed rule into the eCQM/MIPS CQM incentive. As explained in the proposed rule (87 FR 46132), incorporating the proposal would result in an ACO only having to achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures to qualify for the incentive in PY 2023 and PY 2024.

We also explained that if we were to modify the eCQM/MIPS CQM incentive to align with the proposed modifications to § 414.1415(b)(2) and (b)(3), we would make corresponding changes to the proposed regulatory text at § 425.512(a)(5)(i)(A)(*2*) by removing the requirement that an ACO achieve a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set in order to meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable. In addition, we would make corresponding changes to the regulatory text governing the eCQM/MIPS CQM incentive for PY 2023 at § 425.512(a)(4)(i)(B). We noted that the requirements to qualify for the eCQM/MIPS CQM incentive for PY 2022 would not be affected by the proposed modifications to § 414.1415(b)(2) and (b)(3).

The following is a summary of the public comments received on the proposed extension of the eCQM/MIPS CQM incentive and our responses:

Comment: Many commenters supported the proposal to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024. Some commenters mentioned that the incentive may help to ease the transition to eCQM/MIPS CQM reporting. One commenter suggested that we extend the incentive beyond 2024 to facilitate the national shift towards eCQM. One commenter indicated if the incentive proves to be effective in getting more ACOs to submit eCQMs, then it suggests that we extend the incentive beyond 2024 to facilitate the national shift towards eCQMs.

Response: We appreciate commenters' support for the proposal. We are not extending the incentive beyond performance year 2024 at this time because this policy is intended to align with the timeline for sunsetting of the CMS Web Interface reporting option at the end of performance year 2024. We will continue to monitor the impact of this policy as we gain more experience with ACOs reporting eCQMs/MIPS CQMs and may revisit the policy in future rulemaking.

Comment: Several commenters suggested that CMS provide greater incentives to offset the financial and operational investments needed for ACOs transitioning to eCQM/MIPS CQM reporting before PY 2025. Some commenters urged CMS to provide ACOs reporting eCQMs/MIPS CQMs prior to 2025 with pay-for-reporting status for all three measures included in the APP measure set or, alternatively, to provide upfront funding and/or adjustments to financial benchmarks, or an increased savings rate to provide funding and incentives for ACOs to report eCQMs/MIPS CQMs prior to 2025.

Response: In this final rule, we are finalizing a number of policies that would strengthen incentives for ACOs to report eCQMs/MIPS CQMs, and thereby, making available funds for ACOs to make appropriate investments needed to transition to reporting eCQMs/MIPS CQMs prior to PY 2025. Additionally, beginning in PY 2021, ACOs that meet the quality performance standard detailed in § 425.512 are eligible to share in savings at the maximum rate allowable by track. Prior to the implementation of this standard, only ACOs in the first year of their first agreement period with the Shared Savings Program or ACOs with a perfect quality score were eligible to share in savings at the maximum rate. This policy enables ACOs to share in savings at a rate higher than was previously permitted under the sliding scale approach. For example, prior to PY 2021, an ACO in Level B of the BASIC track (otherwise eligible to share in savings) with a quality performance score equal to 90 percent would have earned a sharing rate of 36 percent, which is the product of the maximum sharing rate for an ACO in Level B of the BASIC track (40 percent) multiplied by the ACO's quality performance score of 90 (expressed as a percentage) (that is, 40 percent $\times$ 90 percent, or 36 percent). Under the current policy, an ACO in Level B of the BASIC track (otherwise eligible to share in savings) with a quality performance score at or above the standard established in § 425.512 would share in savings at the maximum rate. In this example, the ACO's sharing rate would have increased from 36 percent to 40 percent. We believe that this increased sharing rate is another

opportunity for ACOs to use additional funds for reinvestment. In section III.G.4.b.2 of this final rule, we are finalizing the proposal to implement the sliding scale methodology to allow ACOs that otherwise would not have received any shared savings, but perform well on quality to share in a portion of the savings they achieve, but at a lower rate. This policy would also potentially allow ACOs to make a greater investment in the infrastructure necessary for transitioning to eCQM/MIPS CQM reporting in PY 2025 or earlier by enabling certain ACOs to receive shared savings that they otherwise would not have received under the current quality performance standard policies. In section III.G.4.b.7 of this final rule, we are finalizing the application of health equity adjustment for ACOs that report eCQMs/MIPS CQMs. Through the health equity adjustment, ACOs that perform well on the three eCQMs/MIPS CQMs in the APP measure set and serve a large proportion of underserved individuals within their assigned beneficiary population may receive up to 10 bonus points. These ACOs could see the largest increases in their quality performance score and would have the most significant impact on determining the rate at which the ACO shares in savings, or for ACOs under the ENHANCED track, the rate at which the ACO shares in losses.

To support ACOs in rural and other underserved areas in building the infrastructure needed to succeed in the program, in section III.G.2.a of this final rule, we are finalizing policies to implement advance investment payments for qualifying ACOs, which include a one-time fixed payment of $250,000 and quarterly payments for the first 2 years of an ACO's 5-year agreement period. In section III.G.5.c.(4) of this final rule, we are finalizing revisions to the benchmarking methodology to reduce the effect of ACO performance on ACO historical benchmarks. We expect these policies will strengthen the incentives for ACOs, including ACOs caring for medically complex, high cost beneficiaries, and/or underserved populations to enter and remain in the Shared Savings Program.

We believe that these policies, coupled with the extension of the eCQM/MIPS incentive that we are finalizing, may provide ACOs with additional resources needed to invest in the infrastructure necessary to transition to reporting eCQMs/MIPS CQMs.

Comment: Commenters supported the idea of modifying the eCQM/MIPS CQM incentive to permit an ACO to meet the quality performance standard when achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures consistent with the proposed amendments to § 414.1415(b)(2) and (b)(3) as described in section IV.A.4.a. of the CY 2023 PFS proposed rule.

Response: With the finalization of the alternative quality performance standard discussed in section III.G.4.b.2 of this final rule, which would qualify an ACO to share in savings but at a lower rate that is scaled based on the ACO's quality performance, we believe that it is appropriate for the eCQM/MIPS CQM reporting incentive to have a higher standard such that ACOs that qualify for the eCQM/MIPS CQM incentive would be eligible to share in savings at the maximum sharing rate.

Comment: Several commenters requested clarification of whether FQHC-only ACOs are required to report MIPS CQMs starting in PY 2025. These commenters noted that currently FQHCs are exempt from MIPS reporting, and they would need technical assistance from CMS on how utilize existing reporting requirements to satisfy MIPS reporting as an ACO.

Response: We note that the reference to ''MIPS CQMs'' refers not to participation in the Merit-based Incentive Payment System (MIPS) but to a particular quality measure collection type and means of submitting quality data used by both MIPS and the Shared Savings Program.[276] In the CY 2021 PFS final rule (85 FR 84720–34), we finalized that Shared Savings Program ACOs are required to report quality data under the Advanced Payment Model (APM) Performance Pathway (APP), which permits the reporting of both eCQMs and MIPS CQMs for the purposes of the Shared Savings Program. In the CY 2022 PFS final rule (86 FR 65262), we finalized that in order to meet the quality reporting requirements under the Shared Savings Program for PY 2025 and subsequent performance years, an ACO must report the three eCQMs or three MIPS CQMs, administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP. If an ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the Shared Savings Program's quality performance standard. The policies discussed in this section and the corresponding proposal do not change the applicability of Merit-based Incentive Program to FQHCs. We refer interested parties to review the resources available on the QPP website on *https://qpp.cms.gov/resources/resource-library* regarding how to report under the APP.

Comment: Some commenters expressed concerns about issues that were not related to the proposal included in this section of the proposed rule. For example, commenters expressed multiple concerns regarding the requirement to report eCQMs/MIPS CQMs beginning PY 2025, such as issues related to meeting all-payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs. A few commenters suggested that a pilot study of eCQM reporting be done first for a subset of ACOs before making it a program-wide requirement. Other commenters were concerned about the use of the MIPS Quality performance category scores to determine ACO performance and raising the threshold to the 40th percentile across all MIPS Quality performance category scores to share in savings at the maximum savings rate in PY 2024.

Response: We note that we did not propose any changes to these previously finalized policies, and therefore, these comments are considered to be out of scope. We note that the sliding scale methodology that we are finalizing in this final rule would alleviate concerns related to the increase in the threshold for sharing in savings at the maximum rate to 40th percentile of all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, beginning in PY 2024 since it would allow ACOs that otherwise would have not received any shared savings, but perform well on quality to share in a portion of the savings they achieve, but at a lower rate. We are exploring how to address some concerns related to data aggregation, de-duplication of patient data, and the all payer requirement and may revisit these and related issues in future rulemaking based on lessons learned. After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46132), we are finalizing our proposed revisions to § 425.512(a)(4) and (5) to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their

[276] *See* Centers for Medicare & Medicaid Services, MIPS Participating in the Quality Performance Category in the 2022 Performance Year: Traditional MIPS 20–31 (Aug. 22, 2022), available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1971/2022%20Quality%20User%20Guide.pdf.*

performance on the eCQM/MIPS CQMs before full reporting of the measures are required beginning in PY 2025. Specifically, we are finalizing an update to the incentive for PY 2024 such that:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and:
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- A quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

Performance benchmarks used to determine the 10th and 40th percentiles will be posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library*. Performance benchmarks differ by collection type (that is, eCQM, MIPS CQM) and are updated for each performance year.

(7) Health Equity Adjustment for ACOs That Report All-Payer eCQMs/MIPS CQMs, and Are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries

(a) Background and Overview

Health care outcome inequalities exist among patients throughout the United States, and empirical research has found that certain patient characteristics are associated with worse health outcomes. Patients experiencing worse health outcomes often face barriers to accessing health care services and have access to fewer health care providers. This research also provides evidence of the relationships between socioeconomic status/social risk factors and health care outcomes. Section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185) called for the Secretary of Health and Human Services (HHS) to conduct a study evaluating the effect of individuals' socioeconomic status (SES) on quality measures and measures of resource use under the Medicare program. The Office of the Assistant Secretary for Planning and Education's (ASPE) March 2020 Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing (VBP) Program, provides insight into whether and how value-based programs should account for beneficiaries' social risk factors such as income, housing, transportation, and nutrition that might adversely affect their access to health care services or health outcomes. A key finding is that dual enrollment status is a strong predictor of poorer health care quality measure outcomes in Medicare's VBP programs, even when accounting for other social and functional risk factors.[277] In addition, several peer-reviewed research studies demonstrate that neighborhood-level factors for those residing in disadvantaged neighborhoods also have a relationship to worse health outcomes for these residents. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[278] [279] [280] [281] [282] Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels. We believe dual Medicare and Medicaid eligibility and ADI score are good indicators of beneficiaries with high needs. Dual eligibility, an indicator at the beneficiary level, is intended to capture socioeconomic challenges that could affect a beneficiary's ability to access care, while ADI, a neighborhood-level indicator, is intended to capture local socioeconomic factors correlated with medical disparities and underservice. We refer readers to the CY 2022 PFS final rule (86 FR 65382 through 65384) for a detailed review of the literature on health care outcome inequalities. The information included in these articles and reports informed our decision to propose and finalize with modification a health equity adjustment in connection with ACO quality performance and our consideration of the appropriate criteria for determining ACO eligibility for the adjustment.

As discussed in section III.G.4.f. of the proposed rule (87 FR 46154 and 46155), health equity, addressing health disparities, and closing the performance gap on the quality of care provided to underserved populations continue to be high priorities for the Agency through inclusion of health equity initiatives in CMS programs, and better addressing the social needs of people with Medicare is an important part of this strategy. As discussed in the proposed rule, we are committed to achieving health equity for Medicare beneficiaries by supporting ACOs in quality improvement activities to reduce health disparities, enabling Medicare beneficiaries to make more informed decisions, and promoting provider accountability for health care disparities.[283] [284] Further, we have set forth a goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030, and are focused on expanding the reach of ACOs into rural and other underserved communities. Among other considerations for reaching this goal, CMS is examining the use of incentives to close gaps in outcomes for Medicare beneficiaries.[285] In section III.G.2.a. of

[277] U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf*.

[278] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' *Annals of Internal Medicine*. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946*.

[279] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' *Annals of Internal Medicine*. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671*.

[280] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' *JAMA Network Open Oncology*. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787244*.

[281] Hutchinson RN, et al., ''Rural disparities in end-of-life care for patients with heart failure: Are they due to geography or socioeconomic disparity?'' *The Journal of Rural Health*. No. 38, pp 457–463, doi: 10.1111/jrh.12597 (2022), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597*.

[282] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' *The Journal of Arthroplasty*. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493*.

[283] CMS website, ''What is the CMS National Quality Strategy?'' *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy* (last accessed June 10, 2022).

[284] CMS Fact Sheet, ''CMS National Quality Strategy,'' April 2022, available at *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet-april-2022.pdf*.

[285] Jacobs D, Rawal P, Fowler L, Seshamani M, ''Perspective: Expanding Accountable Care's Reach

the proposed rule (87 FR 46098 through 46110), we proposed to provide advance shared savings in the form of AIPs to certain ACOs participating in the Shared Savings Program using beneficiary dual eligibility status and ADI data to determine the amount of quarterly payments. To align with these goals, we proposed a health equity adjustment that would upwardly adjust quality performance scores for ACOs that serve a high proportion of underserved individuals and achieve high quality performance.

As discussed in section III.G.4.a. of the proposed rule (87 FR 46127 through 46129), section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs, while section 1899(b)(3)(A) of the Act provides that that the Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO. We stated that we have concerns that our current quality performance standard and the quality performance measures we have adopted do not adequately assess the quality of care provided by ACOs with clinicians who serve a high proportion of underserved individuals. We also stated that we have similar concerns that the current quality performance standard and quality measures set do not adequately incentivize all ACOs to provide high quality care to underserved beneficiaries nor do we want to create an incentive for ACOs to avoid underserved populations as we transition to all payer eCQMs/MIPS CQMs because patients with social risk factors tend to have worse quality scores overall. The concern about lower quality scores for underserved populations is magnified in eCQMs compared to reporting via the CMS Web Interface, because all-payer reporting in eCQMs includes quality scores for people with Medicaid (correlating with low levels of income and increased prevalence social risk factors when compared to people with Medicare); whereas, historical reporting via the CMS Web Interface has only included those quality scores for people with Medicare. Therefore, ACOs that serve a higher proportion of Medicaid enrollees may receive lower quality scores during the switch to eCQMs without an adjustment. In turn, without an adjustment during the switch to eCQMs, ACOs that serve a higher proportion of people with Medicaid or other underserved populations outside of Medicare could be incentivized to avoid underserved populations, delay switching to eCQMs for as long as possible, or even cease participation in the Shared Savings Program altogether. We stated that this concern has been raised by interested parties serving large proportions of underserved populations.

We have previously been urged to adopt risk-adjusted quality measures that account for beneficiary characteristics such as geographic location, socioeconomic status, education, race, ethnicity, gender, preferred language, disability status, or health literacy (76 FR 67873). A number of our measures do adjust for certain beneficiary characteristics, such as age and gender; however, we do not broadly adjust measure performance on the numerous demographic characteristics listed. Quality performance approaches that incorporate risk adjustment, while intended to promote equity, can mask real differences in quality and make it more difficult to identify and address disparities where they exist. Risk adjustment for social risk factors may also have the unintended effect of setting lower quality standards for underserved populations, rather than ensuring high quality standards for all populations receiving care that is established in the move to eCQM/MIPS CQM all payer quality measures.

In considering how to modify the existing quality performance requirements under the Shared Savings Program to more fully assess the quality of care furnished by ACOs that serve a high proportion of underserved individuals, we believe that rather than risk adjusting for disparities in the health status of underserved populations, it would be more appropriate to adopt an approach that rewards high quality performance across all populations served by an ACO. For this reason, we proposed in the CY 2023 PFS proposed rule to revise how we assess the quality of care furnished by ACOs through the creation of a health equity adjustment designed to support those ACOs serving a high proportion of underserved individuals while also mitigating disparities in health care by encouraging all ACOs to treat underserved populations (87 FR 46127 through 46142). We noted that we believe the approach, as proposed, would also continue encouraging high ACO quality performance, reinforce ACOs' transition to reporting all-payer eCQMs/MIPS CQMs, and provide an incentive for ACOs to provide high quality care to all of the populations they serve. Additionally, because every year a greater proportion of ACOs are making the switch to eCQMs, instituting a health equity adjustment for those ACOs making the switch to eCQMs will allow us to study the impacts and make refinements during subsequent rulemaking.

As described in the proposed rule (87 FR 46132 through 46142), we proposed that the health equity adjustment would be available for PY 2023 and for subsequent performance years to an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey. We proposed such ACOs may receive up to a maximum of 10 additional points added to their MIPS Quality performance category score. The level of the adjustment would be determined based on the joint consideration of an ACO's performance on quality measures and the population served by the ACO, such that ACOs that perform well on quality measures and serve a higher proportion of beneficiaries who are from underserved neighborhoods (residing in census block group with an ADI national percentile rank of 85 or higher) or are dually eligible for Medicare and Medicaid would receive a higher number of bonus points.

The following is a summary of the general public comments we received on the overall proposal to add a health equity adjustment to the MIPS Quality performance category score for ACOs that report all-payer eCQMs/MIPS CQMs, are high performing on quality, and serve a high proportion of underserved beneficiaries and our responses:

Comment: Numerous commenters shared their support for our health equity adjustment proposal. Many commenters specifically supported the proposal to incorporate a health equity adjustment to an ACO's MIPS quality performance category score. Several commenters agreed that this adjustment will reward and incentivize ACOs for providing high-quality care to underserved populations, will help achieve the goal of greater health equity, and that ACOs are uniquely positioned to improve and innovate on population health efforts. One commenter also appreciated that the heath equity adjustment is designed to increase ACO performance and not decrease scores; another commenter appreciated that this approach did not set lower quality standards. Another commenter appreciated CMS's review of its own regulations to identify and remediate those that reinforce or fail to mitigate health inequities. One commenter supported the use of the health equity

among Medicare Beneficiaries.'' *New England Journal of Medicine* (April 27, 2022), *https://www.nejm.org/doi/full/10.1056/NEJMp2202991.*

adjustment among providers who report eCQMs, asserting that eCQMs are the future of quality reporting and these providers should not be left behind. Another commenter agreed that this aspect of the proposal will negate concerns that the transition to all-payer measures would impact savings for providers who treat a higher proportion of underserved populations.

Some commenters supported the proposal and agreed with CMS that the proposed health equity adjustment is better than a risk adjustment approach. One commenter applauded CMS for not masking health disparities through risk adjustment. A few commenters generally supported a policy to improve health equity in the Shared Savings Program, but noted it should be pilot tested first to ensure that it does not have unintended consequences. Additional commenters urged us to carefully monitor the health equity adjustment after implementation.

While these commenters were all supportive of the health equity adjustment proposal and recognized the importance of supporting health equity in the Shared Savings Program, many shared additional feedback on specific aspects of this proposal which is summarized below in each subsection of the proposal.

Response: We appreciate the comments in support of the proposed health equity adjustment. Regarding the use of the health equity adjustment instead of risk adjustment, we appreciate commenters' support for the approach. We agree with commenters who supported the use of the health equity adjustment among ACOs that report all-payer eCQMs/MIPS CQMs.

Regarding the need to pilot test the health equity adjustment, we expect the early years of this policy to effectively serve this purpose given that the adjustment will only be applicable to ACOs that report eCQMs/MIPS CQMs, which currently represent a small portion of all ACOs. We note that we do intend to monitor the impact of the adjustment and may, as necessary, consider modifications to the design of the adjustment through future notice and comment rulemaking.

Comment: Several commenters voiced general concerns about the overall health equity adjustment proposal rather than specific concerns about the methodology being proposed. One commenter voiced concerns about ''Advanced APMs'' not receiving the health equity adjustment bonus points because the commenter believed the adjustment would be added to MIPS. Another commenter had concerns that the methodology for the adjustment could potentially worsen disparities in care. A couple of commenters encouraged CMS to take a simpler approach and risk adjust the Shared Savings Program quality measures for demographic and social risk factors. One commenter supported the goal of health equity, but recommended generally that CMS modify programs so that they better address different aspects of health equity, rather than just encouraging ACOs to serve underserved populations. Another commenter was concerned that this policy could negatively impact rural providers, citing that they see fewer patients overall than their urban counterparts due to population density.

A few commenters supported rewarding ACOs that perform highly on quality and serve underserved beneficiaries, but believed that the proposal does not create enough incentives for treating this population. One commenter further noted that the only ACOs that would benefit from the proposed adjustments are those ACOs that are below the minimum quality standard, and that ACOs with a high proportion of disadvantaged patients will have to provide additional services that would not be recouped. This commenter noted additional services would likely be needed for those patients to achieve the same quality performance as an ACO that has fewer such patients. Another commenter noted that the health equity adjustment as currently designed, which gives a maximum of 10 bonus points, is not a sufficient incentive to drive smaller, independent practices to prioritize and make investments to increase services to currently underserved populations. This commenter also cited the lag time between the time of an investment and the time at which the practice realizes any financial return, and had concerns that the return would not cover the cost of the investment in these communities, particularly given the medical complexity of patients in many underserved areas.

Response: We clarify that we interpret the comment raising concerns about Advanced APMs to refer to MIPS eligible clinicians and APM entities, because ''Advanced APMs'' are a type of payment model, not a type of entity participating in the Quality Payment Program. Advanced APM Shared Savings Program ACOs have to report the APP under Shared Savings Program requirements and would be eligible for the health equity adjustment added to their ACO quality performance score for purposes of determining shared savings and losses if they report eCQM/MIPS CQM all payer measures and have a proportion of assigned beneficiaries that are underserved based on the underserved multiplier definition as described in section III.G.4.b.(7)(d) of this final rule. As we noted in the proposed rule (87 FR 46141), the health equity adjustment would not impact a MIPS eligible clinician's final scores because the health equity adjusted quality performance score would be limited to the Shared Savings Program, where it would be used at the ACO level to determine an ACO's shared savings or losses. While the Shared Savings Program has made efforts to align some quality standards with MIPS (*see for example,* § 425.510(b)), extending the health equity adjustment to MIPS eligible clinicians would require separate rulemaking specific to MIPS and would be outside the scope of this proposal.

As we stated in the proposed rule (87 FR 46133 and 46134), we have received suggestions from stakeholders to consider risk adjusting quality measures to account for various beneficiary characteristics that are tied to health disparities (76 FR 67873) and expressed our concern that this approach may have unintended consequences such as masking real differences in quality or setting lower quality standards for underserved populations. We believe it is more appropriate to reward high quality performance across all populations served by an ACO and apply an adjustment for those serving a high proportion of underserved individuals. Program modifications that address other aspects of health equity may be considered in the future.

We disagree with the commenters that do not believe the health equity adjustment provides incentives for treating underserved populations or voiced concern about the methodology of the health equity adjustment worsening disparities. We also disagree that ACOs that may benefit from the adjustment will not benefit financially from the additional bonus points. The proposed bonus points will reward existing high quality care to underserved populations immediately (without any lag), and these bonus points could increase in the future as ACOs improve their inclusion in care and care quality to underserved populations. While it is possible that there could be a lag between future investments to improve quality and quality score improvements, we believe this would depends on what investments the ACO makes and how those are prioritized. Furthermore, it is also not expected that these bonus points represent the sole motivation for ACOs seeking to improve quality and

health equity, though as outlined in the proposed rule (87 FR 46134 and 46135) bonus points will increase the ACO's quality score used for financial reconciliation, and so could potentially impact shared savings or losses.

As we stated in the CY 2013 proposed rule (87 FR 46139 through 46141), we believe that a health equity adjustment would upwardly adjust quality performance scores for ACOs that serve a high proportion of underserved individuals and achieve high quality performance and would encourage all ACOs to treat underserved populations. We believe this because we have observed that many ACOs serving underserved beneficiaries are performing well on quality, and that serving a large proportion of underserved patients does not necessarily mean that the ACO performs worse on quality than ACOs with fewer such patients. Furthermore, when examining performance for the 12 ACOs reporting via eCQMs/MIPS CQMS, we observed that quality performance varied on different measures such that an ACO was not in the top third for all measures or the bottom third for all measures. With the move to eCQMs/MIPS CQMs and our understanding of the concern voiced by the commenter, underserved populations may result in lower quality scores and this could be magnified by eCQM or MIPS CQM reporting due to all-payer data. Therefore, we believe this is a tangible incentive for ACOs to continue serving these populations and avoid delaying the switch to eCQMs or MIPS CQMs.

Small differences in quality scores can have a noticeable financial impact on an ACO. The health equity adjustment can provide ACOs up to an additional 10 points on their MIPS quality performance category score, which, when coupled with our adoption of a sliding policy for shared savings as described in section III.G.4.b.(5) of this rule, may not only assist ACOs in qualifying to earn shared savings but also enhance the rate at which ACOs qualify to share savings. We believe that limiting the health equity adjustment bonus to a maximum of 10 points creates a balanced incentive through increasing an ACO's quality performance score without dominating the score creating unintended incentives while also aligning with the scoring of the required measures under the APP, as previous bonuses within the MIPS program have not exceeded 10 points. Improving care to underserved populations will not only increase an ACO's health equity adjustment bonus points but also their overall quality score which in turn will help with shared savings and shared losses. We intend to closely monitor the impacts of the health equity adjustment and make refinements as needed during subsequent rulemaking; however, we remind readers that the heath equity adjustment as it is currently being finalized does not decrease ACOs' quality performance scores and that ACOs can only benefit from the adjustment.

Regarding the concern that this policy could negatively impact rural providers, we believe our final decision in response to commenters to modify the underserved multiplier calculation and use National ADI, dual eligibility, and LIS in the health equity adjustment, as described in section III.G.4.b.(7)(d) of this final rule, provides opportunity for all providers, whether located in rural or urban areas. In the CY 2023 PFS proposed rule (87 FR 46138), we requested comment on the addition of LIS in calculating the underserved multiplier and received many comments in support of this modification. We will be closely monitoring the impacts of the policy in rural areas and make refinements as needed in future rulemaking.

Comment: Many commenters recommended that CMS apply the health equity adjustment to all ACOs, including those that report via the CMS Web Interface, rather than only those reporting eCQMs/MIPS CQMs. A couple of these commenters noted this would ensure the proposal has the intended effects of encouraging participation in the Shared Savings Program and advancing health equity. A few others noted that all ACOs could benefit from this proposal given that quality performance includes two claim-based measures which are all-Medicare populations. One commenter mentioned that some ACOs may be working toward improving health equity in their attributed population, but will not be recognized or rewarded for this work until they are reporting eCQMs/MIPS CQMs. Another commenter stated that the adjustment being available to all ACOs would boost CMS's goal of 100 percent of all Medicare patients to eventually be in an ''accountable relationship''.

Many commenters voiced concerns that restricting the policy to just those ACOs that report via eCQMs/MIPS CQMs does not align with the intent of the proposal and will limit who qualifies for the adjustment, noting that ACO populations do not differ based on reporting mechanism and some ACOs that could benefit most may be excluded. One commenter believed that incentivizing caring for structurally marginalized communities does not and should not depend on the data reporting mechanism and another commenter suggested that this conditional approach to the adjustment may result in unintended consequences because the bonus will not fall equally across participants in the ACO program. Many commenters were concerned that it is difficult for ACOs that serve areas of high disadvantage to participate in existing more sustainable payment models thus creating a gap between those who can and cannot transition out of FFS.

Several commenters understood that we want to find ways to incentivize ACOs to adopt eCQM/MIPS CQM reporting before it becomes mandatory in PY 2025, but believed tying this to the health equity adjustment was inappropriate and misguided. Commenters noted that ACOs continue to face challenges with the new quality reporting requirement, including challenges with upgrading systems, and that ACOs that serve a high proportion of underserved beneficiaries may have higher costs caring for these patients and thus may be additionally challenged to devote resources to invest in their health IT infrastructure. Many commenters were concerned that few ACOs will qualify for the adjustment, at least in the early years, thus limiting its usefulness and urged us to remove the eCQM/MIPS CQM reporting requirement and consider policies in which all types of practices and ACOs have viable opportunities to transition to a more sustainable payment model to promoting a more equitable health system.

Response: We understand the concerns raised by commenters regarding the eCQMs/MIPS CQMs reporting criteria for being eligible to receive a health equity adjustment. However, we reiterate what we stated in the proposed rule, that the health equity adjustment is designed to upwardly adjust the ACO's quality performance score and will not financially penalize ACOs that are not eligible for the adjustment such as those who do not report using eCQMs/MIPS CQMs. Furthermore, the proposal had several goals and while commenters noted the goal of rewarding ACOs serving a high proportion of underserved individuals when high quality is achieved, another goal of the proposal design was to support these ACOs during the transition to eCQMs/MIPS CQMs. ACOs that serve a higher proportion of Medicaid enrollees may receive lower quality scores during the switch to all-payer eCQMs/MIPS CQMs without an adjustment or could be incentivized to

avoid underserved populations, delay switching to eCQMs/MIPS CQMs for as long as possible, or even cease participation in the Shared Savings Program altogether.

As the transition to reporting all-payer eCQMs/MIPS CQMs continues, with this reporting mechanism becoming mandatory starting in PY 2025, this proposal would reinforce the timeline while supporting ACOs that may be experiencing challenges with the new quality reporting requirement and providing an incentive for ACOs not to seek to avoid underserved populations during the transition to reporting eCQMs/MIPS CQMs. Based on the all-payer quality data reported via eCQMs/MIPS CQMs in PY 2021, we observed that, as an example, one ACO would have received 6 out of the 10 maximum bonus points which would have increased its final quality performance category score to a level that would be comparable to the scores of ACOs reporting via the CMS Web Interface. We believe this demonstrates that the health equity adjustment can assist with the transition to all-payer eCQMs/MIPS CQMs and want to reinforce that this adjustment is a development opportunity for ACOs to serve a higher proportion of underserved beneficiaries, to improve on quality measures, and to move to all-payer eCQMs/MIPS CQMs. Therefore, we will not modify our proposal and apply the health equity adjustment to ACOs that report via the CMS Web Interface. When all ACOs have transitioned to eCQMs/MIPS CQMs by PY 2025, all ACOs will receive a health equity adjustment to their MIPS quality performance category score if they meet the other eligibility criteria.

(b) Application of the Adjustment

We proposed to apply the health equity adjustment in the form of bonus points added to the ACO's MIPS Quality performance category score. Under the proposed approach, the ACO's health equity adjusted quality performance score would be the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points, if applicable (87 FR 46134 and 46135). The proposal would not change the current policy for determining and calculating an ACO's MIPS Quality performance category score.

Under the existing regulations at § 425.512 and under the proposed modifications to the quality performance standard described in the proposed rule, there are specific programmatic uses of the ACO's MIPS Quality performance category score. In applying the proposed health equity adjustment to the ACO's MIPS Quality performance category score, which constitutes the ACO's aggregate, or overall score, across the APP measure set, we proposed to limit the application of the health equity adjustment to certain specified Shared Savings Program determinations and calculations. The use of the ACO's health equity adjusted quality performance score in these calculations would allow ACOs that report the eCQMs/MIPS CQMs and provide high quality care to underserved beneficiaries to share in savings at relatively higher sharing rates, or in the case of ENHANCED track ACOs that owe shared losses, to reduce the shared loss rate used to calculate the amount of shared losses owed to CMS. We noted in the proposed rule that we believe this approach would serve as a means to incentivize ACOs by offering a financial reward for providing high quality care to underserved beneficiaries, further financially support ACOs that serve underserved beneficiaries, encourage ACOs to add ACO participants in underserved areas, and avoid creating adverse incentives for ACOs to avoid underserved populations or the health care providers serving those populations.

We proposed to apply an ACO's health equity adjusted quality performance score in determining whether the ACO met the quality performance standard set at the 30th percentile for PY 2023 as specified under § 425.512(a)(4)(i)(A), or the 40th percentile for PY 2024 and subsequent performance years, as specified in the proposed revised regulations at § 425.512(a)(5)(i)(A)(*1*) and (a)(5)(i)(B), respectively (87 FR 46448). Use of the ACO's health equity adjusted quality performance score in making this determination would potentially allow more ACOs that provide high quality care to underserved beneficiaries to meet the quality performance standard. Under the Shared Savings Program's current policies, ACOs that meet this quality performance standard share in any savings generated at the maximum sharing rate under their track (or payment model within a track), up to the performance payment limit. For ENHANCED track ACOs that meet the quality performance standard, the ACO's shared losses are scaled based on its quality performance.

We further proposed to apply an ACO's health equity adjusted quality performance score in the determining shared savings and losses as specified in certain existing provisions of the Shared Savings Program regulations and under proposed modifications to the regulations as described elsewhere within the proposed rule (87 FR 46439).

We proposed to use an ACO's health equity adjusted quality performance score to determine the final sharing rate for calculating shared savings payments under the BASIC track (under § 425.605(d)) and the ENHANCED track (under § 425.610(d)) for an ACO that meets the proposed alternative quality performance standard allowing for application of a sliding scale based on quality performance, as specified in proposed modifications to § 425.512(a)(4)(ii) and (a)(5)(ii) (87 FR 46448). Among ACOs whose shared savings would be determined according to the sliding scale approach (described in sections III.G.4.b.(2) and (3) of the CY 2023 PFS proposed rule (87 FR 46129 through 46131)), the application of the proposed health equity adjustment would allow for relatively higher quality performance scores in calculating the final sharing rate and make it possible for an ACO to share in savings at a relatively higher final sharing rate under its track (or payment model within a track).

For ENHANCED track ACOs that owe shared losses, we proposed to apply the health equity adjustment to the ACO's quality performance score used in calculating the ACO's shared loss rate, to allow the ACO to share in losses at a relatively lower rate, based on its quality performance. Specifically, we proposed to use an ENHANCED track ACO's health equity adjusted quality performance score in calculating shared losses under § 425.610(f) when the ACO meets the quality performance standard specified under § 425.512(a)(4)(i) or (a)(5)(i) (which includes the incentive for reporting eCQMs/MIPS CQMs for PY 2023 and the extension of the incentive for PY 2024, as proposed) or meets the proposed alternative quality performance standard under § 425.512(a)(4)(ii) and (a)(5)(ii) allowing for the application of a sliding scale based on quality performance (87 FR 46448). For an ENHANCED track ACO in the first performance year of its first agreement period that meets the quality performance standard by reporting data via the APP and meeting the data completeness and case minimum requirements in accordance with § 425.512(a)(2), the ACO's quality performance score is utilized in calculating any shared losses under § 425.610(f). Therefore, we also proposed to use the ACO's health equity adjusted quality performance score to determine the shared loss rate for such ACOs.

Further, we proposed to apply the health equity adjustment in calculating the ACO's quality performance score for an ACO affected by extreme and uncontrollable circumstances if the ACO is able to report quality data via the APP and meet data completeness and case minimum requirements, as provided in § 425.512(b)(3) in the current regulations. As discussed in section III.G.4.b.(8) of the proposed rule (87 FR 46142 through 46143), the proposed approach of using an ACO's health equity adjusted quality performance score to determine the ''higher of'' score under the extreme and uncontrollable circumstances policy would have no practical impact on the sharing rate for an ACO that is eligible to share in savings. For an ACO participating in the ENHANCED track that is liable for shared losses, the proposed application of the health equity adjustment could increase the ACO's quality performance score used to determine the ACO's shared loss rate, and thus potentially reduce the amount of shared losses owed to CMS.

We received one public comment on the proposed application of the health equity adjustment to the ACO's MIPS Quality performance category score and provide this comment and our response below.

Comment: One commenter supported our proposed approach to apply the health equity adjustment bonus points to ACOs' MIPS Quality performance category scores, and specifically stated they support maintaining the original score and then transparently adding the points awarded from the health equity adjustment.

Response: We agree that transparency is important for any bonus points or other adjustments to an ACO's MIPS Quality performance category score because this provides information to support ACOs' ability to improve on the adjustment such as whether they received the health equity adjustment bonus and how many bonus points were applied. We are finalizing as proposed our approach to apply any bonus points an ACO received for a given performance year to the ACO's MIPS quality performance category score.

(c) Identifying Top Quality Performance Among ACOs Reporting eCQMs/MIPS CQMs; Determining the Measure Performance Scaler

We proposed the health equity adjustment would be available to an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set and meets the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs and administers the CAHPS for MIPS survey.

We noted that we believe that limiting the proposed health equity adjustment to ACOs reporting all-payer measures (eCQMs/MIPS CQMs) would further encourage ACOs to report all-payer measures in PY 2023 (while the Web Interface is still an available reporting option) (87 FR 46132 through 46134). ACOs may opt to report eCQMs/MIPS CQMs in order to have the benefit of the application of the health equity adjustment. As stated previously, the concern about lower quality scores for underserved populations is magnified in eCQMs/MIPS CQMs compared to reporting via the CMS Web Interface, because all-payer reporting in eCQMs/MIPS CQMs includes quality scores for people with Medicaid (correlating with low levels of income and increased prevalence social risk factors when compared to people with Medicare). In addition, offering a health equity adjustment to ACOs that report all three eCQMs/MIPS CQMs would support ACOs that are serving greater proportions of underserved populations as the shift to all-payer reporting takes place. ACOs not yet familiar with their performance on these measures or how they may be impacted by the change to all-payer populations may be incentivized by the proposal to begin reporting these measures before the full transition occurs.

The proposal takes into account interested parties' concerns regarding challenges in improving quality of care for underserved populations, while recognizing ACOs that provide high quality of care for this population. The proposal also helps address the concerns that we have heard from ACOs that serve higher proportions of people with Medicaid and other underserved populations with regards to all-payer quality reporting during the switch to eCQMs/MIPS CQMs. As we also noted in the proposed rule, social risk factors may adversely affect access to health care services or preferred health outcomes, and dual-enrollment status is a strong predictor of poorer health care quality measure outcomes in Medicare's VBP programs. We acknowledged that using the all-payer quality measures, as well as outcome measures may make it even more difficult for ACOs that serve underserved populations to achieve the quality performance standard, since all-payer reporting will newly include people with Medicaid as part of quality reporting, and people with Medicaid tend to have a higher amount of social risk factors and lower quality scores. As we discussed in section III.G.4.b(2) of the proposed rule (87 FR 46129 through 46130), most ACOs are still developing strategies and workflows to combine data across EHR systems in advance of requirements to report eCQMs/MIPS CQMs. Adding health equity adjustment bonus points to the ACO's MIPS Quality performance category score could allow more ACOs that care for underserved populations to potentially meet the quality performance standard set at the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores, and therefore, support these ACOs reporting eCQMs/MIPS CQMs.

We proposed to consider the ACO's performance on all measures in the APP measure set in calculating the health equity adjustment (87 FR 46135 and 46136). Table 63 outlines the APP measure set for eCQM/MIPS CQM reporting for PY 2023. To determine an ACO's performance on quality for the purpose of calculating health equity adjustment bonus points, we proposed to create three groups based on measure performance (or ''performance groups''): (1) a group comprised of the top third performing ACOs; (2) a group comprised of the middle third performing ACOs; and (3) a group comprised of the bottom third performing ACOs. These groups would be created for each of the six measures independently such that an ACO in the top group based on performance on one measure may be in the bottom group based on performance on another measure. Consistent with current implementation of eCQMs and MIPS CQMs, the three groups would be created by reporting mechanism so that ACOs that report eCQMs would have each measure grouped into a top, middle, and bottom third based on the performance of other ACOs that also report eCQMs. The same methodology would be used for ACOs that report the MIPS CQMs. For the CAHPS for MIPS survey and claims-based measures, ACOs would be compared to all ACOs with data on those measures (including those that reported via the Web Interface, eCQMs, or MIPS CQMs).

We proposed to assign to an ACO a value of 4 for each measure for which its performance places it in the top performance group, a value of 2 for each measure for which its performance places it in the middle performance group, and a value of 0 for each measure for which its performance places it in the bottom performance group. We would sum the values assigned to each measure in the APP measure set to determine an ACO's total assigned value, which we refer to as the ACO's ''measure performance scaler.'' Under this approach, an ACO could have a

measure performance scaler of up to 24 if it is among the top performance group for each measure and thereby received a value of 4 for each of six measures.

As discussed in the CY 2023 PFS proposed rule (87 FR 46136), we would assign a value of 0 to a measure in certain cases when we would not evaluate the ACO's performance on a measure. For purposes of calculating the health equity adjustment, an ACO would receive 0 for a claims-based measure or an eCQM/MIPS CQM for which the ACO does not meet the case minimum requirements at § 414.1380. Similarly, an ACO would receive 0 for the CAHPS for MIPS survey in the event it does not meet the minimum sample size requirements. An ACO that cannot meet case minimum requirements or does not have a sufficient sample size to administer the CAHPS for MIPS survey would still qualify to receive the health equity adjustment bonus for those measures that were accurately and completely reported and provided the ACO met the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs.

We also considered and analyzed scaling quality performance for the bottom, middle, and top third of measure performance by different values to evaluate how these values interact with the underserved multiplier (described in detail below) to calculate ACOs' health equity adjustment bonus points. Specifically, we also analyzed assigning a value of 0, 1, and 2 for the bottom, middle, and top third of measure performance, respectively, and decided on proposing 0, 2, and 4 instead. As proposed, the scaling would allow ACOs that have high levels of an underserved multiplier and high quality performance on most or all measures to receive near or at the maximum of 10 health equity adjustment bonus points. That is, an ACO with an underserved multiplier of 0.45 (or 45 percent) that achieved a measure performance scalar of 24 would receive the maximum of 10 health equity adjustment bonus points. With the alternate scaling approach, this ACO would achieve a measure performance scalar of 12 (that is, a value of 2 for each measure in the top third × 6 measures) but would not receive the maximum of 10 health equity adjustment bonus points even though the ACO would have achieved high-quality while caring for a large proportion of underserved beneficiaries (that is, measure performance scalar of 12 × an underserved multiplier of 0.45 = 5.4 points). Thus, the proposed scaling is consistent with CMS' goal to incentivize greater inclusion of underserved populations and the delivery of high quality care.

We received several public comments on our proposal to use the measure performance scaler to identifying top quality performance among ACOs reporting eCQMs/MIPS CQMs. The following is a summary of the comments received and our responses.

Comment: Several commenters noted concern on our proposal to use a measure performance scaler in the calculation of the health equity adjustment. A few commenters had concerns about determining an ACO's performance on quality among their underserved population using the measure performance scaler. Specifically, these commenters stated that the measure performance scaler did not achieve the goals of this proposal because using the ACO's overall quality score may not provide insight into whether the ACO provides high-quality care to underserved populations, and that an ACO may still have large disparities in its quality performance for certain groups. One commenter supported a policy where ACOs serving the highest proportion of underserved beneficiaries would receive a health equity adjustment regardless of performance, and referenced the complex patient bonus in MIPS as a similar concept.

Response: We appreciate the commenters' sharing their concerns and recommendations. However, we believe the measure performance scaler does achieve the goals of this proposal because in order for an ACO to be eligible for the health equity adjustment, at minimum 20 percent of the ACO's assigned beneficiaries must be classified as underserved as proposed in the CY 2023 PFS proposed rule (87 FR 46136 through 46138). If a large proportion of an ACO's population is classified as underserved and if this subset is receiving low quality of care, then the health equity adjustment will appropriately decrease. The health equity adjustment was purposefully designed to not reward poor quality. Likewise, if the quality of care received by an ACO's underserved beneficiaries is high and if these underserved beneficiaries represent only a small proportion of an ACO's total population, then the health equity adjustment will be lower (all else being equal) as the adjustment was not designed to reward ACOs that serve a low number of underserved beneficiaries. However, we note that the adjustment does not penalize poor quality or having a low underserved population. While ACOs with an underserved beneficiary population that is less than 20 percent are not eligible for the health equity adjustment bonus, they also are not penalized by this policy. The health equity adjustment instead incentivizes ACOs to increase the number of underserved beneficiaries they serve and to improve quality of care as these are the two ways to receive more bonus points on their MIPS Quality performance category score. As we continue to examine additional data it is possible that the incorporation of beneficiary-level quality data is something we would consider for this adjustment in the future.

Comment: A few commenters were concerned about the three-tiered approach used in determining the measure performance scaler and the number of ACOs that would be awarded the maximum bonus points based on the way the scaler is designed. One commenter noted that the tiered performance category groups may create a small numbers issue, with only a few ACOs in each tier, if these groups are based on an ACO's reporting mechanism and not many ACOs are currently reporting through eCQMs. An additional commenter was concerned that ACOs serving a large proportion of underserved population may end up in the bottom third for all or most of the quality measures and earn a 0 or very low measure performance scaler. This commenter recommended we consider an approach that will support these ACOs such as providing additional guardrails to help ACOs that serve higher proportions of underserved populations avoid a score of 0 and stay motivated to continue to participate in the Shared Savings Program and encourage other Medicare providers in underserved areas to join the Shared Savings Program. Another commenter was concerned we have not provided information on the number of ACOs that would reach the maximum 10 bonus points and suggested we calibrate the measure performance scaler in such a way that results in awarding 10 bonus points to those ACOs that have a health equity adjustment in the 90th percentile among all eligible ACOs, even if they are below 10 bonus points based on the health equity adjustment calculation steps provided in the proposed rule (87 FR 46139 through 46141).

Response: We wish to re-emphasize that the goal of the proposal is to incentivize high quality care by ACOs serving a greater proportion of underserved populations. Correspondingly, the health equity adjustment bonus points are designed to award higher points for ACOs that (1) serve greater percentages of underserved populations, and (2) have higher quality

performance, rather than being designed to guarantee that a certain percent of ACOs will receive the maximum number of bonus points. Based on PY 2019 Web Interface quality data, ACOs that serve a higher proportion of underserved beneficiaries have generally had similar quality performance to other ACOs, although with slightly lower scores on average. We also have observed variation across quality measures in the APP measure set within ACOs serving both high and low proportions of underserved populations, such that ACOs tend to not perform in the top or bottom across all quality measures but perform differently across quality measures. For example, we have observed that an ACO that performs well on measures related to hospitalization may or may not perform well on measures related to preventive care. While there were not many ACOs reporting eCQMs in 2021, we believe this number will increase each year and that the health equity adjustment will further incentivize ACOs to report eCQMs. We note that the tiered approach uses the entire population of ACOs for determining the top, middle, and bottom third based on performance for the CAHPS for MIPS survey and the claims-based measures avoiding small numbers issues for those measures.

Comment: A couple commenters voiced concerns specific to the complexity of the Measure Performance Scaler, noting that the Measure Performance Scaler was unnecessarily complicated and recommended simplification by using the ACO's MIPS quality performance score rather than creating a new measure of quality performance. One of these commenters requested a rationale for why the proposed approach used a new and different methodology than what is used in calculating the ACO's quality performance score. This commenter was concerned that the proposed approach could result in large changes in the ACO's scaler based on small changes in relative performance or in no change in an ACO's scaler based on large quality performance changes. As an example, the commenter noted that the tiered approach makes no distinction between an ACO with a quality score in the 67th percentile and an ACO with a quality score in the 99th percentile; both would receive 4 points on the relevant measure. Another commenter requested CMS clarify what happens when an ACO does not receive a score for a claims-based measure (for example, ACOs did not receive a score on Measure 479 because they are FQHC-only ACOs and do not have an eligible MIPS participating clinician group).

Response: While we appreciate the suggestion related to using the ACO's Quality performance category score, our goal is to focus on quality performance among ACOs, whereas the Quality performance category score incorporates other factors, such as bonus points and other scoring factors. We disagree that the Measure Performance Scaler is unnecessarily complicated and furthermore note that the Scaler is designed to consider each quality measure individually when determining the value an ACO will receive for their performance on that measure. These values are then summed to create the total Measure Performance Scaler used in the health equity adjustment calculation. This allows ACOs that perform well on some measures but not all measures to still receive bonus points if the ACO meets the criteria of having an underserved population that is 20 percent or greater (see III.G.4.b.(7)(e) of this final rule). The scaler is also designed to assess an ACO's measure performance on each quality measure against other ACOs, such that an ACO's efforts in quality performance improvement may make a difference in their tier for a given measure relative to other ACOs. The Quality performance category score, in contrast, involves comparisons to non-ACOs, whereas the health equity adjustment bonus points are meant to reward ACOs that achieve high quality performance relative to other ACOs (rather than smaller individual providers). We note that by design the health equity adjustment bonus points do not adversely impact ACOs such as they are not awarded until after the calculation of the quality performance standard, and therefore, do not raise the quality performance standard.

Finally, we note that, as described in the CY 2023 PFS proposed rule (87 FR 46135 and 46136), unscored measures are removed from the calculation of the health equity adjustment, effectively receiving a performance scaler of 0 for that measure. As mentioned in the CY 2023 PFS proposed rule, we reserve the right to refine the methodology used to calculate the measure performance scaler or any other aspects of the health equity adjustment over time.

After reviewing the public comments and for the reasons described above and in the proposed rule (87 FR 46135 and 46136), we are finalizing the methodology of calculating the measure performance scaler as proposed.

(d) Identifying ACOs Serving High Proportions of Underserved Beneficiaries; Determining the Underserved Multiplier

Through the proposed health equity adjustment we seek to improve health equity outcomes by providing incentives to ACOs and their ACO participants and ACO providers/suppliers to achieve high levels of performance on all-payer and outcome focused Medicare quality measures for underserved populations, given the concerns we have heard regarding reporting eCQMs/MIPS CQMs, which require reporting of data on all patients and are considered all-payer measures. We proposed to award higher positive adjustments to ACOs providing higher quality of care to underserved populations, with the amount of the adjustment increasing as an ACO's proportion of underserved beneficiaries increases. Such an approach would support ACOs currently serving a high proportion of underserved individuals while also encouraging all ACOs to treat underserved populations.

We proposed to identify ACOs serving larger proportions of underserved beneficiaries, by considering the proportion of dually eligible Medicare and Medicaid beneficiaries and the proportion of beneficiaries residing in areas of high socioeconomic disadvantage within the ACO's performance year assigned beneficiary population. We proposed to calculate an ''underserved multiplier'' for each ACO that would be determined using the higher value of either the proportion of an ACO's assigned beneficiary population that is considered underserved based on beneficiaries who are from underserved neighborhoods, identified using ADI data, or the proportion of an ACO's assigned beneficiary population that are dually eligible for Medicare and Medicaid. As noted above, dual eligibility status and ADI are good indicators of socioeconomical disadvantages, with ADI associated with medical disparities and underservice and dual eligibility associated with beneficiary's inability to access care. We would then multiply this underserved multiplier by the aforementioned measure performance scaler to determine the ACO's health equity adjustment bonus points.

We referred readers to the discussion in section III.G.2.a. of the proposed rule (87 FR 46098 through 46110) for a general description of the ADI data, including the 17 input variables from census data that make up the ADI composite measure. Each census block group's ADI score is ranked nationally,

with higher national percentile ranks corresponding to more socioeconomically disadvantaged areas. Census block groups have been found to have stronger associations with hospitalization rates than larger areas used to create ADIs.[286] For each ACO, we explained that we would create an underserved multiplier that ranges from zero to one and is based on the higher value of either the proportion of the ACO's performance year assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85 or the proportion of the ACO's performance year assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries).[287] An ADI national percentile rank of at least 85 or above is being used as a cutoff because this is the value at which some empiric studies have demonstrated worse outcomes. In particular, one study demonstrated that 30-day rehospitalization rates did not vary significantly across the least disadvantaged 85 percent of neighborhoods, but hospitalizations within the most disadvantaged 15 percent persons increased with worsening ADI, with a pattern that was similar amongst individuals with congestive heart failure, acute myocardial infarction, and pneumonia.[288] As proposed, an ACO serving mostly beneficiaries residing in areas of high socioeconomic disadvantage or serving a larger proportion of dually eligible Medicare and Medicaid beneficiaries would receive a multiplier value closer to one and a larger health equity adjustment to its quality performance score, all else equal. An ACO serving mostly beneficiaries from areas that are not considered to be of low socioeconomic disadvantages and serving a smaller proportion of dually eligible Medicare and Medicaid beneficiaries would not likely receive an underserved multiplier value that meets the proposed floor of 20 percent (described in section III.G.4.b.(7)(e) of the CY 2023 PFS proposed rule), and therefore, would not receive health equity adjustment bonus points. Thus, the result of the underserved multiplier would be that ACOs serving a higher proportion of underserved beneficiaries would be eligible for a greater number of bonus points, assuming they achieve high quality performance. Therefore, the use of the underserved multiplier, combined with the proposed floor to receive any bonus points, is consistent with our goal of rewarding ACOs that include a higher proportion of underserved beneficiaries while delivering high quality care.

The proposed use of ADI and Medicare and Medicaid dual eligibility status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries. As discussed in the proposed rule, we proposed to use ADI and dual eligibility status to determine levels of quarterly AIPs for eligible Shared Savings Program ACOs (see section III.G.2.a. of the proposed rule (87 FR 46098 through 46110)). These two factors reflect different types of characteristics, which may relate to patient populations differently. An ADI is a multidimensional evaluation of the socioeconomic characteristics of the neighborhoods the beneficiaries live in, and incorporates domains such as education, income, employment, housing, and household characteristics. It also reflects neighborhood factors that may influence health, health care, and care delivery regardless of individual circumstance. Dual Medicare and Medicaid eligibility status is a direct measure of the beneficiary, reflecting their individual income status, and has been shown to be a predictor of worse health outcomes. While there is some overlap between ADI and dual eligibility, we proposed to utilize both because they can be used to identify complementary populations that may not be fully recognized using only one of the factors, by taking the higher of the ACO's proportion of assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the ACO's proportion assigned beneficiaries that are dually eligible for Medicare and Medicaid, to determine an ACO's underserved multiplier for calculating health equity adjustment bonus points. Our proposal for the underserved multiplier used for calculating the health equity adjustment and our proposal for calculating quarterly AIPs are directionally aligned in that they both seek to provide greater benefit to ACOs that are serving underserved populations. For the health equity adjustment, we noted that we believe use of ACO-level indicators (that is, the proportion of the ACO's performance year assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the proportion that are dually eligible for Medicare and Medicaid) to measure the extent to which an ACO serves underserved populations is preferred to an approach that would establish an underserved multiplier at the beneficiary-level. We also noted that we believe it would be appropriate to apply an ACO-level underserved multiplier to the measure performance scaler, which would be determined based on ACO-level performance on the measures in the APP measure set. This would allow for alignment between the underserved multiplier and the measure performance scaler to which it is being applied.

Our proposal to use a ''higher of'' either the proportion of an ACO's assigned population residing in census block groups [289] with high ADI or the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid to calculate the underserved multiplier is intended to avoid double-counting overlapping beneficiaries (as could happen when taking the sum of the two proportions), while also allowing an ACO alternate ways to achieve a higher multiplier value, recognizing that no single value would fully represent its population.

We also noted that this approach to determining the underserved multiplier based on the ACO's assigned population is a means of approximating the extent to which the ACO and its ACO participants and ACO providers/suppliers are serving underserved beneficiaries. The ADI component of the underserved multiplier would be based on the neighborhood level characteristics among ACO assigned beneficiaries, and these characteristics may generally reflect the social determinants of health in the communities served by the ACO and thus serve as a proxy for the all payer population characteristics and their neighborhoods. The use of dual Medicare and Medicaid eligibility is based on the status of beneficiaries attributed to the ACO.

[286] Maroko AR, et al., ''Integrating Social Determinants of Health With Treatment and Prevention: A New Tool to Assess Local Area Deprivation.'' Preventing Chronic Disease, No. 13(E128), pp.1–5, doi: 10.5888/pcd13.160221 (September 2016), available at *https://www.cdc.gov/pcd/issues/2016/16_0221.htm*.

[287] In computing this proportion, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

[288] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13–2946*.

[289] We note that in the proposed rule we inadvertently referred to census blocks rather than census block groups when describing this proposal at 87 FR 46137.

Although we proposed to determine the underserved multiplier as the higher of two characteristics—the proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage or the proportion of dually eligible Medicare and Medicaid assigned beneficiaries—we explained that we considered an alternative approach that would use a combination of these characteristics in calculating the underserved multiplier (87 FR 46136 through 46138). Together these characteristics may be complementary in identifying an ACO's underserved populations, one based on neighborhood characteristics and the other based on dual eligibility status among the ACO's assigned beneficiaries. However, while the two characteristics allow for recognition of the ACO's underserved population at the neighborhood and beneficiary levels, there is potential overlap and thus double-counting with the approach to combine (sum) these characteristics. We sought comment on this alternative approach to calculating the underserved multiplier as the sum of an ACO's proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage and an ACO's proportion of dually eligible Medicare and Medicaid assigned beneficiaries. We noted that such an approach would result in a potentially higher underserved multiplier for ACOs, and thereby higher total health equity adjustment bonus points compared to the proposed approach. As a result, under this alternative calculation of the underserved multiplier, more ACOs would likely achieve the maximum of 10 bonus points.

More generally, we noted that CMS is considering similar methodologies for determining underserved populations outside of the Shared Savings Program. For example, as discussed in the Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,[290] we noted that we are developing a health equity index as a potential methodological enhancement to the Part C and Part D Star Ratings that would summarize performance among groups with social risk factors across multiple measures into a single score. The goal of this health equity index would be to advance equity and support underserved communities by incentivizing contracts to perform well serving enrollees with social risk factors such as low-income subsidy (LIS)/dual eligibility and disability.

As discussed in the proposed rule, we also considered alternative approaches for calculating the underserved multiplier that would additionally consider whether an ACO's assigned beneficiaries receive the LIS available under the Medicare Part D prescription drug program. LIS, as an indicator, may capture a different group of low-income beneficiaries than dual eligibility status and the eligibility criteria for LIS does not vary by State. Specifically, we explained that we considered alternatives under which we would use the LIS indicator in place of, or in addition to, a beneficiary's dual Medicare and Medicaid enrollment status. We also considered using the higher of three factors based on the ACO's performance year assigned beneficiary population: (1) the proportion of the ACO's assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85; (2) the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid; or (3) the proportion of the ACO's assigned beneficiaries receiving LIS. We sought comment on these alternative approaches, or other approaches, to incorporating assigned beneficiaries' LIS status into the underserved multiplier.

The following is a summary of the public comments received on the proposal to create an underserved multiplier to identifying ACOs serving high proportions of underserved beneficiaries and our responses.

Comment: Many commenters supported the underserved multiplier which will be used to identify ACOs serving a high proportion of underserved beneficiaries and including how the proportion is calculated for the purpose of the health equity adjustment calculation. Supportive commenters stated that the underserved multiplier should comprehensively represent the underserved assigned beneficiaries for each ACO, appreciated the inclusion of dual eligibility, valued that the multiplier used neighborhood-level metrics in assessing social risk, and stated it was ''a step in the right direction.'' One commenter also agreed that the program should account for differences in the providers' patient populations to counter the disadvantages they could face in achieving good outcomes. One commenter specifically asked us to define the criteria for ''providing care for a higher proportion of underserved or dually eligible beneficiaries.''

Numerous commenters voiced their support for adding the Part D low-income subsidy to the calculation of the underserved multiplier and stated that they support a national eligibility criterion being included and that multiple approaches in capturing risk are more sensitive and appropriate. One commenter supported our proposal to use the higher of either dual eligibility or ADI 85 and above approach in calculating an ACO's underserved multiplier. One commenter supported our proposal to use a threshold of 85th percentile of ADI, stating this approach is consistent with the literature reporting that health systems caring for the most vulnerable beneficiary populations were more likely to be financially penalized under prior programs.

Response: We agree that dual eligibility and neighborhood-level deprivation are valuable measures for capturing an ACO's underserved population. We appreciate support for the proposal as outlined in the proposed rule, specifically backing the use of ADI, a threshold of 85th percentile, and using the higher of approach when calculating the underserved multiplier. In response to the commenters who requested additional details about the calculation of the health equity adjustment, we refer these commenters to the details provided in the proposed rule (87 FR 46139 through 46141), which included an outline of the steps involved in the calculation and provided several examples.

Comment: A couple commenters suggested we consider criteria beyond those we listed in the proposed rule, such as defining essential hospitals, and including this status when calculating the underserved multiplier or considering a factor that would account for serving beneficiaries in noncore rural areas. Other commenters in support of the proposal recommended CMS consider the underserved multiplier being a combination of the criteria we finalize (that is, dual eligibility, ADI 85 and above, and LIS) to allow for the most sensitive capture of high social risk and to allow more ACOs to qualify for the adjustment. Other commenters supported using ADI but recommended we evaluate whether ADI is the appropriate measurement to differentiate by regional populations; *they* recommended we incorporate both national and State percentiles in the ADI definition, and assess whether the 85th percentile nationally is too high for ACOs to meaningfully benefit from the adjustment. Another supportive commenter recommended a blended approach to ADI that incorporated the

[290] Available at *https://www.cms.gov/files/document/2023-announcement.pdf.* See for example the discussion of Health Equity Index (Part C and D) on pages 101–103.

CDC's Social Vulnerability Index (SVI) into a single composite value of social need at the census block group level to generate a more accurate approach to the regional aspect of the underserved multiplier.

Response: We understand that some commenters prefer we combine the different criteria for defining underserved, rather than taking the higher of, to be more sensitive to capturing high social risk and allow for more ACOs to qualify for the adjustment. We appreciate these comments; however, our proposal to use the higher of approach, which uses either the proportion of an ACO's assigned population residing in census block groups with high ADI or the proportion of an ACO's assigned population that are dually eligible for Medicare and Medicaid, is intended to avoid double-counting overlapping beneficiaries which can happen when taking the sum of two proportions. This higher of approach, however, allows ACOs an alternate way to achieve a higher multiplier value while being more accurate since it does not duplicate beneficiaries in the calculation of the proportion of an ACO's assigned population who are underserved. The addition of LIS in the calculation of the underserved multiplier, which has high overlap with dual eligibility, further supports our using the higher of approach rather than summing the proportions.

We acknowledge that a few commenters in support of our using ADI in the calculation of the underserved multiplier still provided recommendations including that we perform additional evaluations on this metric, consider both national and State percentiles, and assess the threshold of 85th percentile of ADI. We confirm that we considered and assessed different methods of ADI including both national and State percentiles and various thresholds, and we believe these analyses supported our proposed approach to use national ADI percentages and an 85th percentile threshold. Additional discussion of this decision is described in the next comment summary and responses in this section of the final rule. Regarding the commenter who requested us to define the criteria for providing care for a higher proportion of underserved or dually eligible beneficiaries, we refer this commenter to section III.G.4.b.7.d of the CY 2023 PFS proposed rule (87 FR 46136 through 46138) that outlines how we plan to identify ACOs serving high proportions of underserved beneficiaries and determine the underserved multiplier used to calculate the health equity adjustment. Furthermore, given the overwhelming support and feedback we received from commenters on the inclusion of the Part D LIS in the underserved multiplier, we are finalizing the proposal with modification to incorporate LIS in the calculation of the health equity adjustment. Thus, the underserved multiplier will be determined based on the higher of: (1) the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85; or (2) the proportion of the ACO's assigned beneficiaries that are enrolled in LIS or are dually eligible for Medicare and Medicaid. As commenters noted, LIS is a national measure and capturing individuals receiving a Part D LIS subsidy who are at risk of being underserved and, combined with the other measures of underserved, will be a more sensitive approach.

We appreciate commenters recommendations for other underserved criteria such as developing ways to capture essential hospitals or noncore rural areas, or to incorporate the CDC's Social Vulnerability Index (SVI) with ADI into a single composite measure. We will take these into consideration as we work to refine the health equity adjustment over time.

Comment: Many commenters had concerns about the approach we proposed for the underserved multiplier which defined the ACO's underserved population for the purposes of the health equity adjustment. Most of these commenters' concerns were regarding the use of ADI to identify areas of disadvantage among different geographic regions of the country and did not support our proposal to use ADI. Concerns included how ADI may not consistently identify disadvantaged areas for all types of communities, that we should consider ADI rankings at the regional or local levels instead of national rankings or develop a blend of a national and State ADI, and that ADI is heavily weighted toward factors that related to income and home values and not other variables that impact disadvantage. Rationales for these concerns included the differences in cost of living throughout the country, that ADI underestimates the vulnerabilities of neighborhoods with the highest burden of chronic disease and lowest life expectancy, and that studies have found higher correlations between disadvantage and health outcomes when using the most local ADI metrics.

One commenter noted that there may not be a single metric to accurately identify underserved communities given the variability in different areas of the country, and several commenters believed the current calculation poorly represents rural communities. These commenters requested we consider a different metric be used specifically for rural versus urban areas. Two commenters recommended that the cutoff of the 85th or higher percentile for ADI should be modified by summing the ADI percentiles for the neighborhoods of each patient assigned to the ACO, with one of these commenters further suggesting that cutoffs should not be set until there is evidence to demonstrate this would accurately capture individuals residing in disadvantaged neighborhoods.

Other comments around the underserved multiplier included concern that an ACO's underserved community was being based only on the ACO's attributed Medicare population and not the broader population served by the ACO, and that dual eligibility will vary across states. Several commenters suggested we use an alternative such as life expectancy when calculating the underserved multiplier. Other commenters requested we utilize publicly available data sets since ACOs may have limited capacity in data analytic capabilities and being able to identify which of their beneficiaries are underserved. A couple commenters requested we continue refining and testing ADI along with alternative measures of high deprivation areas before settling on a definition of the underserved multiplier.

Though the commenters summarized here were generally opposed to our approach to the underserved multiplier, several agreed with the use of Part D LIS data as either a replacement or a supplement for the dual eligibility status and ADI given LIS eligibility is uniform nationwide. A couple commenters supported the idea to combine dual eligibility status and ADI rather than only taking the higher of the two proportions when calculating the underserved multiplier.

Response: We agree with the commenters that low-income subsidy status is a more standardized measure of low income among the Medicare FFS population. We note that the Part D LIS has certain limitations. For example, all beneficiaries with dual eligibility status or who receive Supplemental Security Income (SSI) automatically receive the LIS designation in CMS data systems. LIS designation means that the beneficiary is enrolled in the Medicare Part D low-income subsidy. Beneficiaries who do not have dual eligibility status or SSI status but whose income is lower than 150 percent of the

Federal poverty level must apply for LIS. Our analysis finds that the vast majority of Medicare beneficiaries with the LIS designation are those who automatically receive this designation, rather than those who applied for the benefit and were approved. Nonetheless, despite this limitation we agree that the use of the LIS designation, in addition to dual eligibility status, is preferable to using dually eligible status alone, as doing so reduces variability across States while moderately expanding the number of beneficiaries we will identify as low income. Furthermore, we note that including LIS in the calculation of the underserved multiplier provides ACOs with an incentive to support eligible beneficiaries who must apply for the benefit to make the connection.

We also acknowledge commenters' concerns that ADI may not accurately identify areas of disadvantage among different geographic regions of the country. As noted in the Advance Investment Payment, III.G.2.a.(5), section of this final rule, ASPE recently conducted an environmental scan and concluded that none of the existing area-level indices are ideal; they concluded that the ADI or Social Deprivation Index (SDI) were the best available choices when selecting an index for addressing Health Related Social Needs or Social Determinants of Health for immediate policy development.[291] After additional consideration and review, we believe the ADI national percentile rank remains one of the best available options to assess underserved populations in the health equity adjustment because it was developed with the goal of quantifying and comparing social disadvantage across geographic neighborhoods and uses a combination of 17 different input variables from census data in the calculation. One key strength we see with ADI is that it is a comprehensive, publicly available dataset that applies a standardized score for all census block groups nationwide. Details about the ADI score and its calculation can be found in section III.G.2.a.(5) of the proposed rule.

Regarding comments that suggested we continue to refine and test ADI before establishing cutoffs and settling on a definition of the underserved multiplier, as we stated in the proposed rule (87 FR 46135 through 46138) we believe the current approach supports our preliminary efforts to address health disparities and close the performance gap on the quality of care provided to underserved populations served by ACOs through incentives and upwardly adjusts an ACO's quality performance score with no penalties to those ACOs that do not qualify for the adjustment. We wish to remind commenters of our intent to monitor the impact of the adjustment as necessary and consider modifications to the design of the health equity adjustment through future notice and comment rulemaking. We also appreciate commenters recommendations for incorporating other underserved criteria such as life expectancy and rural versus urban indicators. We will take these into consideration as we work to refine the health equity adjustment over time.

After consideration of the public comments, including their support for the use of Part D LIS in the calculation of the underserved multiplier, and for the reasons stated earlier in this section and in the proposed rule (87 FR 46136 through 46138), we are finalizing our proposal with a modification to use enrollment in the LIS in addition to dual eligibility and ADI in the calculation of the underserved multiplier. As commenters noted, the criteria for LIS enrollment are consistent nationwide and including multiple factors when capturing individuals at risk of being underserved will be a more sensitive approach. We believe the addition of LIS will establish criteria that are more uniform nationwide such that eligibility for the subsidy is the same regardless of geographic differences.

(e) Determining the Health Equity Adjustment Bonus Points an ACO Is Eligible To Receive Based on the ACO's Measure Performance Scaler and Underserved Multiplier

We proposed the ACO's health equity adjustment bonus points would be calculated by multiplying the measure performance scaler and the ACO's underserved multiplier. However, we also proposed to impose a number of limitations on the availability of and the amount of the health equity adjustment bonus points.

We proposed that ACOs would be ineligible to receive any bonus points if their underserved multiplier is less than 20 percent, thereby establishing a ''floor'' on the size of the ACO's underserved population under the health equity adjustment. Imposing a floor of 20 percent for the underserved multiplier, for an ACO to be eligible to receive bonus points, reinforces that the health equity adjustment is intended to reward ACOs that are serving higher proportions of underserved beneficiaries while also achieving high levels of quality performance. We explained that we believe this approach is necessary to remain consistent with the goal to reward and incentivize care for these populations. Absent such a floor, ACOs that perform well on quality measures but serve relatively small populations of underserved beneficiaries would be further rewarded, which could create incentives that are inconsistent with the purpose of the health equity adjustment. We anticipate the percent of ACOs meeting the 20 percent floor for the underserved multiplier would increase over time, as existing ACOs seek to expand their reach into underserved communities, and as a result of the proposed new participation options that are designed to foster greater entry into the Shared Savings Program by ACOs that serve underserved communities. For example, among ACOs receiving the proposed AIPs, the amount of the quarterly payments would increase as beneficiaries' risk factors-based scores increase (set to 100 if the beneficiary is dually eligible for Medicare and Medicaid, or set to the ADI national percentile rank of the beneficiary's census block group if the beneficiary is not dually eligible). ACOs receiving AIPs that expand the size of their underserved populations would thereby receive higher amounts of quarterly AIPs to build their care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other proposed criteria for use of the funds (as described in section III.G.2.a. of the proposed rule (87 FR 46098 through 46110)). Under the proposed health equity adjustment, these ACOs would have a further incentive to deliver high quality of care and thereby perform well on the APP measure set for eCQM/MIPS CQM reporting.

We proposed the number of health equity adjustment bonus points to be awarded would not exceed a maximum of 10 points. We explained that we believe that limiting the health equity adjustment bonus to a maximum of 10 points strikes a balance between creating an incentive for ACOs to report eCQM/MIPS CQM measures and rewarding ACOs that are high performing on quality and serve higher proportions of underserved beneficiaries, while not overly inflating an ACO's quality performance score. Further, allocating a maximum of 10 points for this bonus would align with

[291] Report: ''Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments.'' Accessed at *https://aspe.hhs.gov/reports/area-level-measures-account-sdoh* on September 27, 2022.

the scoring of the required measures under the APP. Previous bonuses within the MIPS program have not exceeded 10 points or been higher than 10 percent of the score the bonus aligns with.[292] [293]

We further proposed that the bonus points would be added to the ACO's MIPS Quality performance category score, with the sum capped at 100 percent. As proposed, the cap at 100 percent would ensure that the application of the health equity adjustment does not cause the ACO's quality performance score to exceed the maximum possible quality performance score an ACO could achieve absent the adjustment. Thus, the proposed cap would align with the current practice which sets the maximum quality performance score at 100 percent.

The health equity adjustment bonus points would be added to the ACO's MIPS Quality performance category score for the purpose of determining whether the ACO meets the quality performance standard for a given performance year by meeting or exceeding the applicable MIPS Quality performance category score percentile and, if applicable, in determining the ACO's final sharing rate or shared loss rate. We noted that this proposal to adopt a health equity adjustment would not impact the calculation of the quality performance standard itself. That is, the required percentile (30th for PY 2023 and 40th for subsequent performance years) would continue to be determined across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, and would not reflect any health equity bonus points earned by Shared Savings Program ACOs.

Further, as described in section III.G.4.b.(2) of the CY 2023 PFS proposed rule (87 FR 46129 through 46130), under the proposed sliding scale approach for determining shared savings, we would calculate an ACO's final sharing rate as the product of the maximum sharing rate under the ACO's track (or payment model within a track) and the ACO's quality performance score (inclusive of any applicable health equity adjustment bonus points). Similarly, as described in section III.G.4.b.(3) of the CY 2023 PFS proposed rule (87 FR 46130 through 46131), under the proposed modifications to the approach to calculating scaled shared losses for ENHANCED track ACOs, we would calculate an ACO's shared loss rate as 1 minus the product of 75 percent and the ACO's quality performance score (inclusive of any applicable health equity adjustment bonus points), not to exceed 75 percent and not to be less than 40 percent. The proposed cap of 100 percent on the sum of the ACO's MIPS quality performance category score and health equity adjustment bonus points would allow for clarity and consistency in the calculation of the final sharing rates under the proposed sliding scale approach, and for the calculation of the shared loss rate for ENHANCED track ACOs.

Accordingly, as proposed, the health equity adjustment would enable more ACOs that serve underserved populations and provide high quality care to share in a portion of the savings that they generate as the addition of the proposed health equity adjustment bonus points should allow more ACOs to meet the quality performance standard by meeting or exceeding the applicable MIPS quality performance category score percentile for a given performance year (that is, 30th percentile for PY 2023, and 40th percentile thereafter). For ACOs that meet the proposed alternative quality performance standard described in section III.G.4.b. of the CY 2023 PFS proposed rule, the addition of health equity adjustment bonus points to the ACO's quality performance score could increase the final sharing rate used to calculate the ACO's shared savings payment. Finally, for ACOs participating in the ENHANCED track that owe shared losses, the addition of health equity adjustment bonus points could reduce the shared loss rate used to calculate the amount of shared losses owed to CMS.

The combination of the measure performance scaler, based on an ACO's performance on different quality measures, and the underserved multiplier, based on an ACO's unique assigned beneficiary population, results in a range of possible health equity adjustment bonus points that is designed to give the highest rewards to ACOs caring for a disproportionate share of underserved individuals and delivering high quality care. Through the proposed health equity adjustment, ACOs that perform well on measures in the APP measure set for eCQM/MIPS CQM reporting and serve a large proportion of underserved individuals within their assigned beneficiary population would be more likely to receive the maximum number of 10 bonus points, and in turn could see the largest increases in their quality performance score, which in turn, would have the most significant impact on determining the rate at which the ACO shares in savings, or for ACOs under the ENHANCED track, the rate at which the ACO shares in losses. We refer readers to mathematical examples for the steps in the calculation of the health equity adjustment, described in section III.G.4.b.(7)(f) of the CY 2023 PFS proposed rule (87 FR 46139 through 46141).

Based on initial modeling, approximately 30 percent of ACOs participating in PY 2020 would have had an underserved multiplier above the 20 percent floor necessary to qualify for the proposed health equity adjustment. Therefore, we noted that we believe the proposed approach could result in a significant number of ACOs earning health equity adjustment bonus points, which in turn would support these ACOs in caring for underserved populations.

Furthermore, by rewarding ACOs when high quality is achieved, the health equity adjustment could create incentives for ACOs to improve care for those who have been historically underserved. As proposed, the approach, which is designed to upwardly adjust the ACO's quality performance score, lacks additional financial penalties for ACOs that are not meeting high standards of care, which we believe is important as such a downward adjustment could worsen disparities and further jeopardize the ability of these ACOs to care for the populations they serve. We believe the proposal aligns with the broader CMS health equity goals and serves as an important step forward in advancing health equity by providing an incentive for ACOs to care for underserved populations and to provide high quality care to all of the populations they serve, rather than merely adjusting measure performance for patient risk factors.

We received several public comments on the provisions to determining the health equity adjustment bonus points an ACO is eligible to receive based on the proposed calculation. The following is a summary of the public comments and our responses.

Comment: A few commenters supported the proposed method of determining whether and how many health equity adjustment bonus points ACOs are eligible to receive, and some

[292] Centers for Medicare & Medicaid Services (CMS), ''Merit-based Incentive Payment System (MIPS) Scoring Guide for the 2020 Performance Year,'' Quality Payment Program, Updated May 20, 2021, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1201/2020%20MIPS%20Scoring%20User%20Guide.pdf.*

[293] Centers for Medicare & Medicaid Services (CMS), ''Merit-based Incentive Payment System (MIPS) Traditional MIPS Scoring Guide for the 2021 Performance Year,'' Quality Payment Program, Updated April 25, 2022, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1527/2021%20Traditional%20MIP%20Scoring%20S Guide.pdf.*

of these commenters had additional feedback for consideration. Two supportive commenters recommended that we consider a potential increase to the health equity adjustment bonus points to have greater and faster impact on the lives of the most at-risk beneficiaries. Another commenter in support of the proposal recommended that we delay incorporating health equity adjustment bonus points in the ACO's MIPS Quality performance category score until all providers have their EHR build complete.

Several commenters opposed the maximum health equity adjustment bonus points ACOs can receive. A few commenters were concerned about the maximum being capped at 10 health equity adjustment bonus points for ACOs. Commenters noted that 10 points is not enough of a tangible incentive for ACOs. These commenters noted that the benefit of health equity adjustment bonus points would not cover the cost of investment in underserved communities, given the medical complexity of many underserved patients. Another commenter noted that the bonus points would not appropriately adjust for the quality score differences that could occur between reporting quality measures via CMS Web Interface and eCQM/MIPS CQMs when ACOs transition to all-payer eCQM/MIPS CQM reporting. One commenter noted that 10 points was not enough to make up for regional benchmarks in which ACOs tend to compete with themselves. This commenter noted that FQHCs have a Medicare population that is not representative of their overall patient or community population, and therefore, the bonus points awarded may not account for an ACO's sub-population differences. Another commenter recommended that we offer opportunities like the Medicare Advantage program's approach of 5 percent and 10 percent benchmark bonuses, and suggested Community Health Benchmark Bonuses (CHBB) for ACO's operating in high ADI communities of 5 percent more for 70–85 ADI score and 10 percent more for ADI 85–100 rather than the current bonus point design. Another commenter noted that 10 points should be the minimum, not the maximum, since they opined the proposal will drive ACOs to onboard more underserved beneficiaries but that this individual will be new to the health care system and the adjustments should counter-balance higher costs associated with care for this patient population.

Response: Regarding an increase in the 10-point maximum, we designed the health equity adjustment to strike a balance between incentivizing ACOs to report eCQM/MIPS CQM measures, rewarding ACOs that are high performing on quality and serve higher proportions of underserved beneficiaries, and avoiding overly inflating an ACO's quality performance score. Adding additional bonus points would upset this balance because it may disproportionately increase an ACO's quality performance score. Allocating a maximum of 10 points for this bonus would align with the scoring of the required measures under the APP, as previous bonuses within the MIPS program have not exceeded 10 points or been higher than 10 percent of the score the bonus aligns with.

Regarding delaying implementation of the health equity adjustment until all ACOs have completed their switch to eCQMs/MIPS CQMS, we note that ACOs that serve a higher proportion of Medicaid enrollees may receive lower quality scores during the switch to eCQMs without an adjustment because eCQMs/MIPS CQMs are all-payer measures. As we stated in the proposed rule, the incorporation of health equity adjustment bonus points in the MIPS Quality Performance category score is consistent with our goal to support ACOs in making the transition to eCQMs/MIPS CQMs. In particular, the health equity adjustment may offset some or all of the reduction in quality scores experienced by ACOs as they switch to eCQMs/MIPS CQMs. Furthermore, though only 12 ACOs reported via eCQMs/MIPS CQMs in PY 2021, we observed that, had the health equity adjustment been available these ACOs would have received a range of bonus points including one ACO receiving the maximum 10 bonus points added to their MIPS Quality performance category score if the health equity adjustment was already implemented. Since ACOs can only increase their MIPS Quality performance category score through the health equity adjustment and ACOs have the potential to receive a high number of bonus points, we believe this supports ACOs as they switch to all-payer reporting and will not delay implementation.

Regarding a quality differential between reporting structures for ACOs, the incorporation of health equity adjustment bonus points in the MIPS Quality Performance category score is consistent with our goal to support ACOs in making the transition to eCQMs/MIPS CQMs. There is concern that an ACO may receive lower quality scores for underserved populations and that this is magnified in eCQMs/MIPS CQMs compared to reporting via the CMS Web Interface because all-payer reporting in eCQMs/MIPS CQMs includes quality scores for all people with Medicaid whereas historical reporting via the CMS Web Interface has only included those quality scores for people with Medicare and who are dually eligible for Medicare and Medicaid. Indeed, we did observe variation in reporting between the CMS Web Interface and eCQMs/MIP CQMs across the different measures for those 12 ACOs that reported all payer data in PY 2021. Therefore, without an adjustment during the switch to eCQMs/MIPS CQMs, ACOs that serve a higher proportion of people with Medicaid or other underserved populations outside of Medicare could be incentivized to avoid underserved populations, delay switching to eCQMs/MIPS CQMs for as long as possible, or even cease participation in the Shared Savings Program altogether.

Comment: Several commenters opposed our approach for determining whether an ACO is eligible for the health equity adjustment. Specifically, several commenters expressed concern that few ACOs will be able to meet the 20 percent floor since the percentage of dually eligible beneficiaries varies across States. Commenters noted issues with geographic differences such that that some regional populations may not appear underserved when comparing ACOs to the ADI national percentile rank and recommended we use LIS data as a substitute or supplement for ADI since LIS eligibility is uniform nationwide. These commenters requested that we share additional data and analysis to compare LIS and ADI by geographic region, which we discuss in section III.G.4.b.(7)(d) of this final rule.

A few commenters requested that we revise the eligibility requirements for health equity adjustment bonus points, with a couple specifically recommending that we remove the 20 percent floor requirement for the underserved multiplier. One of these commenters noted that the 20 percent floor was arbitrary such that ACOs with high quality performance but an underserved population that is 19 percent of its assigned beneficiaries would be ineligible for any health equity adjustment bonus points. This commenter suggested that the floor discourages ACOs from expanding underserved population because the shared savings payments do not cover the cost of providing high quality care to those patients. Another commenter noted that unconditional eligibility for ACOs would reduce concerns regarding the transition to eCQM reporting and

provide additional resources to address unmet social needs for a Shared Savings Program participating practice's clients. A different commenter noted that the threshold for qualifying for the adjustment is slightly too high and suggested an alternative solution to increase the number of eligible ACOs: one is to lower the underserved multiplier threshold to 15 percent, which would increase the number of eligible ACOs.

Response: We appreciate the commenters' concerns and recommendations. Regarding eligibility requirements for health equity adjustment bonus points, as stated in the proposed rule (87 FR 46138 and 46139) the establishment of a ''floor'' for the underserved multiplier reinforces that the adjustment is intended to reward ACOs that serve higher proportions of underserved beneficiaries. We believe the proposed approach would result in a significant number of ACOs earning health equity adjustment bonus points. Based on data from PY 2021, approximately 34 percent of ACOs would have had an underserved multiplier above the 20 percent floor necessary to qualify. Therefore, we believe the proposed approach would result in a significant number of ACOs earning health equity adjustment bonus points, which in turn would support these ACOs in caring for underserved populations and support these ACOs as they transition to report eCQM/MIPS CQM measures. We also anticipate that meeting the 20 percent floor for the underserved multiplier would increase over time, as existing ACOs seek to expand their reach into underserved communities.

We address any comments about ADI, dually eligible beneficiaries, LIS or the underserved multiplier that extend beyond the 20 percent floor in section III.G.4.b.(7)(d) of this final rule.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46138 and 46139), we are finalizing as proposed the eligibility criteria for the health equity adjustment and the limits on how many bonus points can be received by any ACOs in a given performance year. Specifically, we are finalizing that an ACO will be ineligible for the health equity adjustment and subsequent bonus points if their underserved multiplier is less than 20 percent of their assigned beneficiaries. We are finalizing that the number of health equity adjustment bonus points will not exceed a maximum of 10 points. Though we did not receive comment on it, we are also finalizing that the health equity adjustment bonus points will be added to an ACOs MIPS Quality performance category score, with the sum capped at 100 points.

(f) Calculation Steps and Examples

In this section, we outline the calculation steps and provide examples of the determination of health equity adjustment bonus points and the application of these bonus points (for eligible ACOs) to an ACO's MIPS Quality performance category score. These example calculations illustrate the variability in the health equity adjustment bonus points resulting from the proposed approach, which accounts for both an ACO's quality performance and the ACO's proportion of underserved beneficiaries among its assigned beneficiary population.

Step 1: Calculate the ACO's measure performance scaler.

In the example calculation of the ACO's measure performance scaler, as shown in Table 57, ACOs with ''high'' measure performance have been assigned a value of four for each of the six measures in the APP measure set for having achieved performance on these measures in the top performance group (top third). ACOs with ''middle'' measure performance have a mix of performance in the top performance group (top third, assigned a value of four per measure) and middle performance group (middle third, assigned a value of two per measure) on the six quality measures. ACOs with ''low'' measure performance have a mix of performance in the middle performance group (middle third, assigned a value of two per measure), and bottom performance group (bottom third, assigned a value of zero per measure) on the six quality measures.

TABLE 57: Example of Measure Performance Scaler Values Assigned for Each Measure

Measure #	ACO 1 and ACO 2 – High measure performance		ACO 3 and ACO 4 – Middle measure performance		ACO 5 and ACO 6 – Low measure performance	
	Performance group	Value	Performance group	Value	Performance group	Value
321	Top third	4	Top third	4	Middle third	2
479	Top third	4	Middle third	2	Bottom third	0
484	Top third	4	Middle third	2	Bottom third	0
001	Top third	4	Top third	4	Bottom third	0
134	Top third	4	Top third	4	Middle third	2
236	Top third	4	Middle third	2	Middle third	2
	Total assigned value per ACO	24	Total assigned value per ACO	18	Total assigned value per ACO	6

Table notes: Measure numbers and names: 321, CAHPS for MIPS; 479, Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups; 484, Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions; 001, Diabetes: Hemoglobin A1c (HbA1c) Poor Control; 134, Preventive Care and Screening: Screening for Depression and Follow-up Plan; 236, Controlling High Blood Pressure.

Step 2: Calculate the ACO's underserved multiplier.

Under the approach presented in the proposed rule and illustrated in Table 58, the underserved multiplier (column [C]) would be calculated as the higher of the proportion of the ACO's performance year assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85 (column [A]) or the proportion of the ACO's performance year assigned beneficiaries that are dually eligible for Medicare and Medicaid (column [B]). In line with our

modification to the proposed rule, we will consider the proportion of an ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid or are enrolled in Part D LIS, or both. To be eligible for the health equity adjustment bonus points, an ACO would need to have an underserved multiplier of 20 percent (0.2) or higher.

TABLE 58: Example of Calculation of the Underserved Multiplier Using Factors Based on ACO's Performance Year (PY) Assigned Beneficiaries

ACO characteristics	Proportion of PY assigned beneficiaries with an ADI national percentile rank of at least 85 [A]	Proportion of PY assigned beneficiaries that are dually eligible for Medicare and Medicaid [B]*	Underserved Multiplier [C] (higher of [A] or [B])
ACO 1	0.4	0.6	0.6
ACO 2	0.1	0.2	0.2
ACO 3	0.3	0.3	0.3
ACO 4	0.1	0.1	0.1
ACO 5	0.8	0.6	0.8
ACO 6	0.2	0.1	0.2

*This measure will also include the proportion of PY assigned beneficiaries that receive Part D LIS in line with modifications to the proposed rule.

Step 3: Calculate the ACO's health equity adjustment bonus points.

As shown in Table 59, to calculate the number of health equity adjustment bonus points awarded to an ACO (column [C]), CMS would multiply an ACO's measure performance scaler (Step 1, column [A]) by the ACO's underserved multiplier (Step 2, column [B]).

TABLE 59: Example of Calculation of the Health Equity Adjustment Bonus Points

ACO characteristics	Measure performance scaler [A]	Underserved Multiplier [B]	Health equity adjustment bonus points [C] (A x B)†
ACO 1	24	0.6	10.0†
ACO 2	24	0.2	4.8
ACO 3	18	0.3	5.4
ACO 4	18	0.1	n/a
ACO 5	6	0.8	4.8
ACO 6	6	0.2	1.2

Table notes:
†The maximum number of health equity adjustment bonus points to be awarded would be 10 points.
n/a = an ACO that does not meet the minimum percentage of underserved individuals in its assigned beneficiary population as determined by the underserved multiplier (that is, 20 percent or 0.2).

Step 4: Add the health equity adjustment bonus points to the ACO's MIPS Quality performance category score to calculate the ACO's health equity adjusted quality performance score.

As shown in Table 60, up to 10 health equity adjustment bonus points (Step 3, column [B]) would be added to the ACO's MIPS Quality performance category score (column [A]), with a maximum health equity adjusted quality performance score (column [C]) of 100 percent (that is, the sum is capped at 100).

TABLE 60: Example of Application of the Health Equity Adjustment to the ACO's MIPS Quality Performance Category Score

ACO characteristics	MIPS Quality performance category score (%) [A]	Health equity adjustment bonus points [B]	ACO's health equity adjusted quality performance score† [C] (A + B; not to exceed 100)
ACO 1	90.0	10.0	100.0
ACO 2	90.0	4.8	94.8
ACO 3	85.0	5.4	90.4
ACO 4	85.0	n/a	85.0
ACO 5	60.0	4.8	64.8
ACO 6	60.0	1.2	61.2

Table notes: †Refer to section III.G.4.b.(8) of the proposed rule for a discussion of how the proposed health equity adjustment would interact with the extreme and unusual circumstances policy.

We did not receive any comments specific to the steps involved in calculating the health equity adjustment bonus points or the examples provided in the proposed rule (87 FR 46139 through 46141). Any comments related to factors involved in the health equity adjustment, including the measure performance scaler, the underserved multiplier, the eligibility criteria or bonus point maximum we have summarized and responded to elsewhere in this final rule where those factors are described and defined.

(g) Incorporating the Health Equity Adjustment Into Shared Savings Program Quality Performance Reports

In the event an ACO reports both the Web Interface measure set and the eCQM/MIPS CQM measure set, the ACO will be assigned the higher of the two quality performance scores for purposes of the MIPS quality performance category (86 FR 65259). If the addition of health equity adjustment bonus points results in the ACO's eCQM/MIPS CQM quality performance score becoming higher than the ACO's Web Interface score (even though it was initially lower), the Shared Savings Program would use the health equity adjusted eCQM/MIPS CQM quality performance score as the ACO's quality performance score. The health equity adjustment would not impact a MIPS eligible clinician's final scores because the health equity adjusted quality performance score would be limited to the Shared Savings Program, where it would be used at the ACO level to determine an ACO's shared savings or losses. Under MIPS, eligible clinicians in ACOs that report both the CMS Web Interface measures and the three eCQMs/MIPS CQMs would receive the higher of either the CMS Web interface or the three eCQMs/MIPS CQMs based on their ACO's MIPS Quality performance category score.

As stated in the proposed rule, we plan to show the calculation of the health equity adjustment for all ACOs that report on eCQMs/MIPS CQM measures, even if the adjustment would not affect the determination of shared savings or shared losses for the ACO. These calculations would be provided to ACOs in their reconciliation reports package. For example, under § 425.512(a)(2)(ii), an ACO in the BASIC track that is participating in the first performance year of its first agreement period meets the quality performance standard if it reports quality data via the APP and meets data completeness and case minimum requirements specified for the performance year. An ACO meeting these criteria would qualify for the maximum sharing rate under the level of the BASIC track under which it is participating, regardless of the health equity adjustment. Likewise, if such an ACO was participating in a two-sided model under the BASIC track and was liable for shared losses, the ACO would be subject to a fixed 30 percent shared loss rate that would also be unaffected by the health equity adjustment. For such an ACO, the calculation and reporting of the health equity adjustment would be for purely informational purposes. This information would provide ACOs with an understanding of the proportion of underserved individuals they care for and give ACOs additional insight into this population and opportunities for improvement as they transition to all payer quality measure reporting and develop associated quality improvement strategies and initiatives.

While we received no comments explicitly addressing our proposal to include information on the health equity adjustment in the reconciliation reports package provided to ACOs, several commenters recommended that we provide more information overall to ACOs related to the adjustment. The following is a summary of the public comments and our responses.

Comment: A few commenters recommended that CMS share additional data and analysis with ACOs regarding dual eligibility status, ADI, and Part D LIS data sources, as well as the number of beneficiaries who would qualify under each metric by geographic regions. One commenter recommended that CMS work with ACOs toward quality reporting that is disaggregated across sub-populations so that implementation of any adjustment would not shield disparities and outcomes. Another commenter encouraged CMS to report ACO quality measure results that are stratified by subgroups of the underserved population. One commenter noted that quality data reporting will be essential when identifying whether the adjustment is achieving its intended aims and helping the relevant populations. A different commenter urged us to consider segmenting patient outcomes to the extent feasible by beneficiary characteristics such as race/ethnicity in addition to implementing the health equity adjustment. A final commenter recommended that CMS provide ADI data for every beneficiary when available as part of the quarterly attribution files ACOs receive.

Response: As we stated in the proposed rule (87 FR 46141 and 46142) and previously in this section of the final rule, we plan to provide ACOs with data related to their health equity adjustment. Specifically, we plan to show the calculation of the health equity adjustment in the reconciliation reports for all ACOs that report on eCQMs/MIPS CQM measures, even if the adjustment does not impact the determination of shared savings or shared losses for the ACO. Regarding the requests for additional data beyond the calculation of the health equity

adjustment, we appreciate commenters' feedback and want to confirm that CMS will make available certain additional information on dual eligibility status, Part D LIS, and ADI to all ACOs on their assigned beneficiary populations under our existing data sharing regulations at 42 CFR part 425, subpart H. Specifically, in quarterly and annual reports such as the assignment list report, we will include beneficiary identifiable information on dual eligibility, ADI, and LIS status. We will also provide aggregate data, such as the proportion of the ACO's assigned beneficiaries that are dually eligible or enrolled in the LIS, and the proportion of the ACO's assigned beneficiaries with an ADI national percentile rank of 85 or above in the quarterly and annual reports. As set forth in our regulations at § 425.702(a), (c)(1)(ii)(B)(1) and (c)(1)(ii)(C), CMS shares certain aggregate reports with ACOs under specific conditions, and this information includes demographic data that represents the minimum data necessary for ACOs to conduct health care operations work, which could encompass the dual eligibility, LIS, and ADI information. We understand ACOs may need this dual eligibility, LIS, and ADI information for quality assessments and population-based activities related to improving health and coordinating care. We also believe ACOs may need this information to conduct other health care operations activities described in paragraph (1) or (2) of the definition of ''health care operations'' in 45 CFR 164.501, such as population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, and quality assessment and improvement activities. Therefore, we believe this dual eligibility, LIS, and ADI information may be made available under our existing data sharing regulations and processes. We will take commenters feedback on other types of beneficiary-level data or data stratification into consideration.

After considering the public comments, we are finalizing as proposed our proposal to provide ACOs with information on the calculation of the health equity adjustment in their reconciliation reports if they report on eCQMs/MIPS CQM measures. We also plan to make available to ACOs on a quarterly and annual basis certain beneficiary-identifiable data on dual eligibility, LIS, and ADI national percentile rank. This will enable greater transparency into the calculation of the health equity adjustment and provide ACOs with data necessary to improve quality and coordinate care, promoting high quality care for underserved populations.

(h) Modifications to the Regulations

We proposed to amend the regulation at § 425.512, which establishes the ACO quality performance standard for performance years beginning on or after January 1, 2021, to include a new paragraph (b) to govern the calculation of an ACO's health equity adjusted quality performance score for PY 2023 and subsequent performance years, including the policies governing calculation of health equity adjustment bonus points (87 FR 46142). We also proposed to make additional conforming changes to § 425.512 to incorporate references to the health equity adjusted quality performance score, through proposed modifications to § 425.512(a)(4)(i)(A), and within proposed revisions to § 425.512(a)(5)(i)(A)(*1*) and (a)(5)(i)(B) (87 FR 46142).[294]

We proposed further technical and conforming changes to § 425.512 to redesignate existing paragraph (b) specifying the alternative approach to calculating the quality performance score for ACOs affected by extreme and uncontrollable circumstances, as a new paragraph (c). We also proposed a modification to update a cross-reference within the newly redesignated § 425.512(c) for accuracy and to revise newly redesignated § 425.512(c)(3) to specify that we would use the health equity adjusted quality performance score in determining the quality performance score for ACOs affected by extreme and uncontrollable circumstances that report quality data under the APP and meet data completeness and case minimum requirements for PY 2023 and subsequent performance years (refer to section III.G.4.b.(8) of the proposed rule).

In addition, as described in the proposed rule, we proposed to revise § 425.605 and 425.610 to specify use of the ACO's health equity adjusted quality performance score determined in accordance with § 425.512(b) for purposes of calculating an ACO's final sharing rate based on a sliding scale. Similarly, as proposed, the modifications to § 425.610 specify use of the ACO's health equity adjusted quality performance score determined in accordance with § 425.512(b) for purposes of calculating the ACO's shared loss rate based on a sliding scale.

As discussed in the proposed rule (87 FR 46142), we believe the health equity adjustment proposal would support ACOs transitioning to all-payer quality measure reporting, incentivize ACOs to report eCQMs/MIPS CQMs, provide stronger incentives for quality improvement, and recognize high performing ACOs serving underserved populations. We sought comment on all aspects of the proposed methodology.

Given that the proposed approach, if finalized, would be the initial implementation of a health equity adjustment under the Shared Savings Program, we noted our intent to monitor the impact of the adjustment to ensure it achieves the goal of rewarding ACOs for high quality performance while caring for larger proportions of underserved beneficiaries (87 FR 46142). We stated that we would consider modifications as necessary to the design of the health equity adjustment through future notice and comment rulemaking.

The following is a summary of the remaining public comments received on the health equity adjustment proposal.

Comment: Some commenters noted the importance of quality data reporting to identify health inequity and support relevant populations. Some of these commenters encouraged CMS to provide incentives for consistent collection of data that can better identify disparities. Others recommended we identify a subset of ACO quality measures that could be stratified using this race, ethnicity and social risk factors. These commenters stated that stratifying subpopulations and incentivizing improvement based on this data could help ACOs invest in resources to make improvements.

Another commenter stated that more administrative support to ACOs in identifying and tracking performance would be needed in order for ACOs to benefit from the health equity adjustment.

One commenter also recommended we reimburse ACOs for social determinant of health screenings and utilizing z-codes. A commenter recommended that we continue to explore a full range of approaches to accounting for social needs in quality measurement, including direct risk adjustment when necessary.

One commenter suggested that we develop a longer-term equity-specific plan and explore how community

[294] We note that we proposed to use the term ''health equity adjusted quality performance score'' uniformly in the regulation provisions enumerated in this section of the proposed rule, even in cases where an ACO's MIPS Quality performance category score is based on its reporting of the Web Interface measure set. For such ACOs, the health equity adjustment is assumed to be zero.

organizations can also be included within broadened ACOs.

A commenter recommended that we consider requiring ACOs to apply a portion of the incentive to help build the nursing facility health-information technology infrastructure interoperability capabilities.

Response: We appreciate commenters' input on the heath equity adjustment and will take them into consideration as we continue to consider efforts to integrate health equity into the Shared Savings Program. At this time, we decline commenters' suggestions to provide additional incentives for data collection as the purpose of the health equity adjustment was not to collect additional data regarding health inequity but to reward ACOs serving a higher proportion of underserved beneficiaries while delivering high quality care. We also note that many of the commenters' alternative suggestions on how to advance health equity and account for social needs go beyond the scope of the health equity adjustment proposed in CY 2023 PFS proposed rule and we will not be addressing them in the final rule, but may be considered in future rulemaking.

In conclusion, after review of the public comments received related to the health equity adjustment and for the reasons stated above and in the proposed rule (87 FR 46132 through 46143), we are finalizing at § 425.512(b) our proposal to create the health equity adjustment with a modification to the calculation of the underserved multiplier to incorporate information on Part D LIS enrollment. Specifically, the underserved multiplier will be determined based on the higher of the proportion of assigned beneficiaries enrolled in LIS or dually eligible for Medicare and Medicaid, or the proportion of the ACO's beneficiaries residing in census block groups with an ADI national percentile rank of at least 85. ACOs will be ineligible to receive any bonus points if their underserved multiplier is less than the ''floor'' of 20 percent.

We are also finalizing the creation of three groups based on measure performance to determine an ACO's performance on quality for the purpose of calculating health equity adjustment bonus points: (1) a group comprised of the top third performing ACOs; (2) a group comprised of the middle third performing ACOs; and (3) a group comprised of the bottom third performing ACOs. These groups will be created for each of the six measures independently such that an ACO in the top group based on performance on one measure may be in the bottom group based on performance on another measure. The three groups will be created by reporting mechanism so that ACOs that report eCQMs/MIPS CQMs will have each measure grouped into a top, middle, and bottom third based on the performance of other ACOs that also report eCQMs. For the CAHPS for MIPS survey and claims-based measures, ACOs will be compared to all ACOs with data on those measures.

We are also finalizing that ACOs will receive a value of four for each measure for which its performance places it in the top performance group, a value of two for each measure for which its performance places it in the middle performance group, and a value of zero for each measure for which its performance places it in the bottom performance group. The values assigned to each measure in the APP measure set will be summed to determine an ACO's total assigned value, which we refer to as the ACO's ''measure performance scaler.'' We are finalizing that the ACO's health equity adjustment bonus points will be calculated by multiplying this measure performance scaler and the ACO's underserved multiplier.

We will assign a value of zero to a measure in certain cases when we would not evaluate the ACO's performance on a measure. For purposes of calculating the health equity adjustment, an ACO will receive zero for a claims-based measure or an eCQM/MIPS CQM for which the ACO does not meet the case minimum requirements at § 414.1380. Similarly, an ACO will receive zero for the CAHPS for MIPS survey in the event it does not meet the minimum sample size requirements. An ACO that cannot meet case minimum requirements or does not have a sufficient sample size to administer the CAHPS for MIPS survey would still qualify to receive the health equity adjustment bonus for those measures that were accurately and completely reported and provided the ACO met the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs.

We are finalizing that the health equity adjustment will be available for PY 2023 and for subsequent performance years to an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey. Such ACOs may receive up to a maximum of 10 additional points added to their MIPS Quality performance category score.

We are also finalizing that an ACO's health equity adjusted quality performance score will be applied in determining whether the ACO met the quality performance standard set at the 30th percentile for PY 2023 as specified under § 425.512(a)(4)(i)(A), or the 40th percentile for PY 2024 and subsequent performance years, as specified in the revised regulations at § 425.512(a)(5)(i)(A)(1) and (a)(5)(i)(B), respectively.

We are finalizing our proposal to apply an ACO's health equity adjusted quality performance score in determining shared savings and losses. Specifically, we will use an ACO's health equity adjusted quality performance score to determine the final sharing rate for calculating shared savings payments under the BASIC track (under § 425.605(d)) and the ENHANCED track (under § 425.610(d)) for an ACO that meets the alternative quality performance standard allowing for application of a sliding scale based on quality performance, as specified in the revisions to § 425.512(a)(4)(ii) and (a)(5)(ii). For ENHANCED track ACOs that owe shared losses, we will apply the health equity adjustment to the ACO's quality performance score used in calculating the ACO's shared loss rate to allow the ACO to share in losses at a relatively lower rate, based on its quality performance. We will use an ENHANCED track ACO's health equity adjusted quality performance score in calculating shared losses under § 425.610(f) when the ACO meets the quality performance standard specified under § 425.512(a)(4)(i) or (a)(5)(i) or meets the alternative quality performance standard under § 425.512(a)(4)(ii) and (a)(5)(ii) allowing for the application of a sliding scale based on quality performance.

We are finalizing that the health equity adjustment be applied in calculating the ACO's quality performance score for an ACO affected by extreme and uncontrollable circumstances if the ACO is able to report quality data via the APP and meet data completeness and case minimum requirements, as provided in redesignated § 425.512(c)(3).

Finally, we are finalizing our proposal to incorporate the health equity adjustment into the Shared Savings Program quality performance reports. If the addition of health equity adjustment bonus points results in the ACO's eCQM/MIPS CQM quality performance score becoming higher than the ACO's Web Interface score, the Shared Savings Program will use the health equity adjusted eCQM/MIPS CQM quality performance score as the ACO's quality performance score. We plan to show the calculation of the health equity

adjustment including dual eligibility, LIS, and ADI data for all ACOs that report on eCQMs/MIPS CQM measures, even if the adjustment would not affect the determination of shared savings or shared losses for the ACO. These calculations will be provided to ACOs in their reconciliation reports package.

(8) Application of Extreme and Uncontrollable Circumstances Policy

The approach used to calculate the quality score for ACOs affected by extreme and uncontrollable circumstances (EUC) is described in § 425.512(b)(2) and (3) of the current regulations, which we proposed to redesignate as § 425.512(c)(2) and (3) (refer to section III.G.4.b.(7)(h) of the proposed rule) (87 FR 46142). In summary, under the current EUC policy, for an ACO that fails to report quality data via the APP or that reports quality data but fails to meet the data completeness or case minimum requirements applicable for the performance year, we will set the ACO's quality performance score to the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores for the relevant performance year, as described in § 425.512(b)(2). For an ACO that reports quality data via the APP and successfully meets data completeness and case minimum requirements, we will use the higher of the ACO's own health equity adjusted quality performance score or the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores as described in § 425.512(b)(3).

By design, any ACO that is deemed to be affected by an extreme and uncontrollable circumstance will receive a score that is at least as high as the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores, thus aligning with the quality performance standard applicable for the performance year as described under § 425.512(a) in the current regulations. An ACO affected by an extreme and uncontrollable circumstance that is eligible for shared savings (by virtue of having savings that meet or exceed its MSR) will thus receive a final sharing rate equal to the maximum sharing rate for the ACO's track (or payment model within a track) in the calculation of its shared savings amount, as described in § 425.605(d) (for ACOs participating in the BASIC track) or § 425.610(d) (for ACOs participating in the ENHANCED track). An ACO affected by an extreme and uncontrollable circumstance participating in the ENHANCED track that is liable for shared losses (by virtue of having losses that meet or exceed its minimum loss rate) will face a shared loss rate that considers the ACO's quality performance as described in § 425.610(f).

An ACO that is determined to have been affected by an extreme and uncontrollable circumstance and is eligible for shared savings would already receive the maximum possible sharing rate for its track (or payment model within a track) under the current extreme and uncontrollable circumstances policy. The sharing rate for such an ACO would not be affected by our proposal to re-institute scaled shared savings as described in section III.G.4.b.(2) of the proposed rule. That is, an ACO affected by an extreme and uncontrollable circumstance that meets the proposed alternative quality performance standard, if finalized, would continue to qualify for the maximum sharing rate for its track (or payment model within a track) rather than receiving a sharing rate scaled based on the ACO's quality performance.

An ACO participating in the ENHANCED track that is affected by an extreme and uncontrollable circumstance and is liable for shared losses already receives a shared loss rate that is scaled by the ACO's quality performance under the current extreme and uncontrollable circumstances policy. If such an ACO meets the proposed alternative quality performance standard, if finalized, it would continue to receive a shared loss rate that is scaled by its quality performance. Thus, our proposal to extend scaled shared losses to ENHANCED track ACOs that meet the alternate quality performance as described in section III.G.4.b.(3) of the proposed rule would not, by itself, have a practical impact on the shared loss rate for an ACOs affected by an extreme and uncontrollable circumstance.

With regard to the proposed health equity adjustment, for an ACO affected by an extreme and uncontrollable circumstance that reports eCQMs/MIPS CQMs via the APP, and successfully meets the data completeness requirement at § 414.1340 and case minimum requirement at § 414.1380, we proposed to apply the health equity adjustment bonus points to the ACO's MIPS Quality performance category score, as described in section III.G.4.b.(7) of the proposed rule (87 FR 46134 and 46135), before determining the ''higher of'' score under the extreme and controllable circumstances policy. That is, the ACO would receive the higher of the quality performance score equal to the sum of the ACO's MIPS Quality performance category score and the ACO's health equity adjustment bonus points (that is, the health equity adjusted quality performance score) or a score equivalent to the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores. We proposed to specify the use of the health equity adjusted quality performance score in determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances within the proposed new provision at § 425.512(b) and in determining the ''higher of'' score under the redesignated provisions at § 425.512(c)(3)(ii) and (iii).

As explained in the proposed rule (87 FR 46134 and 46135), the proposed approach of applying the health equity adjustment before determining the ''higher of'' score under the extreme and uncontrollable circumstances policy would have no practical impact on the sharing rate for an ACO that is eligible to share in savings. By design, such an ACO would meet or exceed the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) MIPS Quality performance category score, and qualify for the maximum sharing rate for its track (or payment model within a track). However, for an ACO participating in the ENHANCED track that is liable for shared losses, the application of the health equity adjustment could increase the ACO's quality performance score used to determine the ACO's shared loss rate, and thus potentially reduce the amount of shared losses owed to CMS.

For an ACO affected by an extreme and uncontrollable circumstance that fails to report quality data via the APP or that reports but fails to the meet data completeness or case minimum requirements, we would continue to set the ACO's quality performance score to the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) MIPS Quality performance category score. Such an ACO would not meet the proposed requirements for the health equity adjustment with respect to reporting and measure performance.

We did not receive any comments on the proposed revisions to the application of the extreme and uncontrollable circumstances policy, and for the reasons stated above and in the proposed rule (87 FR 46142 and

46143), we are finalizing the revisions as proposed.

(9) Summary of the Final Policies

The following provides an overview of the quality performance standards that apply to future performance years for the purpose of determining the rate at which an ACO may share in savings.

Performance Year 2023

• PY 2023, to share in savings at the maximum savings rate under its track (or payment model within a track), an ACO must:

++ Report the 10 CMS Web Interface measures in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP, and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or

++ Report the three eCQMs/MIPS CQMs in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, the ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

• An ACO that fails to meet the criteria above may qualify to share in savings on a sliding scale based on its performance on any of the 10 CMS Web Interface measures or three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS' calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.

• If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Performance Year 2024

• PY 2024, to share in the savings at the maximum rate under its track (or payment model within a track) an ACO must:

++ Report the 10 CMS Web Interface measures in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP, and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or

++ Report the three eCQMs/MIPS CQMs in the APP measure set and administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, the ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

• An ACO that fails to meet the criteria above may share in savings on a sliding scale based on its performance on any of the 10 CMS Web Interface measures or three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS' calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.

• If an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Performance Year 2025 and Subsequent Performance Years

• PY 2025 and subsequent performance years, to share in savings at the maximum savings rate under its track (or payment model within a track), an ACO must: report quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

• An ACO that fails to meet the criteria above may share in savings on a sliding scale based on its performance on any of the three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS's calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.

• If an ACO does not report any of the 3 eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Similarly, we are adopting a methodology for calculating shared losses under the ENHANCED track to account for the sliding scale approach, which would remove the ''cliff'' from the all-or-nothing approach instituted in the CY 2021 PFS final rule (85 FR 84734 through 84736) whereby an ACO that does not meet the quality performance standard would automatically face the maximum shared loss rate of 75 percent. For PY 2023 and subsequent performance years, an ACO that has losses that exceed its minimum loss rate and either meets the quality performance standard or does not meet that standard but meets the proposed alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would have a shared

loss rate that is 1 minus the product of the maximum sharing rate for the ACO's track (75 percent) and the ACO's health equity adjusted quality performance score. The shared loss rate would be subject to a minimum of 40 percent and a maximum of 75 percent.

An ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, may receive up to a maximum of 10 points added to its MIPS Quality performance category score. This combined score would be the ACO's health equity adjusted quality performance score and would be used in determining whether the ACO met the quality performance standard and in determining scaled shared savings and shared losses, as applicable, as summarized in this section of the proposed rule. This health equity adjusted quality performance score will also be used when applying the extreme and uncontrollable circumstances policy for ACOs that report quality data via the APP and meet data completeness and case minimum requirements.

In addition, we clarify that any requirements that are based on achieving a specified quality performance score on outcome measures are limited to outcome measures that are scored. For example, please refer to Table 62 in section III.G.4.c.(1) of this final rule, which indicates the CMS Web Interface measure Depression Remission at Twelve months is an outcome measure that is not scored.

We reiterate our statement in the CY 2022 PFS final rule that for PYs 2022, 2023 and 2024 if an ACO: (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs; and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65261). In addition, we are adopting that, for PYs 2023 and 2024, an ACO that does not meet these requirements would also fail to meet the alternative quality performance standard. Such an ACO would not be eligible to share in savings and, if in the ENHANCED track, would automatically face the maximum shared loss rate.

Additionally, as finalized in the CY 2022 PFS final rule, beginning with PY 2025, ACOs will be required to report eCQMs/MIPS CQMS, as the Web Interface reporting option sunsets after PY 2024 (86 FR 65261).

As discussed in section III.G.5.f. of this final rule, we are finalizing our proposal to allow certain ACOs in the BASIC track that do not meet their MSR to receive reduced shared savings. Accordingly, ACOs that meet the requirements of that policy will share in savings at a rate equal to one half of the final sharing rate determined based on the ACO's quality performance, as described in this section.

In Table 61 in section III.G.4.b.(9) of this final rule, we summarized the proposed changes to the regulation at § 425.512(a)(4) and (5) to reflect these proposed changes to the quality reporting requirements for PY 2023 and subsequent performance years.

We are finalizing the proposed health equity adjustment calculation of an underserved multiplier at § 425.512(b)(2)(iv)(A) with a modification to use enrollment in the Part D LIS, in addition to Medicare and Medicaid dual eligibility and ADI score to determine the underserved multiplier. Specifically, the underserved multiplier will be determined based on the higher of the proportion of an ACO's assigned beneficiaries who are enrolled in LIS or dually eligible for Medicare and Medicaid and the proportion of the ACO's assigned beneficiaries who reside in a census blocks with high ADI. We are also finalizing a revision to § 425.512(b)(3)(iii) which provides that the health equity adjusted quality performance score is used for determining the shared loss rate for calculating shared losses under the ENHANCED track with a modification to correct the citation to the applicable performance standard. The language contained in the CY 2023 PFS proposed rule inadvertently omitted any reference to paragraph (a)(5)(ii), which includes the performance standard for PY 2024 and subsequent years.

We note that the quality performance standard policies we finalized in the CY 2022 PFS final rule (86 FR 65270) for the first performance year of an ACO's first agreement period under the Shared Savings Program will continue to remain applicable in addition to the quality performance standard policies we are finalizing in this final rule.

In Table 61 of this final rule, we summarize the final changes to the regulation at § 425.512(a)(4) and (5) to reflect these final changes to the quality reporting requirements and quality performance standard for PY 2023 and subsequent performance years. Performance benchmarks used to determine the 10th, 30th, and 40th percentiles will be posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library*. Performance benchmarks differ by collection type (that is, eCQM, MIPS CQM, CMS Web Interface) and are updated for each performance year.

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TABLE 61: Final APP Reporting Requirements and Quality Performance Standard for Performance Year 2023 and Subsequent Performance Years

	Performance Year 2023	Performance Year 2024	Performance year 2025 and Subsequent Performance Years*
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface **or** the 3 eCQMs/MIPS CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.	Same as PY 2023	ACOs are required to report on the 3 eCQMs/MIPS CQMs and field the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.
Shared Savings Program ACO Quality Performance Standard	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring; or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement and the case minimum requirement for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet either of the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement and the case minimum requirement for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or An ACO that fails to meet the criterion above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

*The CMS Web Interface reporting option sunsets after PY 2024 and is no longer available beginning with PY 2025.

c. Quality Measures

(1) Final APP Measure Set

We refer readers to Table 62, which lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for PY 2022 and subsequent performance years. These are the same measures finalized in the CY 2022 PFS final rule (86 FR 65264 through 65266); however, we note that the Meaningful Measures 2.0 area for each measure has been updated to be consistent with the latest information available on the Meaningful Measures website and a measure number has been added for the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS measure.[295] We proposed to change the nomenclature of this measure to align with the MIPS program. There are no other changes to this measure except for the name and the addition of a measure number. The measure title we proposed to use moving forward is Measure 484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. In addition, we have included the measure type in Table 62, for each measure in the measure set. We are including this information to

[295] Centers for Medicare & Medicaid Services, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization,* (2022), available at *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

provide ACOs a list of the outcome measures for purposes of meeting the quality performance incentive for reporting eCQMs/MIPS CQMs. This information is also relevant to our proposal to establish an alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score at the 10th percentile on 1 of the 4 outcome measures in the APP measure set, may be eligible to share in savings on a sliding scale. We noted inclusion of this information does not change any of the measures in the measure set.

TABLE 62: Measures included in the Final APM Performance Pathway Measure Set (APP) for Performance Year 2022 and Subsequent Performance Years [a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	PRO-PM*
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface**	APM Entity/Third Party Intermediary	Safety	Process
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Process
Quality ID#: 370	Depression Remission at Twelve Months***	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Outcome^

[a] We note that we proposed not to score the following CMS Web Interface measures: the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID#438) and Depression Remission at Twelve Months (Quality ID #370); as these measures do not have benchmarks and we are therefore proposing for them not to be scored for PY 2022; they are however required to be reported in order to complete the Web Interface data set.

^ Indicates this is an outcome measure.

* Patient-reported outcome-based performance measure (PRO-PM) is a performance measure that is based on patient-reported outcome measure (PROM) data aggregated for an accountable healthcare entity.

**ACOs will have the option to report via the Web Interface for the 2022, 2023, and 2024 performance years only.

*** This measure is not included as one of the four outcome measures for purposes of the Quality Reporting Standard as this measure is not scored.

Table 63 includes the proposed eCQM/MIPS CQM measure set for the Shared Savings Program and outlines the measure types, especially for ACOs that may elect to report on eCQM/MIPS CQMs for PY2023 in order to qualify for the incentive under § 425.512(a)(4)(i)(B).

TABLE 63: Proposed APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2023

Measure #	Measure Title	Measure Type	SSP Quality Performance Standard	
			MIPS Comparable Measure	Outcome Measure
Quality ID#: 321	CAHPS for MIPS	Patient-Reported Outcome	Yes	No
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes	Yes
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes	Yes
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes	Yes
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	Yes	No
Quality ID#:236	Controlling High Blood Pressure	Intermediate Outcome	Yes	Yes

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The CMS Web Interface collection type under traditional MIPS and the APP includes 10 measures. One of the 10 measures included in the CMS Web Interface collection type is measure Q110: Preventive Care and Screening: Influenza Immunization (also referred to PREV–7 under the CMS Web Interface collection type). Table Group CC of Appendix 1 of the proposed rule includes a proposal to remove measure Q110: Preventive Care and Screening: Influenza Immunization from traditional MIPS for the Medicare Part B Claims, eCQM, and MIPS CQM collection types starting with the 2023 performance period and a proposal to retain the measure for use in relevant MVPs and as a measure in the CMS Web Interface collection type under the APP for purposes of APM Entity-level reporting applicable to Medicare Shared Savings Program ACOs. Because Shared Savings Program ACOs report under the APP, this measure would still be available as a measure under the CMS Web Interface collection type. Please refer to Table Group CC of Appendix 1 where we discuss this proposal further. We also proposed to make changes to measure specifications for the CMS Web Interface starting in PY 2023. As proposed, the changes would update measures and align these measures with the CQM practice workflows and for consistency with clinical guidelines.

We did not receive any comments on the proposed change to the name and addition of a measure number to one of the administrative claims-based measures (Measure 484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions) to align with the MIPS program.

For the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46097), we are finalizing the proposal to change the name and add a measure number to the administrative claims-based measure, Measure 484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions, to align this measure with the MIPS program for PY 2022 and subsequent performance years.

(2) Benchmarking Policies for CMS Web Interface Measures for Performance Years 2022, 2023, and 2024

In the CY 2021 PFS final rule, we finalized a change to the quality reporting requirements for purposes of the Shared Savings Program (85 FR 84720 through 84734). Effective for PY 2021 and subsequent performance years, Shared Savings Program ACOs are required to report quality data via the APP. Under this new approach, ACOs only need to report one set of quality metrics via the APP to satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. In the CY 2021 PFS final rule (85 FR 84720), we explained that the APP measure set would address the highest priorities for quality measurement and improvement, while also reducing reporting burden, promoting alignment of measures and consolidation of reporting requirements across CMS programs, moving payment toward value, and identifying consumers' key quality performance metrics. We also stated that, under the APP, the quality performance score for an ACO will be calculated using the same benchmarks that are established for quality measures available under MIPS (85 FR 84724). Measure benchmarks established under MIPS are based on performance by collection type (that is, eCQM or MIPS CQM) using data from all available sources, including MIPS eligible clinicians and APM Entities, to the extent feasible, during the applicable baseline or performance period (§ 414.1380(b)(1)). Under § 414.1380(b)(1)(ii)(A), the benchmarks from the corresponding reporting year of the Shared Savings Program are used to score CMS Web Interface measures for purposes of the MIPS Quality performance category. Accordingly, in the preamble to the CY 2021 PFS we indicated that for PY 2021, we would continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface measures for PY 2020, which were based on data reported by ACOs, MIPS eligible clinicians, and groups through the CMS Web Interface, and/or a registry from 2016, 2017 and 2018, which would allow us to be consistent with the approach that had been used for scoring CMS Web Interface measures in the Shared Savings Program under § 425.502(b) (85 FR 84724). Furthermore, consistent with the final policy to require ACOs to report quality data via the APP and to score those measures using the MIPS benchmarks, in the CY 2021 PFS final rule, we

revised § 425.502 to apply only to performance years beginning on or before January 1, 2020.

Under the policies adopted in the CY 2021 PFS final rule, PY 2021 would have been the final year in which ACOs would have the option to report either the 10 CMS Web Interface measures or the 3 eCQMs/MIPs CQMs under the APP, and starting in PY 2022 all ACOs would be required to report the 3 eCQMs/MIPS CQMs (85 FR 84722 and 84723). However, as explained in the proposed rule, in response to concerns raised by commenters regarding the timeline for implementing eCQM/MIPS CQM reporting requirements under the APP for Shared Savings Program ACOs in the CY 2022 PFS final rule, we further extended the CMS Web Interface as a collection type under the Quality Payment Program for PYs 2022, 2023, and 2024 for Shared Savings Program ACOs reporting under the APP (85 FR 65261).

When we finalized the extension of the CMS Web Interface as a collection type for the Shared Savings Program, we failed to consider the policies that would apply for purposes of establishing the performance benchmark and minimum attainment level for the CMS Web Interface measures for PYs 2022, 2023, and 2024. As noted previously, when we adopted the requirement that ACOs report quality for purposes of the Shared Savings Program using the APP, our intent was to use the measure benchmarks established under MIPS to score the measures in the APP measure set. However, under § 414.1380(b)(1)(ii)(A), we use the benchmarks from the corresponding reporting year of the Shared Savings Program to score CMS Web Interface measures for purposes of the MIPS Quality performance category. Thus, because the benchmarking policies under § 425.502(b) that were used to establish quality measure benchmarks in the Shared Savings Program prior to the development and implementation of the APP were sunset with the 2020 performance year, there are no policies currently in place that can be used to establish benchmarks for the CMS Web Interface measures in the APP measure set for purposes of determining quality performance under the Shared Savings Program for PYs 2022, 2023, and 2024. Additionally, the absence of benchmarking policies under the Shared Savings Program also impacts MIPS because MIPS uses the CMS Web Interface measure benchmarks established by the Shared Savings Program (§ 414.1380(b)(1)(ii)(B)).

Under the regulation at § 425.502(b)(4)(i), CMS updated the quality performance benchmarks every 2 years. The last set of CMS Web Interface measure benchmarks were established for PY 2020 and were also used to score the Web Interface measures for PY 2021 as explained in the CY 2021 PFS final rule (85 FR 84724). In light of the decision to extend the availability of the CMS Web Interface measures under the APP, we now need to establish benchmarks under the Shared Savings Program for these measures for PYs 2022, 2023, and 2024. We noted in the CY 2023 PFS proposed rule (87 FR 46150) that we believe that the previously established benchmark policies at § 425.502(b) continue to be appropriate for purposes of establishing the quality measure benchmarks and minimum attainment levels and establishing a point scale for the CMS Web Interface measures under the Shared Savings Program for PYs 2022, 2023, and 2024. In the 2015 PFS final rule (79 FR 67927), we finalized the benchmarking proposal to set benchmarks for 2 years for stability in quality improvement targets while also maintaining reasonable current practices. We proposed in the 2023 PFS proposed rule to use this approach for PYs 2022, 2023 and 2024, using available data for PYs 2022 and 2023 and establishing benchmarks for PY 2024 which is the last year of Web Interface reporting (87 FR 46150). We noted that we believe the policies are still appropriate as it would provide stability during the transition to all-payer reporting and sunsetting of the Web Interface reporting option, as well as prevent potential variations that could unintentionally create provider burden. In addition, this would allow CMS to score as many of the Web Interface measures as possible, providing stronger incentives for improving and delivering high quality care. Furthermore, using the same policies to establish the benchmarks for the CMS Web Interface measures for PYs 2022, 2023, 2024, would maintain consistency in the development of CMS Web Interface measure benchmarks. Therefore, we proposed to amend the regulation at § 425.512, which governs the ACO quality performance standard for performance years beginning on or after January 1, 2021, to include a new paragraph (a)(6), which will provide that for PYs 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b) (87 FR 46150).

We acknowledged that to the extent we proposed to apply these benchmark policies to determine performance benchmarks for the Web Interface measures for PY 2022, the proposal would be retroactive and would require the use of our authority under section 1871(e)(1)(A) of the Act, which permits the retroactive application of a substantive change in the regulations when the failure to do so would be ''contrary to the public interest.'' We stated our belief that this proposal meets the standard for retroactive rulemaking as absent retroactive application of the proposed benchmarking policies the CMS Web Interface measures could not be scored in PY 2022 for use under the Shared Savings Program in determining shared savings and losses or under MIPS for purposes of the MIPS payment adjustments (87 FR 46150). We also note that by establishing policies that will allow us to adopt benchmarks for these measures, we will ensure that we can determine the ACOs' quality performance score. If we did not have the authority to establish benchmarks, we would be unable to score ACO quality performance which is used to calculate shared savings and losses inhibiting our ability to successfully implement the Shared Savings Program and recognize and reward ACOs for better care coordination and quality improvement. At the same time, the lack of benchmarks to score quality measures submitted by ACOs would prevent their MIPS eligible clinicians from receiving any MIPS payment adjustment they may be eligible for and could subject them to negative MIPS payment adjustments if they are determined to have poor performance due to the inability to benchmark performance and score the measures submitted by the ACO. In addition, as mentioned above it is in the public interest to establish benchmarks as it should strengthen the incentive for ACOs to deliver high quality and coordinated care consistent with the goals of the Shared Savings Program. We believe there are advantages in having a greater number of scored measures in the CMS Web Interface, including the ability for Shared Savings Program ACOs to report on a larger number of measures to have a potentially higher score, as well as collecting data on measures that can be used for ACOs' quality improvement. An ACO's performance on each measure is assessed against its benchmark to determine points and the overall Quality performance category score. Additionally, when CMS determines

that a benchmark cannot be provided for a Web Interface measure, the measure will not be scored for Shared Savings Program ACOs. However, ACOs would still be required to report on any measure that is not scored in order to complete the CMS Web Interface dataset.

We also need to make a correction from the CY 2022 PFS final rule (86 FR 65266) in which we inadvertently indicated that a benchmark would not be created for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226). In the CY 2022 PFS final rule (86 FR 65262), we noted three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Cessation: Screening and Cessation Intervention (Quality ID# 226)) did not have benchmarks for PY 2022 and would not be scored, however, the measures were required to be reported in order to complete the CMS Web Interface dataset (87 FR 46150). We refer to Table 62 for a listing of the measures that would not have benchmarks, and therefore, would not be scored for PY 2022.

We have determined that we do not have adequate historical data available for benchmarking for the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) measure for the 2022 performance year. Therefore, we proposed pursuant to § 425.512(b)(6) to set flat percentage benchmarks for the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) measure (87 FR 46150). Since we stated in the CY 2022 PFS final rule (86 FR 65266) that a benchmark would be created for Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134), we find it suitable to use flat percentage benchmarks to measure performance on the measure.

We proposed in the CY 2023 PFS proposed rule to score the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure using flat percentage benchmarks under the approach we proposed to amend the regulation at § 425.512 (87 FR 46151). The Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure triggered flat percentage benchmarks by the policies described at § 425.502(b)(2)(ii) in the previous benchmarking update for the 2020 and 2021 performance years. Therefore, as noted in the proposed rule, we believe it would be advantageous for the measure to keep its flat percentage benchmarks for the 2022 performance year for continuity and that having another scored measure can be beneficial to an ACO's overall quality performance.

As we proposed for Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) to be scored using flat percentage benchmarks for the 2022 performance year, ACOs would be scored on eight out of ten CMS Web Interface measures. We also noted that we believe ACOs might prefer to be scored under a greater number of measures which may improve their overall score and performance for purposes of Shared Savings Program quality assessment. Lastly, use of flat percentages allows ACOs with high scores to earn maximum or near maximum achievement points while allowing room for improvement and rewarding that improvement in subsequent years. Use of flat percentages also helps to ensure that ACOs with high performance on a measure are not penalized as low performers. For the 2023 performance year, we expect to apply flat percentages for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) as the Medicare data may not be unavailable or may be inadequate.

We sought comment on this proposal.

The following is a summary of the public comments received on the proposed revisions to the benchmarking policies for CMS Web Interface measures for PYs 2022, 2023, and 2024 and our responses:

Comment: A few commenters supported the proposal to set flat percentage benchmarks for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) measures.

One commenter stated that this policy change may allow some ACOs with high performance to earn maximum achievement points but noted that it could be difficult for ACOs to adjust their performance unless the flat benchmarks are provided in advance. The commenter recommended that a flat benchmark of 75 percent of the average score of all ACOs in the prior year be utilized for both measures.

Response: We note that use of flat percentages allows ACOs with high scores to earn maximum or near maximum achievement points while allowing room for improvement and rewarding that improvement in subsequent years. Use of flat percentages also helps to ensure that ACOs with high performance on a measure are not penalized as low performers.

Comment: Most of the commenters opposed the proposal to use flat percentage benchmarks to score these two quality measures for PY 2022. The commenters stated that this proposed policy change would mean that ACOs would be scored on eight out of 10 Web Interface measures versus 7 measures for PY 2022 which diverges from the policy previously finalized for CY 2022. The commenters requested that CMS maintain the previous finalized policy, especially because the change was proposed after the start of the performance year and would apply retroactively.

Response: As stated in the proposed rule, we acknowledge that we inadvertently indicated in the CY 2022 PFS final rule (86 FR 65266) that a benchmark would not be created for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226). We note, however, that in the CY 2022 PFS final rule (86 FR 65266), the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) measure was included in the final APP measure set that must be reported by Shared Savings Program ACOs for PY 2022 and subsequent performance years.

In the CY 2023 proposed rule, we proposed to score the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure using flat percentage benchmarks under the approach we proposed at § 425.512(a)(6). During the previous benchmarking update for the 2020 and 2021 performance years, this measure was subject to a flat percentage benchmark pursuant to § 425.502(b)(2)(ii). Correcting our inadvertent statement in the CY 2022 PFS final rule that this measure would not have a benchmark does not result in a departure from our long-standing benchmark methodology for the measure. Accordingly, we believe that correcting this inadvertent error is in the public interest because it provides continuity of policy and having another scored measure allows for a more accurate measure of an ACO's overall

quality performance. More broadly, flat percentage benchmarks allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for improvement for ACOs with lower scores and rewarding that improvement in subsequent years. Furthermore, use of flat percentages also helps to ensure that ACOs with high performance on a measure are not penalized as low performers.

Comment: One commenter supported the previous finalized policy for establishing benchmarks for the Web Interface measures but did not support switching from pay for reporting to pay for performance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure stating that changing whether a measure will be scored or not this late within the reporting period is unreasonable and will likely require additional data collection effort and burden on ACOs while they are still operating under the COVID–19 PHE. The commenter noted that this change sets an unreasonable precedent and CMS should not make these kinds of significant revisions this late in the reporting period. Another commenter also stated that making changes to the policy during the performance year is unfair and ignores how quality improvement efforts are operationalized in ACOs. The commenter urged CMS to continue making these measures pay-for-reporting for 2022, as was finalized in the 2022 MPFS rule. In addition, one commenter suggested that CMS treat the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) as a new measure for PY 2022 and giving it a 7-point scoring floor since ACOs were not expecting to be scored on this measure for PY 2022. The commenters requested that CMS maintain the previous finalized policy, especially when the retroactive application would apply during a performance year.

One commenter stated that if CMS uses data submitted during CY 2023, that ACO eligible clinicians will not have a clear understanding of their performance and areas for improvement if benchmarks are not set in advance. The commenter encouraged CMS to continue using historical benchmarks for quality reporting.

Response: As stated in the proposed rule (87 FR 46150), we acknowledge that to the extent we proposed to apply these benchmark policies to determine performance benchmarks for the Web Interface measures for PY 2022, our proposal was retroactive and would require the use of our authority under section 1871(e)(1)(A) of the Act. We continue to believe that applying these benchmark policies to assess ACOs' quality performance for PY2022 is in the public interest for the reasons stated in the proposed rule and above.

We appreciate that some commenters believe that correcting our inadvertent designation of the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure as ''pay for reporting'' may require changes in processes for some ACOs; however, we note that prior to this correction, ACOs were still obligated to collect data and report on this measure. There is thus no new reporting burden on ACOs resulting from this correction. Additionally, we note that this correction does not introduce requirements related to or the scoring of a novel measure with which ACO providers/suppliers may be unfamiliar; the measure has been used in the Shared Savings Program for over four years. We also note that based on measure scores in prior performance years, most ACOs would score sufficiently well on this measure that scoring this measure would not negatively affect their overall quality performance score. Lastly, we note that the Shared Savings Program's extreme and uncontrollable circumstances policy is applicable for the duration of the COVID–19 Public Health Emergency.[296] For the months this policy is applicable, an ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category performance score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year (42 CFR 425.512(b)(2)(i)). The application of this policy thus mitigates potential negative effects of an ACO's poor Quality performance score on this measure that might arise from CMS correcting its error at this time. For these reasons, the benefits to the Shared Savings Program, ACOs, and the public justify correcting this error now.

We separately note that there are not ''pay for reporting'' measures under the APP. A measure that is not benchmarked is excluded from the quality performance category score. Prior to adoption of the APP, if an ACO satisfactorily reported a ''pay for reporting'' measure, they would receive full points for the measure (§ 425.502(c)(5)). If a measure without a benchmark is not reported or does not meet data completeness, a score of zero will be added to the measure calculation.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46148 through 46150), we are finalizing the proposal to add new § 425.512(a)(6), which provides that for performance years 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b). We anticipate providing flat percentage benchmarks for the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) measures will not create additional burden for or adversely affect the Quality performance scores of ACOs and will likely have a positive impact to ACO quality performance scores. Additionally, we are finalizing the proposal to establish and use flat benchmarks to score the following CMS Web Interface measures during PY 2022 and subsequent performance years: Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID#: 134) and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#: 226).

d. Clarifying the Use of Unweighted MIPS Quality Performance Category Scores for Quality Performance Standard Determinations Under the Shared Savings Program

In the CY 2022 PFS proposed and final rules (86 FR 39274 and 86 FR 65271), we stated that the PY 2018 MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For PY 2019, the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7. We also stated that, for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores would be calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for scoring for facility-based scoring. Therefore, we are not able to provide performance rate information prior to or during the

[296] *https://www.cms.gov/files/document/medicare-shared-savings-program-cms-flexibilities-fight-covid-19.pdf.*

performance year. Nevertheless, we stated that we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We stated that we would release this historical information on the Shared Savings Program website as soon as it becomes available.

While conducting analysis on the MIPS Quality performance category score data files after the publication of the CY 2022 PFS final rule, we determined that we erroneously used the weighted distribution of Quality performance category scores, rather than an unweighted distribution of Quality performance category scores, to calculate the 30th and 40th percentile MIPS Quality performance category scores provided in the CY 2022 PFS proposed and final rules for 2018 and 2019. The weighted distribution of Quality performance category scores is used in MIPS for final payment calculations. The unweighted distribution of Quality performance category scores submitted by ACOs, groups, and individuals has historically been used to calculate benchmarks for quality measure performance under MIPS and the Shared Savings Program.

In the proposed rule, we clarified that, despite the publication error, we used the submission level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Savings Program. We also clarified that we use an ACO's submission, which is considered the unweighted distribution of Quality performance category scores, to calculate its MIPS Quality performance category score for purposes of determining whether the ACO meets the quality performance standard under the Shared Savings Program in PY 2021 and subsequent performance years. As noted in the proposed rule (87 FR 46148), the policy aligns with the MIPS and Shared Savings Program benchmarking policies and is consistent with our original intended methodology of using the unweighted distribution based on submission data to calculate the MIPS Quality performance category scores for ACOs as we did to calculate the impacts of the Shared Savings Program quality performance standard proposals in the CY 2021 PFS proposed rule (85 FR 50380).

Based on the use of the unweighted distribution of the Quality performance category scores, for PY 2018, the MIPS Quality performance category score at the 30th percentile is equivalent to 59.30 and the MIPS Quality performance category score at the 40th percentile is equivalent to 70.80. For PY 2019, the MIPS Quality performance category score at 30th percentile is equivalent to 58.00 and the MIPS Quality performance category score at the 40th percentile is equivalent to 70.82. For PY 2020, the MIPS Quality performance category score at 30th percentile is equivalent to 63.90 and the MIPS Quality performance category score at the 40th percentile is equivalent to 75.59. See Table 54 of the CY 2023 PFS proposed rule (87 FR 46151) outlining the historical unweighted MIPS Quality performance category scores for PYs 2018–2020.

The following is a summary of the public comments received on our clarification of the use of unweighted MIPS Quality performance category scores for quality performance standard determinations under the Shared Savings Program and our responses:

Comment: One commenter supported the clarification regarding the use of the unweighted distribution of MIPS Quality performance category scores to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the quality performance standard under the Shared Savings Program.

Response: We appreciate the commenter's support of the clarification.

Comment: Several commenters requested that CMS clarify what is meant by ''unweighted'' and ''weighted'' distribution of MIPS Quality performance category scores.

Response: In response to comments, we are clarifying what is meant by the ''unweighted'' and ''weighted'' distribution of MIPS Quality performance category scores. The weighted distribution of Quality performance category scores is used in MIPS for final payment calculations and applies the Quality performance category scores to individual providers (rather than to the submitting entity, which can be an ACO, other APM entity, group, or individual provider). The unweighted distribution of Quality performance category scores is based on the Quality performance category scores of the submitting entity (for example, ACOs, other APM entities, groups, and individual providers), and each submission contributes one score to the distribution. The submission-level quality data has historically been used to calculate benchmarks for quality measure performance under MIPS and the Shared Savings Program. The MIPS Quality performance category score values do not change from the unweighted to weighted distribution. The only difference between the two distributions is the number of data points observed with a given score.

For illustrative purposes, we are providing an example using the average (instead of the 30th or 40th percentile) for the quality performance standard. In this example, there are three submitting entities: an ACO, a MIPS group, and an individual MIPS provider. The MIPS Quality performance category scores for these submitting entities are 90 for the ACO, 70 for the MIPS Group, and 50 for the individual MIPS provider. The average of the unweighted distribution of scores is $(90 + 70 + 50)/3 = 70$ where each submitting entity contributes one score. The weighted distribution of scores takes into account the number of individual providers from each submitting entity. The ACO has 10 providers, the MIPS Group has four providers, and the individual MIPS provider has one provider. The average of the weighted distribution is $((90 \times 10) + (70 \times 4) + (50 \times 1))/15 = 82$.

As clarified in the CY 2023 PFS proposed rule (87 FR 46148), we use the submission-level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Savings Program. As noted in the proposed rule (87 FR 46148), the policy aligns with the MIPS and Shared Savings Program benchmarking policies and is consistent with our original intended methodology of using the unweighted distribution based on submission-level data to calculate the MIPS Quality performance category scores for ACOs and other entities/providers, as we did to calculate the impacts of the Shared Savings Program quality performance standard proposals in the CY 2021 PFS proposed rule (85 FR 50380).

Comment: A few commenters requested more transparency in the application of MIPS Quality performance scores to the Shared Savings Program and recommended that CMS publish MIPS Quality performance category scores in the Public Use Files (PUF) annually so that ACOs and other

stakeholders can reproduce the calculations and have more transparency around how the performance standard is established.

Response: We appreciate the commenters' feedback. In the Medicare Shared Savings Program Performance Year Financial and Quality Results PUF, we provided several ACO-specific variables related to quality performance results including the ACO's quality score, an indicator for if the ACO met the quality performance standard, indicators for each of the three measure reporting options (that is, Web Interface, eCQM, MIPS CQM), and an indicator if the ACO did not completely report quality for any of the reporting options. We may consider adding additional ACO-specific variables in future years.

ACOs can review their measure-specific performance used to calculate their MIPS Quality performance category score in their MIPS performance feedback. For PY 2021, the quality performance score was based on the ACO's performance on the quality measures reported under the Alternative Payment Model (APM) Performance Pathway (APP), any applicable MIPS bonus points, and quality improvement points. For ACOs determined to have been affected by an extreme and uncontrollable circumstance, the quality score was the higher of the ACO's MIPS Quality performance category score or the 30th percentile across all MIPS Quality percentile category scores, excluding entities/providers eligible for facility-based scoring. We also provide quality measure benchmarks for the current performance year on the Shared Savings Program website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications*.

Since the publication of the CY 2023 PFS proposed rule, we have calculated that, for PY 2021, the MIPS Quality performance category score at the 30th percentile is equivalent to 61.73 and the MIPS Quality performance category score at the 40th percentile is equivalent to 77.83. See Table 64 outlining the historical unweighted MIPS Quality performance category scores for PYs 2018–2021.

TABLE 64: Historical Unweighted MIPS Quality Performance Category Scores

PY	30th percentile of the MIPS Quality performance category score	40th percentile of the MIPS Quality performance category score
2018	59.30	70.80
2019	58.00	70.82
2020	63.90	75.59
2021	61.73	77.83

e. Addressing MIPS Quality Performance Category Score Corrections in the Shared Savings Program's Reopening Authority

As finalized in the CY 2021 PFS final rule, beginning with PY 2021, the Shared Savings Program will use an ACO's MIPS Quality performance category score under the APP to determine whether the ACO has met the Shared Savings Program's quality performance standard. In turn, the ACO's quality performance informs the amount of shared savings earned or shared losses owed. There are interactions between the Shared Savings Program's financial reconciliation timeline and the Merit-Based Incentive Payment System (MIPS) targeted review process and other MIPS Quality performance category score-related corrections, and as a result, CMS may learn of errors in the calculation of MIPS Quality performance category scores after the issuance of an initial determination of financial performance under the Shared Savings Program.

CMS has sole discretion over when to reopen determinations of ACO shared savings and shared losses to correct errors for good cause. As discussed in the CY 2023 PFS proposed rule (87 FR 46151 through 46154), we believe that it would be appropriate to clarify the circumstances in which we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. In this section, we discuss these circumstances and explain how we will approach such reopenings, the process by which we would make any corrections, and the manner in which we will adjust shared savings payments to the ACO or shared loss recoupments from the ACO, if applicable.

Under § 425.315, CMS may reopen the initial determination or a final agency determination under 42 CFR part 425 subpart I and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. Good cause may be established when: (1) there is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or (2) the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

In the June 2016 Medicare Shared Savings Program final rule, we noted in response to comments, that in order to provide an opportunity for CMS to consider updated information and make other adjustments to payment determinations across all ACOs, and to minimize program disruptions for ACOs resulting from multiple reopenings, we would, to the extent feasible, use a unified reopening (as opposed to multiple reopenings) to correct errors for a given performance year (81 FR 38001). In addition, we indicated that we would consider other ways to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments to correct errors for good cause under the reopening provisions. For example, we explained that if, during the 4-year time period following notification of the initial payment determination, we determine that a correction needs to be made to a prior performance year's results for good cause, we would seek to potentially adjust the shared savings payment to the ACO or the shared loss recoupment from the ACO for a *subsequent* performance year (81 FR 38001). To illustrate, we stated that if an ACO that

generated shared savings for the second performance year of its agreement period owed CMS money based on a correction made to the payment determination for the prior performance year, we might be able to deduct the amount owed prior to making the shared savings payment for the current year (subject to the general Shared Savings Program requirement for ACOs to repay monies owed to CMS within 90 days of notification of the obligation). We also explained that ACOs would not be able to delay recoupment of any payments owed by notifying us of a possible error that could merit reopening (81 FR 38002). Instead, we stated that if we later determine that a correction should be made, we would subsequently combine, if feasible, the revised calculation of shared savings or shared losses for the affected performance year with the financial reconciliation for the most recent performance year. For example, we indicated that we would add any amount owed to the ACO as a result of a reopening, to any shared savings payment for which the ACO is eligible for the most recent performance year. We indicated that we expected to be able to provide ACOs with sufficient details regarding these corrections that they would be able to attribute the additional payment or recoupment arising from the reopening internally and, as applicable, distribute additional funds to or collect amounts from the appropriate ACO participants from the prior PY.

Further, we explained that in considering when to reopen an error for good cause, we intend to strike a careful balance between important Medicare program integrity concerns that payments be made timely and accurately under the Shared Savings Program with our desire to minimize unnecessary operational burdens for ACOs and CMS, and to support the ACOs' ability to invest in additional improvements to increase quality and efficiency of care (81 FR 38001). To achieve this careful balance in objectives, for reopenings to address CMS technical errors, we indicated that we may consider whether an error satisfies a materiality threshold, such as when it affects 3 percent of the total amount of net shared savings and shared losses for all ACOs for the applicable performance year. This was a threshold based on guidance from the Government Accountability Office (GAO) for financial audits of Federal entities.[297] We explained that although ACOs are not Federal entities, we believed it would be reasonable to consider the GAO guidance in determining when a technical error has a material effect across all ACOs, such that we should use our discretion to reopen for good cause.

As finalized in the CY 2021 PFS final rule, beginning with PY 2021, Shared Savings Program ACOs are required to report quality data for purposes of the Shared Savings Program via the APP under the Quality Payment Program (85 FR 84720 through 84736). An ACO will meet the Shared Savings Program quality performance standard if the ACO achieves a quality performance score that is equivalent to or higher than the percentile specified for the relevant performance year, across all MIPS Quality performance category scores (§ 425.512(a)(3) and (4)). In the CY 2022 PFS final rule, we finalized an extended phase-in of the quality performance standard under the Shared Savings Program (§ 425.512(a)(3) through (5); 86 FR 65266), which we discussed in detail in section III.G.4.b. of the proposed rule. In the proposed rule, we also explained that because ACOs are now reporting quality data via the APP and receiving MIPS Quality performance category scores, we are concerned that CMS may learn of errors in the calculation of MIPS Quality performance category scores after the Shared Savings Program has issued financial reconciliation reports (which are initial determinations of an ACO's financial performance for the applicable performance year). For this reason, we stated our belief that it would be appropriate to clarify the circumstances in which we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

We issue (typically in the summer) MIPS performance feedback reports for the previous performance year to MIPS eligible clinicians, eligible practices that submitted data as a group, virtual groups, and APM entities. For ACOs, the MIPS performance feedback report includes data on ACO quality performance, but does not indicate whether the ACO has met the Shared Savings Program's quality performance standard. Each ACO's MIPS Quality performance category score is calculated using the ACO's performance on the measures reported under the APP (ACO-reported measures, CAHPS for MIPS survey measure, claims-based measures), any applicable MIPS bonus points, and quality improvement points.[298]

MIPS eligible clinicians, groups and APM entities (such as ACOs) may request a targeted review of the calculation of the MIPS payment adjustment factor pursuant to § 414.1385. The MIPS targeted review submission period starts once the MIPS performance feedback report is issued and remains open for 60 days with the reviews concluding on a rolling basis and may extend into October or November (§ 414.1385(a)(2)). If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores with regard to measures, activities, performance categories (including the quality performance category), and the final score, as well as the MIPS payment adjustment factors (§ 414.1385(a)(6)). For Shared Savings Program ACOs, changes to MIPS Quality performance category scores could affect the quality performance standard and have an impact on the amount of shared savings earned or shared losses owed by the ACOs. Further, because we were proposing to incorporate a sliding scale approach as part of the quality performance standard, we also acknowledged that a change to an ACO's own MIPS Quality performance category score could have an impact on the amount of shared savings earned by the ACO or the amount of shared losses owed to CMS under the ENHANCED track.

CMS aims to deliver the Shared Savings Program financial reconciliation reports that incorporate MIPS Quality performance category scores for the previous year to ACOs in August on an embargoed basis (that is, ACOs may not publicly release the information in these reports), and typically 2–3 weeks later an unembargoed basis, at which point ACOs can publicly share the information in the reports. Unlike the MIPS performance feedback reports, these reports indicate whether an ACO has met the Shared Savings Program's quality performance standard. In the proposed rule, we explained that under the proposed policies, an ACO's health

[297] GAO updated the guidance in 2020 and the recommended materiality threshold remains 3 percent. *See Financial Audit Manual,* Volume 1, Updated April 2020, 230–4, available at *https://www.gao.gov/assets/gao-18-601g.pdf.*

[298] *See* 2021 APP Toolkit, *2021 APM Performance Pathway for Shared Savings Program Accountable Care Organizations (ACOs) Guide,* slide 15, available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1495/2021%20APM%20Performance%20Pathway%20(APP)%20Toolkit.zip.*

equity adjusted quality performance score for a performance year and the determination of whether the ACO met the Shared Savings Program quality performance standard would affect the determination of shared savings for that performance year and, for ACOs participating in the ENHANCED track, the amount of any shared losses owed. The unembargoed financial reconciliation reports constitute an initial determination of the ACO's financial performance for the applicable performance year. With the initial determination, we also send demand letters to ACOs that indicate the amount of shared losses that must be paid in full to CMS within 90 days of receipt. CMS initiates payments to ACOs that have earned shared savings for a performance year in September of the year following the applicable performance year in order to pay with the correct fiscal year funds. Given that the timeline for conducting a MIPS targeted review of the MIPS performance feedback report may extend past the date that we issue unembargoed financial reconciliation reports, we may learn of errors in the calculation of MIPS Quality performance category scores after the issuance of initial determinations of financial performance under the Shared Savings Program.

In the CY 2023 PFS proposed rule, we explained our belief that it would be appropriate to clarify how we would exercise our discretion to reopen for good cause in the event of errors in the MIPS Quality performance category scores, such as those identified through the MIPS targeted review process, that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. We explained that we are contemplating an approach under which we would reopen initial determinations of ACO financial performance to account for any corrections that have been made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings [299] or the amount of shared savings or shared losses, with no restrictions on the magnitude of the error or the number of ACOs affected. Under this approach, the determination of whether there has been an error in the determination of a MIPS Quality performance category score that affects the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO; whether a correction would be warranted; and the timing of any correction would be within the sole discretion of CMS as provided in § 425.315(a)(4).

For illustrative purposes, we described how a correction to a MIPS Quality performance category score, based on a targeted review or other changes to the MIPS Quality performance category score, could affect the determination of whether an ACO is eligible for shared savings. In this example, an ACO participating under the BASIC track received an initial determination indicating that it met the MSR requirement and that it met the quality performance standard because it achieved a MIPS Quality performance category score that is equivalent to or higher than the percentile specified as the quality performance standard for that performance year. Because the ACO was otherwise eligible to share in savings for the performance year, CMS issued an initial determination that the ACO was eligible to share in savings at the maximum sharing rate under its track (or payment model within a track). Several weeks after that initial determination is issued, CMS learns of an error in the calculation of the MIPS Quality performance category scores that caused the ACO's health equity adjusted quality performance score to be higher than it would have been absent the error. As a result, the ACO's actual health equity adjusted quality performance score was less than the percentile specified as the quality performance standard for that performance year. In this example, we would exercise our discretion to reopen the determination of the ACO's financial performance for good cause to correct the ACO's MIPS Quality performance category score. As a result of this correction, the ACO would no longer have a health equity adjusted quality performance score that is equivalent to or higher than the percentile specified as the quality performance standard for that performance year. Accordingly, the ACO would no longer meet the quality performance standard and thus would be ineligible for shared savings or alternatively might be eligible to receive a reduced shared savings payment in the event we finalize the proposed sliding scale approach.

Alternatively, a correction to a MIPS Quality performance category score could affect the amount of shared savings or shared losses owed to an ACO. For example, an ACO under the ENHANCED track might receive an initial determination indicating that it owes shared losses to CMS calculated at the maximum shared loss rate because it: (1) exceeded the minimum loss rate; and (2) it failed to meet the quality performance standard for that performance year.[300] Several months after that initial determination is issued, as a result of a MIPS targeted review, we learn of an error in the calculation of the ACO's MIPS Quality performance category score that caused the ACO's health equity adjusted quality performance score to be lower than it would have been without the error. In this case, we would exercise our discretion to reopen the determination of the ACO's financial performance for good cause to correct the ACO's MIPS Quality performance category score. In making this correction, the ACO now achieves a health equity adjusted quality performance score that causes it to meet the quality performance standard. While the ACO would still owe shared losses because it exceeded the minimum loss rate, the amount of shared losses it owes could be reduced based on the ACO's corrected health equity adjusted quality performance score as we would now determine the ACO's shared loss rate using a sliding scale approach.

As we explained in the proposed rule, in the event that we learn of errors in the calculation of MIPS Quality performance category scores (from a MIPS targeted review or some other MIPS Quality performance category score-related corrections) that change the percentile score an ACO must achieve in order to meet the quality performance standard, we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO due to the miscalculation of MIPS Quality

[299] Unlike shared savings, the determination of whether an ACO is eligible for shared losses is not dependent upon whether the ACO meets the quality performance standard. If an ACO meets or exceeds the minimum loss rate, it will be responsible for sharing losses. *See, for example,* § 425.610(b)(3).

[300] Section 425.610(f)(2)(ii). Under the current regulations, an ENHANCED track ACO that is liable for losses and fails to meet the quality performance standard automatically faces the maximum shared loss rate of 75 percent, whereas an ACO that meets the quality performance standard would face a shared loss rate that is scaled by the ACO's quality performance (subject to a minimum and maximum rate). We note that in the event we finalize our proposal to extend the sliding scale approach to determining shared losses to ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set, a larger number of ACOs could potentially have their shared losses reduced as the result of a MIPS targeted review.

performance category scores. Moreover, as noted previously, if we determine that there is good cause to make a correction to a prior performance year's determination of ACO financial results as a result of corrections made to MIPS Quality performance category scores, we would seek to potentially adjust the shared savings payment to the ACO or any shared loss recoupment from the ACO for a subsequent performance year. This approach would not alter the current requirement that ACOs repay shared losses within 90 days after notification of the initial determination of shared losses.

As we stated in the proposed rule, we believe this approach is flexible and balanced and would allow us to exercise our discretion to reopen initial determinations of ACO financial performance for good cause to account for any corrections that have been made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. We also acknowledged that from year to year, corrections could sometimes advantage individual ACOs and sometimes disadvantage individual ACOs.

We sought comment on this clarification of the circumstances in which we would exercise our discretion to reopen for good cause when either an initial determination or a final agency determination regarding an ACO's financial performance needs to be corrected as a result of any corrections made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

The following is a summary of the public comments received on this clarification and our responses:

Comment: Two commenters supported our clarification of the Shared Savings Program's authority to reopen for good cause an initial determination of an ACO's financial performance to correct errors in the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO due to the miscalculation of MIPS Quality performance category scores. Many commenters encouraged CMS to reconsider the approach discussed in the clarification and expressed concerns about the feasibility of returning savings to CMS and the disincentive that this would create for Shared Savings Program participation. These commenters recommended that if CMS continues with this approach, CMS should only reopen ACO financial determinations if the MIPS Quality performance category score error would result in a change that holds the ACO harmless (we understand this to refer to changes that do not result in the ACO returning funds to CMS or changes that do not reduce the amount of shared savings owed by CMS to the ACO), because it is unreasonable and not practical to expect ACOs to claw back savings from ACO participants after the funds have been distributed. One commenter explained that ACOs should not be penalized for errors that are discovered with MIPS Quality performance category scores after ACOs have already received initial financial reconciliation report calculations. Another commenter stated that while they understood the purpose of the approach discussed in the clarification, it creates uncertainty and instability in the program, which is counter to CMS' objectives to grow the program to include 100 percent of beneficiaries with original Medicare in a value-based care program by 2030.

Response: We acknowledge the concerns raised by commenters about the challenges that could arise if a correction to a MIPS Quality performance category score either reduces the amount of shared savings previously calculated for an ACO or increases the amount of shared losses owed to CMS by an ACO. As we discussed in the proposed rule, however, where possible we would seek to adjust the shared savings payment to the ACO or any shared loss recoupment from the ACO as part of the reconciliation for a *subsequent* performance year. For example, if an ACO that generated shared savings for the second performance year of its agreement period owed CMS money based on a correction made to the payment determination for the prior performance year, we might be able to deduct the amount owed prior to making the shared savings payment for the current year (subject to the general Shared Savings Program requirement for ACOs to repay monies owed to CMS within 90 days of notification of the obligation). We also explained that ACOs would not be able to delay recoupment of any payments owed by notifying us of a possible error that could merit reopening. Instead, we stated that if we later determine that a correction should be made, we would subsequently combine, if feasible, the revised calculation of shared savings or shared losses for the affected performance year with the financial reconciliation for the most recent performance year. We indicated that we expected to be able to provide ACOs with sufficient details regarding these corrections that they would be able to attribute the additional payment or recoupment arising from the reopening internally and, as applicable, distribute additional funds to or collect amounts from the appropriate ACO participants from the prior PY.

We believe this approach strikes an appropriate balance between important Medicare program integrity concerns that payments be made timely and accurately under the Shared Savings Program with our desire to minimize unnecessary operational burdens for ACOs and CMS, and to support the ACOs' ability to invest in additional improvements to increase quality and efficiency of care. Moreover, as discussed earlier in this section and in the proposed rule, the QPP issues MIPS performance feedback reports for the previous performance year prior to the release of the Shared Savings Program financial reconciliation reports (that incorporate MIPS Quality performance category scores). We intend to work with the QPP to identify potential errors to MIPS Quality performance category scores (through the MIPS targeted review process and other MIPS Quality performance category score-related corrections), so that we can resolve most, if not all, discrepancies or systemic issues prior to issuing the Shared Savings Program unembargoed financial reconciliation reports, which constitute the initial determination of the ACO's financial performance for the applicable performance year. Accordingly, we decline to adopt commenters' suggestions to reconsider the approach we discussed in the proposed rule.

Comment: Several commenters recommended that CMS place a limit on the length of time that can pass between the initial determination of an ACO's financial performance and any reopening to retroactively change ACO financial determinations. Most of these commenters suggested this time limit be 12 months, and one commenter suggested 60 days. One commenter stated that it is not feasible for CMS to reopen the determination of an ACO's financial performance two or more years after the performance year, which often happens with MIPS adjustments. The commenter explained that CMS already delays shared savings payments to ACOs by up to 10 months after the end of the performance year, so it would be highly impractical for CMS to hold

ACOs accountable for MIPS errors that happen after the performance year reconciliation has occurred. The commenter emphasized that reopening financial determinations after the distribution of shared savings to participating physicians presents a very difficult operational issue for ACOs.

Response: We acknowledge the concerns raised by commenters and the recommendations to impose a limit on the timeframe within which CMS would be able reopen initial determinations of ACO financial performance to account for any corrections that have been made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, or the amount of shared savings or shared losses. As we explained in the proposed rule, however, under § 425.315, CMS may reopen the initial determination or a final agency determination under 42 CFR part 425 subpart I and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. Moreover, the determination of whether there is good cause to reopen a payment determination is within the sole discretion of CMS as provided in § 425.315(a)(4) and any instances where it would be necessary to reopen an initial determination of an ACO's financial determination to correct MIPS Quality performance category scores would occur not later than 4 years after the date of the notification to the ACO of the initial determination, consistent with § 425.315(a)(1)(ii). Therefore, we decline commenters' suggestions to further limit the length of time that can pass between financial reconciliation and a reopening of the initial determinations of an ACO's financial determination. We may revisit our approach in future notice and comment rulemaking, after we gain additional experience with the interactions between MIPS and Shared Savings Program calculations and the timing and frequency of any reopenings.

Comment: Several commenters expressed concern that tying ACO quality performance thresholds to MIPS scores is inappropriate and makes unfair comparisons. These commenters urged CMS to adopt a different approach that does not tie Shared Savings Program quality performance determinations to MIPS quality performance category scores. Other commenters urged CMS to work closely with stakeholders in exploring alternative ways to align the timelines of MIPS errors reporting and ACO quality performance. One commenter mentioned that the MIPS program's error correction process under the QPP has not gone smoothly and the problems with that process should not be imported into financial reconciliation under the Shared Savings Program. Another commenter stated that it seems that either more alignment between the programs is needed to allow more time to complete the MIPS targeted review for MIPS before the Shared Savings Program issues initial determinations for financial reconciliation or there needs to be a separation between the programs for scoring purposes to resolve the issue of timing.

Response: We note this clarification is limited to the approach we will follow in using our discretion to reopen under the Shared Savings Program to revise the initial determination of an ACO's financial performance to reflect updated MIPS scoring information. We appreciate the commenters' suggestions that we explore alternative ways to align the timelines of MIPS errors reporting and ACO quality performance and to improve alignment between the programs. We may consider these suggestions in the development of policies for future notice and comment rulemaking.

f. Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development—Request for Information (RFI)

In the CY 2022 PFS proposed rule, we solicited comments on addressing health disparities and promoting health equity (86 FR 39269 and 39270). We indicated our belief that assessing Shared Savings Program ACOs' quality performance on a broader population can have a positive impact on the quality of care for all groups, including Medicare beneficiaries (86 FR 39270). Additionally, we affirmed our expectation that the transition to all-payer eCQM/MIPS CQMs would help to address disparities and promote health equity by promoting a single standard of care across all patients receiving care from practices participating in Shared Savings Program ACOs regardless of location or racial/ethnic group (86 FR 39270). We sought comment and recommendations on how ACOs could utilize their resources to ensure all patients have access to equal care and how to improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare (86 FR 39270). Furthermore, we sought comment on how we could encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives, including whether any adjustments should be made to quality measure benchmarks to take into account ACOs serving vulnerable populations (86 FR 39270).

We received many comments in support of CMS' commitment to advancing health equity and addressing health disparities within the Shared Savings Program, including several comments supporting stratification of data and quality measures by social risk factors such as race and ethnicity and inclusion of health equity measures in the program. In addition, we received some feedback expressing concerns that eCQM/MIPS CQM measures would divert resources into electronic systems instead of focusing on health equity. Commenters also noted that changes to the payment structure under the Shared Savings Program could help ACOs improve infrastructure to address health equity and disparities. As we stated in the November 2011 final rule (76 FR 67872), our principal goal in selecting quality measures for the Shared Savings Program has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes.

Health equity and addressing health disparities continue to be high priorities for the agency through inclusion of health equity initiatives in CMS programs, and better addressing the social needs of people with Medicare is an important part of this strategy. Communities experiencing persistent poverty or inequality tend to disproportionately experience unmet social needs.[301] According to the U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion's Healthy People 2030, which has a strong focus on eliminating health disparities and creating equitable opportunities for people to live healthy lives, social determinants of health have a major impact on people's health, well-being, and quality of life. This report cites safe housing, transportation, neighborhoods and access to nutritious foods as examples of social determinants of health.[302] For health care providers to

[301] Centers for Medicare & Medicaid Services, Office of Minority Health, *CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

[302] U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion, *Healthy People 2030,* refer to website

help improve health outcomes by addressing these needs for people with Medicare, there is growing evidence to support screening patients for social needs, referring patients who screen positive to local community-based organizations that can help patients address these needs, and finally ensuring that follow-up is obtained and the social needs are addressed. In addition, screening patients for social needs would allow clinicians to develop treatment plans, if needed, which would better capture a patient's unique needs and priorities.[303]

In the proposed rule, we sought comment on the potential future inclusion of two new structural measures in the APP measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. The National Quality Forum (NQF) provided conditional support for these two measures during the 2021–2022 cycle and indicated the measures would be appropriate for consideration in the Shared Savings Program.[304] The measure Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. This screening for health-related social needs is consistent with the priorities of the agency and the Shared Savings Program, including Meaningful Measures 2.0 priority areas specific to equity. Meaningful Measures 2.0 includes addressing measurement gaps such as development and implementation of measures that reflect social and economic determinants.[305]

The measure Screening for Social Drivers of Health assesses the rate at which providers screen beneficiaries 18 years and older for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Below are the numerator and denominator for the measure:

- Numerator: The number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance, and interpersonal violence.
- Denominator: The number of beneficiaries 18 and older in practice (or population).

We refer readers to IV.A.10.c.(1)(c)(i) of the proposed rule and Table Group A of Appendix 1 of the proposed rule, where we discuss the proposed health equity measure for purposes of MIPS, ''Screening for Social Drivers of Health.'' We refer readers to section IV.A.10.c.(1)(d) of the proposed rule for the request for information regarding measure development related to health equity under MIPS.

If the measure is adopted in the traditional MIPS program, we noted that we will consider proposing, in future rulemaking, the addition of this measure as an eCQM/MIPS CQM under the APP beginning in PY 2025, once the Web Interface reporting option sunsets and the transition to reporting eCQMs/MIPS CQMs is complete. It is important to note that the measure specifications are not being developed for electronic health record (EHR) reporting at this time, but would be considered for purposes of any future rulemaking.

Per the Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care final report,[306] this measure would also address a significant performance gap ''in which 84 percent of physician offices do not screen for all five needs, even though approximately one-third of patients would screen positive for one or more social needs.'' We believe the potential inclusion of this measure in the APP measure set reported by Shared Savings Program ACOs could advance health equity by ensuring ACO participants better understand the needs of the patients that they serve. We expect that, by screening for these social determinants of health, the ACO would accomplish the first step in helping people with Medicare address their social needs—understanding their needs. This screening would also enable clinicians to develop treatment plans, if needed, that are focused on beneficiaries' unique needs and priorities. We may consider including additional quality measures in the future that would assess how well ACOs address the social needs of Medicare beneficiaries more directly. We noted that any changes to the measures included in the APP measure set, including the addition of new measures, would be proposed through future rulemaking.

We sought input on Screen Positive Rate for Social Drivers of Health, which assesses the percentage of patients who screened positive for health-related social needs. We also sought feedback from ACOs and other interested parties on the value of implementing a quality measure that indicates a patient's social needs as a part of the quality of care provided to them.

We solicited comments on the potential addition of these two social determinant of health measures to the APP measure set reported under the Shared Savings Program if these measures are adopted for the traditional MIPS program and other ways to incorporate health equity into public reporting. We also sought comment on the following:

- How to best implement the measures and how they could further drive health equity and health outcomes under the Shared Savings Program?
- What are the possible barriers to implementation of the measures in the Shared Savings Program?
- What impact would the implementation of these measures in the Shared Savings Program have on the quality of care provided for underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? While supporting flexibility, how can we advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

In the CY 2023 PFS proposed rule (87 FR 45860), we solicited comments on the inclusion of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures in the APP measure set for ACOs. We also solicited comments on implementation best practices, barriers to implementation, impact of implementation, flexibilities that should be considered, and if the measures should be considered pay-for-reporting.

https://health.gov/healthypeople/priority-areas/social-determinants-health.

[303] *AHRQ.gov, Identifying and Addressing Social Needs in Primary Care Settings, (2021),* refer to *https://www.ahrq.gov/sites/default/files/wysiwyg/evidencenow/tools-and-materials/social-needs-tool.pdf.*

[304] National Quality Forum, Measure Applications Partnership (*MAP*), 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care, final report (March 3, 2022), available at website *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[305] Centers for Medicare & Medicaid Services, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization,* (2021), available at website *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[306] National Quality Forum, Measure Applications Partnership (MAP), 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care, final report (March 3, 2022), available at website *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

g. Addition of New Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-Based Incentive Payment System (MIPS) Survey Questions—Request for Information (RFI)

We sought to gather ACOs and other interested parties input on the potential and modified questions in the CAHPS for MIPS Survey pertaining to health disparities and price transparency, which would support implementation of the No Surprises Act. The No Surprises Act includes provisions specific to improvements in transparency and greater oversight of prescription drug and medical costs.

The CAHPS for MIPS Survey measures 10 key domains of patients' experience of care that are referred to as summary survey measures (SSMs) and include the following:

- Getting Timely Care, Appointments, and Information
- How Well Providers Communicate
- Patient's Rating of Provider
- Access to Specialists
- Health Promotion and Education
- Shared Decision Making
- Courteous and Helpful Office Staff
- Care Coordination
- Stewardship of Patient Resources
- Health Status and Functional Status

CAHPS surveys are an integral part of the Shared Savings Program's efforts to meaningfully assess patient experience and have been a requirement of the program since the November 2011 final rule establishing the Shared Savings Program (76 FR 67872). We stated in that final rule that we believe there is evidence that the CAHPS survey assesses important aspects of provider-patient interaction that can be influenced by an ACO's level of organizational support, training and incentive structure (76 FR 67874). In the CY 2021 PFS final rule (85 FR 84722), we finalized that beginning in PY 2021, Shared Savings Program Accountable Care Organizations (ACOs) are required to report quality data via the APP. As part of the APP, Shared Savings Program ACOs are required to administer the CAHPS for MIPS survey (85 FR 84730 through 84732).

The No Surprises Act,[307] which took effect on January 1, 2022, includes provisions such as billing protections for consumers covered under group and individual health plans, as well as certain improvements to transparency and oversight of prescription drug and medical costs (86 FR 36872). The No Surprises Act aligns with President Biden's goals of increased transparency, competition, and fairness across healthcare systems.[308] We are firmly committed to the advancement of the President's vision for health care and the resulting benefits, which include empowerment of consumers in making more informed and value-based health care decisions. We believe certain provisions of the No Surprises Act are relevant in consideration of the questions we are seeking input on for the CAHPS for MIPS survey. The Office of Personnel Management, the Internal Revenue Service, the Department of Labor, and CMS issued an interim final rule with comment period entitled ''Requirements Related to Surprise Billing; Part 1'', which appeared in the July 13, 2021 **Federal Register** (86 FR 36872). This interim final rule notes that regulations promulgated under the No Surprises Act should ensure that all individuals, particularly those from underserved and minority communities, trust and believe information they receive related to healthcare costs and coverage (86 FR 36875). The agencies also note that regulations issued pursuant to the No Surprises Act should encourage regulated entities to address barriers to access of care, including trust concerns with the health care system, and to communicate with individuals in a language they can understand, in a respectful way that addresses cultural differences, and at an appropriate level of literacy (86 FR 36875).

As previously described in this section of the proposed rule, in developing policies for the Shared Savings Program, we are also committed to prioritizing the advancement of health equity through program initiatives with a focus on underserved populations, improving data collection and analysis on health disparities, and incorporating actionable measures addressing health disparities in future notice and comment rulemaking.

An article in the Journal of the American Medical Association titled *Patient-Reported Experiences of Discrimination in the US Health Care System* describes a cross-sectional national survey conducted in 2019 that included 3,253 US adults. This survey was designed to determine the prevalence, frequency and main types of discrimination experienced in the health care system.[309] Of the 2,137 survey respondents, 458 (21.4 percent) indicated they had experienced discrimination in the health care system, and 330 (72 percent) of those who had experienced discrimination reported experiencing it on more than one occasion. The most frequently reported type of discrimination experienced in the health care system was racial/ethnic discrimination, followed by educational or income level discrimination, weight, sex and age. According to the authors, the survey results suggested that health care discrimination experiences were more prevalent than previously recognized and a need existed for additional analysis of how discrimination related to structural inequities and social determinants of health.

One of the additional questions that we are considering adding to the CAHPS survey would be specific to health disparities and focuses on the patient's experience with discrimination based on the characteristics of the patient. We sought input on the following question: ''In the last 6 months, did anyone from a clinic, emergency room, or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you? '' We noted the potential responses include; health condition, disability, age, culture, sex (including sexual orientation and gender identity) and income. We sought feedback on additional or modified potential response categories for this health disparities question. We noted that feedback received through the RFI, along with analysis and findings from the testing of the survey question in other programs and future testing in this program would be used to inform future rulemaking.

We also noted that we believe that the question aligns with the goals of the quality performance standard under the Shared Savings Program. Section 1899(b)(3)(C) of the Act provides that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs, and the Secretary shall seek to improve the quality of care furnished by ACOs over time, in part, by specifying new measures. Inclusion of this question to the CAHPS for MIPS Survey would allow CMS to better understand the extent to which patients perceive

[307] Title I of Division BB of the Consolidated Appropriations Act, 2021, Public Law 116–260.

[308] Centers for Medicare & Medicaid Services, *HHS Kicks Off New Year with New Protections from Surprise Medical Bills,* (2022), available at website *https://www.cms.gov/newsroom/press-releases/hhs-kicks-new-year-new-protections-surprise-medical-bills.*

[309] Nong P, Raj M, Creary M, *Patient-Reported Experiences of Discrimination in the US Health Care System, JAMA Network,* (2020), available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774166.*

discrimination in their health care, in alignment with HHS efforts to provide culturally and linguistically appropriate services (CLAS). The National CLAS Standards, were developed by the HHS Office of Minority Health and provide a blueprint for individuals and healthcare organizations to implement services that are respectful of health beliefs, practices and needs of diverse patients with the goal to advance health equity, improve quality of services and assist with elimination of disparities.[310] In addition, the Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (Behavioral Health Guide) underscores the ways in which the National CLAS Standards can improve access to behavioral health care, promote quality behavioral health programs and practice, and ultimately reduce persistent disparities in mental health and substance use treatment for underserved minority communities.[311]

In addition, inclusion of a health disparities question in the CAHPS for MIPS survey would align with the five priorities outlined in the CMS Framework for Health Equity 2022–2032.[312] The priorities include both system and community level approaches for achievement of equity in Medicare and include:

- Priority 1: Expand the Collection, Reporting and Analysis of Standardized Data;
- Priority 2: Assess Causes of Disparities Within CMS Programs and Address Inequities in Policies and Operations to Close Gaps;
- Priority 3: Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities;
- Priority 4: Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services; and
- Priority 5: Increase All Forms of Accessibility to Health Care Services and Coverage.

In addition, we noted that we believe that the inclusion of a health disparity question in the CAHPS for MIPS Survey would assist CMS in understanding the patient's perspective of their treatment during health care visits, as well as provide insight for health care providers on how to improve upon patient interactions, promotion of health equity and delivery of care. In addition, this question is already being tested in the Medicare Advantage program and based on the findings from this testing in the Medicare Advantage program, we may consider including this question in the CAHPS for MIPS survey through future rulemaking. Including the question in the CAHPS for MIPS survey would provide consistency across CMS programs in learning more about patient experiences with discrimination from various health care providers.

We also sought input on the addition of questions to the CAHPS for MIPS survey specific to price transparency. These questions would build upon the goals of the No Surprises Act to improve transparency and oversight of drug and medical costs, allowing patients to have more information on which to base their healthcare decisions. We also noted that the questions under consideration are patient focused, which is one of the goals of the CAHPS for MIPS survey. Currently, the CAHPS for MIPS survey includes the question ''In the last 6 months, did you and anyone on your health care team talk about how much your prescription medicines cost?'' [313] We considered adding a question that would be more general in nature and encompass additional areas of a patient's care, such as whether the patient talked with anyone on their health care team about the cost of health care services and equipment. An additional question or questions encompassing a patient's health care costs would allow us to better understand how extensively health care providers are considering and discussing costs with their patients, so they are more able to make informed health care decisions. We noted that we believe the inclusion of such questions would also support the goals of the Shared Savings Program which include promotion of accountability for patient populations and fostering coordination of items and services under Medicare Parts A and B. The program also encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery. ACOs work to reduce fragmentation in patient care and cost by giving their ACO participants and ACO providers/suppliers the incentives and tools to deliver high-quality, coordinated, team-based care that proactively promotes improved health for all patients.[314]

We also noted that we considered revisions to the CAHPS for MIPS Survey measure in order to make it more broadly applicable to specialty groups in addition to primary care groups. In particular, we solicited public comment on shortening the survey to remove survey items that are relevant only to primary care providers. Alternately, we noted that we may create an alternate shortened survey version for specialty groups while maintaining the existing survey questions for primary care groups.

In summary, we sought information and feedback from commenters on: (1) the potential future inclusion of health disparities and price transparency questions and whether there are other questions that should also be considered for potential future inclusion in the CAHPS for MIPS survey; and (2) whether they have any input on creating a shortened version of the CAHPS for MIPS Survey measure such that it is more applicable to specialty groups. Feedback received through this RFI, along with analysis and findings from the testing of the survey questions in other programs and future testing in this program would be considered to inform future rulemaking, as previously indicated.

We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

5. Financial Methodology

a. Overview

In the CY 2023 PFS proposed rule (87 FR 46157 through 46202), we proposed modifications to the financial methodologies used under the Shared Savings Program. We proposed a combination of modifications to the

[310] U.S. Department of Health and Human Services Office of Minority Health, *Cultural and Linguistic Competency, National CLAS Standards,* (2021), available at website *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6.*

[311] U.S. Department of Health and Human Services Office of Minority Health, *Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care,* available at *https://www.minorityhealth.hhs.gov/Assets/PDF/clas%20standards%20doc_v06.28.21.pdf.*

[312] Centers for Medicare & Medicaid Services, *CMS Framework for Health Equity,* available at website *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity.* See also, Centers for Medicare & Medicaid Services, Office of Minority Health, *CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

[313] Centers for Medicare & Medicaid Services, *2022 CAHPS for MIPS Survey Sample Copy,* (2022), available at QPP Resource Library website *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1894/2022%20CAHPS%20for%20MIPS%20Survey%20Sample%20Copy.pdf.*

[314] Centers for Medicare & Medicaid Services, *Affordable Care Act's Shared Savings Program Continues to Improve Quality of Care While Saving Medicare Money During COVID–19 Pandemic,* (2021), available at website *https://www.cms.gov/newsroom/press-releases/affordable-care-acts-shared-savings-program-continues-improve-quality-care-while-saving-medicare.*

Shared Savings Program's benchmarking methodology and financial models to encourage sustained participation by ACOs in the program and remove barriers for ACOs serving medically complex and low-income populations. Specifically, we proposed to revise the benchmarking methodology by: incorporating a prospective, external factor for updating the benchmark (section III.G.5.c.(3) of the proposed rule); adjusting rebased benchmarks to account for an ACO's prior savings (section III.G.5.c.(4) of the proposed rule); and reducing the impact of negative regional adjustments on ACO benchmarks (section III.G.5.c.(5) of the proposed rule). We also sought comment on alternatives to the combination of policies in sections III.G.5.c.(3) through (5) which would be aimed at addressing concerns about the effect of an ACO's assigned beneficiaries on regional FFS expenditures used in establishing, adjusting, updating, and resetting an ACO's historical benchmark (section III.G.5.c.(6) of the proposed rule). We also proposed changes to how we calculate regional factors used in benchmarking to reflect differences in prospective and preliminary prospective assignment (section III.G.5.d. of the proposed rule), how we conduct annual risk adjustment to better account for medically complex, high cost populations and to guard against coding initiatives (section III.G.5.e. of the proposed rule), and we proposed a methodology to increase opportunities for low revenue ACOs participating in the BASIC track to share in savings (section III.G.5.f. of the proposed rule). We discussed ongoing considerations of the impact of the PHE for COVID–19 on ACO expenditures (section III.G.5.g. of the proposed rule), and we proposed to exclude from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program a proposed new supplemental payment under the IPPS for IHS/Tribal Hospitals and hospitals located in Puerto Rico (section III.G.5.h. of the proposed rule). We concluded with a discussion of the proposed modifications to 42 CFR part 425, subpart G (section III.G.5.i. of the proposed rule), to incorporate the related proposed changes discussed throughout section III.G.5 of the proposed rule, as well as certain technical and conforming changes, and corrections. Within this section of this final rule we summarize and respond to public comments on these topics.

Comment: Some commenters expressed concern that several of the proposed changes to the financial methodology would only go into effect for ACOs entering a new agreement period in 2024 or a subsequent year. Many of these commenters suggested that CMS allow ACOs the option of opting into the proposed changes without having to complete the early renewal process or wait until they enter a new agreement period.

Response: We decline the commenters' suggestions. ACOs will be subject to the changes we are finalizing to the Shared Savings Program's financial methodology on an agreement period basis, unless specified otherwise. Specifically, the changes in the benchmarking methodology (as discussed in sections III.G.5.c–e of this final rule) and to allow for increased opportunities for low revenue ACOs participating in the BASIC track to share in savings (as discussed in section III.G.5.f of this final rule) will be applicable to ACOs entering a new agreement period beginning on or after January 1, 2024. However, as discussed in section III.G.5.h of this final rule, the policies we are finalizing to account for supplemental payment to IHS/Tribal hospitals and hospitals located in Puerto Rico in expenditure and revenue calculations under the Shared Savings Program will be applicable to all ACOs for the performance year beginning January 1, 2023, and subsequent performance years.

We believe the timing of applicability for the benchmarking changes will allow sufficient time for current ACOs to decide whether to renew for a new agreement period under the Shared Savings Program, for providers/suppliers to consider the business case for forming or joining a Shared Savings Program ACO, and for CMS to prepare to implement these changes.

Further, we do not believe it is desirable to implement an approach that would allow each ACO to select from a menu of options for customizing the benchmark methodology that would apply in any given performance year during an agreement period. An approach that allows an ACO to choose the more favorable of several methodologies for establishing its cost target would exacerbate our concerns about the potential for benchmarks to become overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings. We are concerned that this flexibility could lead to opportunities for arbitrage and may dull incentives for ACOs to improve their performance under the Shared Savings Program. Further, doing so would introduce considerable operational complexity into the program's benchmarking methodology.

As the commenters point out, ACOs have the option to ''early renew'', meaning to terminate their current participation agreement under § 425.220 and immediately enter a new agreement period to continue participation in the Shared Savings Program. (See paragraph (2) of the definition of ''renewing ACO'' in § 425.20, and 83 FR 67885 through 67890, and the application procedures set forth in § 425.224.) Early renewal would allow a currently participating ACO to be subject to the modified financial methodology policies applicable to agreement periods beginning on January 1, 2024, and in subsequent years, sooner than if the ACO were to wait to renew to continue its participation in the Shared Savings Program after completing its current agreement period of at least 5 years. We note that early renewing, like renewing upon completion of an agreement period, will result in rebasing of the ACO's historical benchmark, and will affect the ACO's eligibility for certain participation options (refer to section III.G.2. of this final rule), as well as the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (refer to § 425.600(f)).

Comment: One commenter supported several of the proposed changes to the financial methodology, but expressed concern over the Shared Savings Program becoming increasingly complex and changing frequently. The commenter expressed concern that this could create a barrier to participation in the Shared Savings Program as sophisticated modeling is necessary to determine if an ACO has a chance for success in the program.

Response: The financial methodology changes we proposed primarily build on the current Shared Savings Program policies. We do not believe that the changes to the financial methodology we are finalizing in this final rule create additional complexity that will create barriers to participation in the Shared Savings Program, and we remain committed to updating our specifications documents, programmatic resources, and other materials to support ACOs in understanding the financial methodology that is applicable to their agreement period, and to provide ACOs with aggregate reports and beneficiary-identifiable claims data, in accordance with the requirements specified in 42 CFR part 425 subpart H, to support ACOs participating in the Shared Savings Program.

Further, as explained in section III.G.1.a of this final rule, we are balancing incentives and participation options to serve a dual purpose of sustaining participation by existing ACOs and increasing program growth, recognizing that ACOs vary in their composition of providers/suppliers, the needs of the populations they serve, and have varying degrees of efficiency relative to their region and experience with accountable care initiatives. We proposed modifications to strengthen financial incentives for long term participation in the Shared Savings Program by reducing the impact of ACOs' performance and market penetration on their benchmarks, and to support the business case for ACOs serving high risk and high dually eligible populations to participate. We continue to believe that such policies will help sustain current participation and grow the Shared Savings Program, which in turn will outweigh any potential drawbacks of making these changes, such as additional programmatic complexity.

b. Statutory and Regulatory Background on Establishing and Updating the Benchmark and Determining Savings

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking and savings determination methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking and savings determination methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

The rules governing the benchmarking calculations and determination of shared savings and losses are set forth in the regulations at 42 CFR part 425, subpart G. In the November 2011 final rule establishing the Shared Savings Program, we adopted policies for establishing, updating, and resetting the benchmark at § 425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to § 425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at § 425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in § 425.601. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; and December 2018 final rule, 83 FR 68005 through 68030).

Calculations related to determination of shared savings and shared losses are specified in § 425.605 for ACOs participating under the BASIC track, and § 425.610 for ACOs participating under the ENHANCED track (formerly referred to as Track 3). In the June 2015 final rule, CMS established Track 3, constituting the program's highest level of risk and potential reward (80 FR 32771 through 32781). In the December 2018 final rule, CMS renamed Track 3 the ENHANCED track (see, for example, 83 FR 67841), and established the BASIC track, which includes a glide path with five Levels (A through E) (83 FR 67841 through 67857). The BASIC track's glide path allows eligible ACOs to begin under a one-sided model and incrementally advance to higher levels of risk and reward. We refer the reader to earlier rules for details on the development of the current policies for determining shared savings and losses under the BASIC track and ENHANCED track.

In the May 8, 2020, COVID–19 IFC (85 FR 27578 through 27582), we established adjustments to benchmark and performance year expenditure calculations to address the COVID–19 pandemic as specified under § 425.611. In the CY 2021 PFS final rule (85 FR 84771 through 84785), we summarized and responded to public comments received on these adjustments, and finalized the regulation at § 425.611 with modifications.

Details on the Shared Savings Program's financial methodology are included in Specifications documents. Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, January 2022), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1*. For details on Shared Savings Program policies to address the impact of the COVID–19 pandemic and the resulting public health emergency (PHE), refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology, Specifications of Policies to Address the Public Health Emergency for COVID–19 (December 2020), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf*.

c. Strengthening Participation by Reducing the Effect of ACO Performance on Historical Benchmarks, Addressing Market Penetration, and Strengthening Incentives for ACOs Serving Medically Complex and High Cost of Care Populations

(1) Regulatory Background

To establish an ACO's historical benchmark for an agreement period, CMS uses ACO historical expenditures for beneficiaries that would have been assigned to the ACO in the 3 most recent years prior to the start of the agreement period. As the statute requires the use of historical expenditures to establish an ACO's benchmark, the per capita costs for each benchmark year must be trended forward to current year dollars and then a weighted average is used to obtain the ACO's historical benchmark. Section 1899(d)(1)(B)(ii) of the Act also requires that the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for

Parts A and B services under the original Medicare FFS program. Therefore, in the November 2011 final rule establishing the Shared Savings Program, we adopted policies for trending forward expenditures for benchmark year (BY) 1 and BY2 to BY3 dollars (76 FR 67924 and 67925), and for updating the benchmark for each performance year during the ACO's agreement period (76 FR 67925 through 67927).

Over the 10 years since the Shared Savings Program was first established, we have used a variety of approaches for determining the trend and update factors to make an ACO's cost target more independent of its own expenditures, including using factors based on national expenditures, regional expenditures, or both. With these approaches, we have maintained a degree of parity between the factors used to trend and update the benchmark, either based on national FFS expenditures, regional FFS expenditures, or a blend of national and regional FFS expenditures.

In the November 2011 final rule establishing the Shared Savings Program, we adopted policies at § 425.602 establishing trend and update factors based on national FFS expenditures (76 FR 67924 through 67927). We finalized use of a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward BY1 and BY2 to BY3 dollars. We also finalized use of a flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the Original Medicare FFS program to update the benchmark for each performance year of the agreement period. We described our belief that using a trend factor based on a national growth rate in Medicare Parts A and B expenditures and an update factor calculated as a flat dollar amount equivalent of the projected absolute amount of growth in national FFS expenditures provides a relatively higher expenditure benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost high growth areas would therefore have an incentive to reduce their rate of growth to bring their costs more in line with the national average; while ACOs in low cost low growth areas would have an incentive to maintain or improve their overall lower spending levels (76 FR 67924 through 67927).

In the June 2015 final rule, we adopted policies for resetting the benchmark for ACOs entering a second agreement period in 2016 at § 425.603(b) (80 FR 32786 through 32796). These policies addressed concerns about the use of an ACO's prior performance years as benchmark years in second and subsequent agreement periods [315] by weighting each benchmark year equally and incorporating an adjustment to account for the average per capita amount of savings generated during the ACO's prior agreement period. We refer to this adjustment as a ''prior savings adjustment.'' We believed that incorporating a prior savings adjustment into the benchmarking methodology for renewing ACOs entering a second agreement period in 2016 would encourage ongoing program participation by ACOs that had lowered expenditures during their first agreement period. We noted that absent this adjustment, an ACO that previously achieved success in the program may elect to terminate its participation in the program rather than face a lower benchmark that reflects the lower costs for its patient population during the performance years of its prior agreement period (80 FR 32788 through 32791). When proposing this policy in the December 2014 proposed rule (79 FR 72838 and 72839), we highlighted the advantages of the prior savings adjustment, including increasing incentives for ACOs to remain in the program and continue generating shared savings and improving quality due to the prospect of a higher benchmark in future agreement periods. Furthermore, we hypothesized that adjusting benchmarks for prior performance would increase the likelihood of ACOs entering two-sided risk models. The prior savings adjustment adopted in the June 2015 final rule applied only to ACOs entering a second agreement period beginning in 2016 because we subsequently finalized an alternative methodology incorporating factors based on regional FFS expenditures to establish, adjust and update the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years.

In the June 2016 final rule (81 FR 37953 through 37991), we modified the benchmarking methodology to finalize an approach that incorporated factors based on regional FFS expenditures when resetting (or rebasing) and updating ACO historical benchmarks, as specified in § 425.603(c) through (f). We replaced the national trend factor used in the rebasing methodology with a methodology incorporating regional trend factors. This revised rebasing methodology applied beginning in 2017 to determine rebased historical benchmarks for ACOs renewing for a second or subsequent agreement period under the Shared Savings Program. We also adopted a phased approach to adjusting the rebased benchmark to reflect a percentage of the difference between an ACO's historical expenditures and FFS expenditures in the ACO's regional service area. A higher percentage would be used in calculating this regional adjustment to the ACO's rebased historical benchmark for the ACO's third agreement period (or fourth agreement period for ACOs that entered a second agreement period in 2016) and all subsequent agreement periods. The finalized methodology also included an annual update to the rebased benchmark to account for changes in regional FFS spending, replacing the update based solely on the absolute amount of projected growth in national FFS spending. We finalized an approach to calculate regional FFS expenditures, which included defining an ACO's regional service area to include all counties where one or more beneficiaries assigned to the ACO reside, calculating risk-adjusted county FFS expenditures for the ACO's regional service area using the assignable beneficiary population residing in each of the counties included in the ACO's regional service area, and weighting county-level FFS costs by the proportion of the ACO's assigned beneficiaries in the county. The approach adopted in the June 2016 final rule was designed to address concerns about an ACO's influence on its historical benchmark by making the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region by incorporating regional expenditures into the determination of an ACO's historical benchmark and applying a methodology for risk adjustment that accounted for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area. This approach, which was sunset through subsequent rulemaking that was finalized in December 2018, applied to determine the rebased historical benchmark for ACOs that renewed their participation agreement for a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019.

In the December 2018 final rule (83 FR 68005 through 68030), we adopted policies at § 425.601 that expanded the use of regional factors in establishing, adjusting, and resetting historical benchmarks to all ACOs, including ACOs in a first agreement period, for

[315] 79 FR 72835 and 72836.

agreement periods beginning on July 1, 2019, or in subsequent years. These policies sought to address concerns about ACOs influencing their own regional trends by using a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark under § 425.601(a)(5) and a blend of national and regional update factors to update the historical benchmark to the performance year under § 425.601(b) (83 FR 68024 through 68030). Under this approach, the weight applied to the national component of the blended trend and update factors increases with an ACO's penetration in its regional service area. We also finalized changes to limit the magnitude of the regional adjustment to address CMS' concerns about windfall gains for low-spending ACOs and to reduce disincentives for ACOs serving medically complex patients (83 FR 68017 through 68024). Specifically, we established a symmetrical cap on the regional adjustment to the historical benchmark equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. We also modified the schedule of weights used to phase in the regional adjustment at § 425.601(f), to reduce the maximum weight from 70 to 50 percent for all ACOs and to slow the phase-in of weights for ACOs with higher spending than their regional service area.

In earlier rulemaking, we have acknowledged that the use of factors based on regional FFS expenditures in calculating benchmarks will have varying effects on ACOs depending on each organization's individual circumstances (see, for example, 81 FR 37954 through 37957, and 81 FR 37975 through 37977; also 83 FR 68017 and 68026).

(2) Overview of Considerations for Modification to the Benchmarking Methodology

In the CY 2022 PFS proposed rule (86 FR 39291 through 39295), we summarized select aspects of the Shared Savings Program's benchmarking methodology and related concerns that have been expressed by ACOs and other interested parties and solicited comments. We discussed some of our considerations based on our initial analyses of these concerns about the methodology for calculating regional FFS expenditures used in certain benchmark calculations, specifically the regional adjustment and the blended national-regional growth rates used in trending and updating the benchmark. We sought comment on possible approaches for removing an ACO's assigned beneficiaries from the assignable beneficiary population used in the regional expenditure calculations to address concerns raised by ACOs and other interested parties that the current approach results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which they suggest may tend to be rural ACOs (86 FR 39292). In the CY 2022 PFS proposed rule (86 FR 39293), we noted the potential, based on initial simulations, for mixed effects on ACOs from modifications to the benchmark methodology to remove the ACO's assigned beneficiaries from the calculation of regional FFS expenditures. We also specified that it would be important to consider the extent to which market penetration should be considered in benchmark calculations, noting that relatively few ACOs have high market shares (86 FR 39293). We also sought comment on alternative benchmarking methodologies that may incorporate data sources other than Medicare FFS expenditure trends, such as by incorporating factors based on Medicare Advantage rates, or other published trends (86 FR 39294). We sought comment on alternate approaches to updating the historical benchmark, noting that in order for us to use our authority under section 1899(i)(3) of the Act to implement payment methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, those payment methodologies must be determined to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures (86 FR 39294).

In the section of the CY 2022 PFS final rule entitled ''Comments on Considerations Related to the Use of Regional FFS Expenditures and the Risk Adjustment Methodology in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark'' (86 FR 65295 through 65306), we summarized comments received, and noted that we would take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies. We noted that we would propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking. In the CY 2023 PFS proposed rule, we included select information on the comments received in response to the discussion in the CY 2022 PFS proposed rule and previously summarized, and referred readers to the aforementioned section of the CY 2022 PFS final rule for more complete summaries of commenters' suggestions.

Several commenters, including MedPAC, did not support removing ACO assigned beneficiaries from the regional FFS expenditure calculations (86 FR 65298). MedPAC expressed concern this would reward historically low spending ACOs without improving their efficiency of care while at the same time further reducing participation incentives among high spending ACOs that were likely to have the greatest opportunity for efficiency improvements.[316] Many commenters favored removing ACO assigned beneficiaries from the regional reference population (86 FR 65298 through 65302), with some commenters suggesting this approach in combination with other modifications to the benchmarking methodology, such as to expand the definition of regional service area, or to modify the blended national-regional growth factors used in trending and updating the ACO's historical benchmark. Some commenters sought clarity on the approach that would be used to remove an ACO's assigned beneficiaries from the assignable population of beneficiaries used to determine regional FFS expenditures given anticipated mixed effects on ACOs, including the impact on ACOs serving patients with high costs of care (86 FR 65298). Commenters offered differing perspectives on unintended consequences that could result from removing ACO assigned beneficiaries from regional FFS expenditures, with some commenters suggesting that this could also inadvertently increase incentives for patient selection and market consolidation (86 FR 65300 and 65301). Commenters offered a variety of alternative approaches (86 FR 65301 and 65302). For example, MedPAC suggested that ACOs selecting prospective assignment be offered a trend factor that is set prospectively prior to the start of the performance year and developed utilizing local and national estimates as is already done for benchmarking under the Global and Professional Direct Contracting Model (to be redesigned and renamed as the ACO Realizing Equity, Access, and

[316] Letter from MedPAC to Chiquita Brooks-LaSure, Administrator, CMS (September 9, 2021), regarding File code CMS–1751–P, available at *https://www.regulations.gov/comment/CMS-2021-0119-26001*.

Community Health (REACH) Model beginning January 1, 2023).[317]

As we explained in the CY 2023 PFS proposed rule (87 FR 46160), we have continued to investigate the commenters' concerns and consider their suggestions, and have performed additional modeling and analysis. We take seriously ACOs' and other interested parties' concerns about the Shared Savings Program's benchmarking methodology. In the CY 2023 PFS proposed rule, we proposed modifications to the Shared Savings Program's benchmarking methodology to address three core concerns (or dynamics):

- How to ensure rebased benchmarks remain accurate and serve as a reasonable baseline, when benchmark years correspond to performance years of the ACO's preceding agreement period, requiring ACOs to continually beat their own performance (also referred to as a ''ratchet effect'').
- How to address a single ACO's or multiple ACOs' collective effects on their own regional expenditures, which are used to calculate the regional adjustment and the regional portion of the trend and update factors.
- How to ensure the benchmarking methodology results in benchmarks of sufficient value to encourage program entry and continued participation by ACOs, ACO participants, and ACO providers/suppliers serving medically complex, high cost populations, and to address selective participation in the program by ACOs, ACO participants, and ACO providers/suppliers resulting from the program's benchmarking methodology.

As indicated in the regulatory background in section III.G.5.c.(1) of this final rule, we have taken incremental steps to address these dynamics through previous rulemaking, such as: using factors based on regional FFS expenditures to trend and update the ACO's rebased historical benchmark instead of a prior savings adjustment, followed by modifications to use blended national-regional growth factors in trending and updating the ACO's historical benchmark beginning with the ACO's first agreement period; incorporating a regional adjustment to the benchmark in the rebasing methodology, followed by modifications to apply the regional adjustment beginning with the ACO's first agreement period, and to adjust the phase-in of weights used in determining the regional adjustment over time; and modifying the risk adjustment methodology to account for changes in severity and case mix of the ACO's assigned beneficiaries during the performance year. While these approaches have made some progress to address the aforementioned dynamics, as discussed in the CY 2023 PFS proposed rule, we continue to receive feedback from ACOs and other interested parties that additional modifications to the benchmarking methodology are needed to further reduce impacts from rebasing and the regional effects of increasing market penetration by ACOs, and to support ACOs, and in particular ACOs serving medically complex, high cost populations, as they work to achieve the program's goal of lowering growth in Medicare FFS expenditures.

In the CY 2023 PFS proposed rule (87 FR 46161), we explained that there is some evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may already deter participation among ACOs with spending above their regional benchmark and those serving medically complex, high cost populations. For example, in PYs 2017 through 2019, just over 80 percent of ACOs subject to a regional adjustment received a positive adjustment, indicating their spending was lower than spending in their regional service area. More recently, the share of ACOs receiving a positive regional adjustment is closer to 90 percent. This pattern suggests selective participation behavior, where ACOs that have already achieved efficiency or that are serving beneficiaries with lower health risks are more likely to participate. Providers with the greatest opportunity to reduce spending (those that are inefficient and high spending relative to their region and that would receive a negative regional adjustment if they formed an ACO) are less likely to participate under the current methodology, limiting savings for the Medicare program. Additional analysis has suggested that ACOs receiving the largest negative regional adjustments tend to be those serving beneficiaries with high average risk scores and/or high proportions of beneficiaries dually eligible for Medicare and Medicaid. This further suggests that these ACOs may be higher cost relative to their regions as a result of caring for the highest needs populations rather than being inefficient, and that ACOs serving medically complex, high cost populations may have more difficulty participating in the Shared Savings Program.

In the CY 2023 PFS proposed rule (87 FR 46161), we explained our belief that addressing the concerning dynamics in the benchmarking methodology, combined with modifications to the risk adjustment methodology and to participation options targeted at improving participation by ACOs serving medically complex, high cost populations,[318] would further CMS' goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[319] This goal informed our consideration of how to approach potential modifications to the benchmarking methodology, and in particular motivated us to consider approaches that would allow for a potentially significant increase in participation in the Shared Savings Program.

We also noted our consideration of additional modifications to the Shared Savings Program benchmarking methodology that may be needed to ensure the program's longer-term sustainability. MedPAC discussed ratchet effects from rebasing and ACOs' affecting their own regional expenditures in its November 2021 public meetingthnsp;[320] and January 2022 public meeting.[321] Many of the commissioners appeared to support a longer-term approach under which CMS would update ACOs' benchmarks annually using ''exogenous'' factors, meaning factors not impacted by the individual or collective performance of ACOs. This approach, which has been referred to as ''administratively set benchmarks'', would use a combination of administratively determined factors

[317] We note that the Global and Professional Direct Contracting Model has gained experience using a prospectively set trend factor utilizing local and national estimates as part of benchmarking; this element of the benchmarking methodology will continue when the model transitions to the redesigned ACO REACH Model on January 1, 2023.

[318] The proposed modifications to the risk adjustment methodology targeted at supporting ACOs serving medically complex, high cost populations are described in section III.G.5.e of this final rule. Our proposed modifications to participation options targeted at ACOs serving underserved populations, and providing a longer on-ramp to performance-based risk for certain ACOs are described in section III.G.2 of this final rule.

[319] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. *Health Affairs.* January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*.

[320] Serna L and Stensland J. MedPAC. Presentation on benchmark incentives for accountable care organizations (November 8, 2021), available at *https://www.medpac.gov/wp-content/uploads/2021/09/aco-benchmarks-medpac-nov-2021.pdf*.

[321] Burton R et al. MedPAC. Presentation on developing a multi-track population-based payment model with administratively updated benchmarks (January 14, 2022), available at *https://www.medpac.gov/wp-content/uploads/2021/10/APM-MedPAC-Jan22.pdf*.

and projected growth in volume and intensity of FFS services, to account for whether an ACO is high or low spending relative to its region. However, at least one commissioner questioned using a projected trend when the actual trend is available and, in their view, has served the program well.[322] In its June 2022 Report to the Congress, MedPAC formally recommended the administratively set benchmarks approach.[323] In section III.G.7. of the CY 2023 PFS proposed rule (87 FR 46208 through 46218), we described and sought comment on a potential longer-term approach for use of administratively set benchmarks that are decoupled from ongoing observed FFS spending.

In the CY 2023 PFS proposed rule, we proposed a combination of policies to ensure a robust benchmarking methodology that would reduce the effect of ACO performance on ACO historical benchmarks and increase options for ACOs caring for high-risk populations. Specifically, we proposed to modify the methodology for updating the historical benchmark (section III.G.5.c.(3) of the proposed rule), incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs (section III.G.5.c.(4) of the proposed rule), and modify the negative regional adjustment (section III.G.5.c.(5) of the proposed rule). We also noted our belief that these proposed modifications could serve as ''stepping stones'' to a potential longer-term approach to the benchmarking methodology, and indicated that they were designed to be consistent with the potential approach for incorporating a methodology for administratively set benchmarks, which was described in the request for information in section III.G.7. of the proposed rule. In section III.G.5.c.(6) of the proposed rule, we also sought comment on two potential alternatives to the package of policies we proposed in sections III.G.5.c.(3) through (5). As explained in the proposed rule, both alternatives would seek to limit the impact of an ACO's own assigned beneficiaries on the regional factors used in benchmarking calculations. While these alternatives would address concerns raised by some interested parties, we noted that we believed they would be less effective than our proposed policies at addressing the full set of core concerns we articulated in section III.G.5.c of the proposed rule.

(3) Incorporating a Prospective, External Factor in Growth Rates Used To Update the Historical Benchmark

(a) Background

As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. In accordance with § 425.601(b), for agreement periods beginning on July 1, 2019, and in subsequent years, we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year. To update the benchmark, we make separate calculations for expenditure categories for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid.

The national-regional blend is a weighted average of national FFS and regional growth rates between BY3 and the performance year for the applicable Medicare enrollment type. The national growth rates are computed using CMS OACT national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries (as defined at § 425.20) identified for the 12-month calendar year corresponding to each year. Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year. To calculate regional expenditures, we determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year, and determine the ACO's regional expenditures as specified under § 425.601(c) and (d).

The national and regional growth rates are blended together by taking a weighted average of the two. The weight assigned to the national component of the national-regional blend for a given Medicare enrollment type is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year, calculated by taking a weighted average of county-level shares as specified in § 425.601(a)(5)(v). To calculate this share, we first calculate the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area for that Medicare enrollment type. We then weight the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries for that Medicare enrollment type. Next, we sum these weighted county-level shares for all counties in the ACO's regional service area for each Medicare enrollment type.

As an ACO's penetration in its region increases, a higher weight is placed on the national component of the national-regional blend and a lower weight on the regional component. The national and regional growth rates are blended together by taking a weighted average of the two. Specifically, for each Medicare enrollment type, the national-regional blended growth rate is equal to the sum of the following: (1) the growth rate for national assignable FFS expenditures for BY3 to the performance year multiplied by the weight assigned to the national component; and (2) the average growth rate for regional FFS expenditures for BY3 to the performance year based on the ACO's regional service area multiplied by the weight assigned to the regional component. In accordance with § 425.601(a)(5), we also use blended national-regional growth rates to trend forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars, making separate calculations for each Medicare enrollment type.

We summarized concerns with the current benchmarking approach in section III.G.5.c.(2) of the proposed rule (87 FR 46159 through 46162). Specifically, ACOs and other interested parties have expressed concerns regarding the dynamic under which an ACO that reduces costs for its own assigned beneficiaries also reduces its average regional costs, resulting in a relatively lower benchmark for the ACO under the blended national-regional growth rates used to trend and update the ACO's historical benchmark. As echoed in public comments, ACOs and other interested parties have suggested that this dynamic particularly

[322] See, for example, Medicare Payment Advisory Commission, Public Meeting, Friday, January 14, 2022, transcript of proceedings starting at 10:02 a.m., available at *https://www.medpac.gov/wp-content/uploads/2021/10/Jan22_MedPAC_Meeting_Transcript_SEC.pdf* (refer to pages 166–246, enumerated pages 3–83).

[323] Medicare Payment Advisory Commission. June 2022 Report to the Congress: Medicare and the Health Care Delivery System (June 15, 2022), available at *https://www.medpac.gov/document/june-2022-report-to-the-congress-medicare-and-the-health-care-delivery-system/* (Chapter 1, pages 3–22).

disadvantages ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas (see, for example, 86 FR 65296 through 65299).

(b) Revisions

In the CY 2023 PFS proposed rule (87 FR 46162 through 46169), we proposed to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) that we refer to as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. Incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor. Because the ACPT would be prospectively set at the outset of an agreement period, any savings generated by ACOs during the agreement period would not be reflected in the ACPT. Accordingly, incorporation of the ACPT would allow for benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. By limiting the negative feedback of efforts by ACOs to slow spending growth on their own benchmarks, we noted that we believed the use of this three-way blend to update ACOs' benchmarks would incentivize both greater savings by ACOs and greater program participation. Because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, we also believed that the proposed change to the update methodology would help to address the concerns discussed in section III.G.5.c.(2) of this final rule regarding the disproportionate impact of an ACO's savings on the benchmark update for ACOs with high market share.

We did not propose to revise the methodology used to trend forward per capita expenditures from BY1 and BY2 to BY3, but indicated our intent to maintain the current two-way blend used in calculating the ACO's benchmark. We acknowledged that modifying the methodology for determining the update factor but not the trend factor would mean there would no longer be parity between these factors, but noted that we believed this would be an appropriate departure from the approach we have maintained since the start of the program. The two-way blend used for trend factors would continue to reflect actual growth rates, which we believed would still be appropriate for purposes of determining the historical benchmark because the benchmark is intended to reflect historical spending prior to any savings achieved during the agreement period for which the benchmark will be used. In contrast, we explained that the proposal to use a three-way blend to update the benchmark would incorporate a projected growth rate, the ACPT, which would reflect increases in spending independent of any savings achieved by the ACO, or ACOs collectively, during the agreement period, thus limiting the extent to which ACOs' success in reducing expenditures for their assigned beneficiaries over the course of an agreement period negatively impacts their ability to share in savings during that agreement period. We also explained that we believed this proposed change to the update factor would incent ACOs to reduce expenditures during the agreement period because there would be less risk of those reductions negatively impacting their benchmark updates. This, in turn, could lead to greater savings generated and increased shared savings payments to ACOs.

Under the proposed approach, a three-way blend would be calculated as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between BY3 and the performance year (PY). The ACPT component of the blend would be an external factor, meaning it would not be impacted by the individual or collective performance of ACOs. The reference to a ''two-way blend'' is synonymous with the existing blended national-regional growth rates under § 425.601.

The CMS Office of the Actuary (OACT) provides projections of Medicare program spending for various recurring deliverables, including the Medicare Trustees Report and the Advance Notice and Announcement of Medicare Advantage capitation rates and Part C and Part D payment policies. These publications include both historical and projected future Medicare spending amounts expressed on a per capita basis (differences in ESRD and non-ESRD calculations, are described in further detail in this section). These amounts published in the Advance Notice and the Announcement are labeled the FFS USPCCs. We proposed to calculate the ACPT component of the blended annual update using an annualized growth rate based on 5-year-projections in per capita spending as of the start of an ACO's agreement period. We explained in the proposed rule that we selected this projection horizon to align with the 5-year agreement periods used under the Shared Savings Program. The ACPT would be projected by OACT and would be a modification of the existing FFS USPCC growth trend projections used annually for establishing Medicare Advantage rates. The modifications to the FFS USPCC, aimed at making the trends more consistent with the Shared Savings Program's existing expenditure calculations, would reflect the following:

- Exclusion of payments for indirect medical education (IME), disproportionate share hospitals (DSH), including both empirically justified DSH payments and uncompensated care payments, and the new proposed supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico that was subsequently finalized in the FY 2023 IPPS/LTCH PPS final rule.
- Inclusion of payments associated with hospice claims.

OACT currently produces separate FFS USPCCs for ESRD (dialysis-only, including aged/ESRD, disabled/ESRD and ESRD-only) and non-ESRD aged/disabled populations. Likewise, OACT would also calculate the ACPT separately for these two populations. Currently, most Shared Savings Program benchmarking calculations are performed separately for four separate Medicare enrollment types: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid. The Shared Savings Program identifies enrollment type status on a monthly basis. A beneficiary month is classified as an ESRD month if the beneficiary was in long-term dialysis or transplant status for that month (including up to 3 months post-graft). All non-ESRD months are then classified as one of the other three categories based on age (under 65 for disabled) and dual eligibility status (for beneficiaries 65 and over only).[324] We proposed to use the ESRD ACPT in calculating update factors for the ESRD population and to use the combined Aged/Disabled ACPT in calculating

[324] Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (January 2022, Version #10), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1* (Appendix E).

update factors for the remaining three enrollment types (disabled, aged/dual eligible, aged/non-dual eligible). We explained that using ACPTs based on the existing populations for which FFS USPCCs are calculated would allow us to leverage existing OACT models which do not currently differentiate among categories within the aged/disabled population. We noted that we did not believe that there would be significant precision gained from revising these existing models to incorporate assumptions regarding these distinctions. Furthermore, we noted that outside of the unforeseen impact of the PHE for COVID–19, national assignable per capita spending growth rates were reasonably consistent across the three non-ESRD enrollment types from 2013–2019 and noted that we anticipated that pattern continuing during the period in which the ACPT would be incorporated into ACO calculations.

We proposed to set the ACPT growth factors for an ACO's entire 5-year agreement period near the start of the agreement period. The ACPT factors would remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs. We noted that we anticipated that we would publish finalized ACPT values in the Spring of the first performance year of an ACO's agreement period, and that earlier years' trends would be available for reference prior to the start of an ACO's agreement period. We acknowledged that, under an approach that sets the value of the ACPT at the start of an ACO's agreement period, ACOs entering agreement periods in different years could be subject to higher or lower updates depending on how projections change from year to year. This could lead ACOs to try to time their entry (or renewal) in the program to try to maximize the fixed portion of their update. However, we noted that this concern would be mitigated because the ACPT would represent only one-third of the three-way blend used to update an ACO's benchmark.

We further proposed that the annualized growth rate(s) would be calculated as either a uniform annualized projected growth rate over each of the 5 performance years of the 5-year agreement period, or as two or more annualized growth rates during the 5 performance years comprising the 5-year agreement period. Two or more annualized growth rates would be used if OACT determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve—for example, if growth is expected to be above- or below-average in the short-run and return to more typical levels later in the agreement period.

We noted that we considered whether the ACPT component of the blend should express projected growth on a relative basis (as the current two-way national-regional blend operates) or on an absolute (flat) dollar basis. Applying the new portion of the update as an absolute dollar growth amount would more closely adhere to the approach stipulated in section 1899(d)(1)(B)(ii) of the Act for the benchmark to be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. However, under the proposed approach, the ACPT would be weighted together with the two-way national-regional blend.

We explained that based on retrospective modeling (described elsewhere in this section), both the relative basis and flat dollar approaches to calculating the ACPT are anticipated to improve the incentive to participate compared with the current two-way blend for both ACOs with higher market penetration within their regional service area (the ACO's assigned beneficiaries constitute at least 30 percent of the assignable beneficiary population within the ACO's regional service area) and ACOs operating in a regional service area with higher ACO market penetration (at least 50 percent of the assignable beneficiaries within an ACO's regional service area are assigned to any Shared Savings Program ACO). During the period examined, ACO benchmarks increased an average of $19 per capita, with an average of 62 percent of all ACOs across all years modeled receiving a larger benchmark increase compared with the current two-way blend. An average of 65 percent of ACOs operating in a regional service area with higher Shared Savings Program market penetration were better off under the three-way blended update factor compared with the current two-way blend. Additional results comparing the benefits of the three-way blend to the current two-way blend are described elsewhere in this section. We also anticipated that introducing the ACPT as part of a three-way blend may incentivize ACOs to achieve additional savings by providing a known prospective trend that allows for improved planning and provides a target for ACOs to compare their performance against. Because the prospective trend would allow ACOs to improve planning, we also noted that a higher percentage of ACOs may benefit from the three-way blend than was reflected in the simulations. In addition, we noted that we expected the three-way blend would further insulate a portion of the benchmark update from the impact of an ACO's own savings, as actual spending trends downward from initial projections.

We explained that while both approaches are, on average, favorable for ACOs, the risk-adjusted flat dollar approach is anticipated to be more beneficial to ACOs because the flat dollar amount would be based on per capita expenditures among the national assignable population, which tend to be higher than per capita expenditures among ACO-assigned beneficiaries. That is, if national per capita expenditures are projected to increase by 3 percent per year, a flat dollar amount representing 3 percent of per capita expenditures from the national assignable population would be greater than 3 percent of a typical ACO's own benchmark amount; thus, the flat dollar ACPT would result in a larger overall increase to the ACO's benchmark amount each year. Another potential advantage of calculating flat dollar amounts based on the national per capita FFS expenditures for the assignable population (rather than simply calculating flat dollar amounts from OACT's original projected dollar values for the ACPT), is that it would allow us to generate separate values for each of the four Medicare enrollment types. This approach would also align projections with actual per capita expenditures of the assignable population, minimizing the degree to which the projections may systematically differ in how they are calculated.

Therefore, we proposed to calculate flat dollar amounts (separately for each Medicare enrollment type) by applying the relevant projected growth rate to truncated national per capita FFS expenditures for assignable beneficiaries for BY3 for the given Medicare enrollment type. The assignable population for this calculation would be identified using the assignment window for the 12-month calendar year corresponding to BY3. Truncation would be done in the same manner as is done when calculating the ACO's own per capita expenditures to draw an equivalent comparison. That is, we would truncate national per capita FFS expenditures for assignable beneficiaries for BY3 for a given Medicare enrollment type, for purposes of calculating the ACPT flat dollar amounts, at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. This

approach would be consistent with the approach to truncating an assigned beneficiary's expenditures in calculating the ACO's benchmark year expenditures as currently specified in § 425.601(a)(4), and in the proposed new provision at § 425.652(a)(4), and performance year expenditures as specified under § 425.605(a)(3) (BASIC track) and § 425.610(a)(4)(ii) (ENHANCED track). This approach to truncation to establish the ACPT flat dollar amounts would also align with the approach to truncating assignable beneficiary expenditures in calculating county expenditures (refer to § 425.601(c)(3), and proposed § 425.654(a)(3)) used in determining factors based on regional FFS expenditures, including the regional component of the two-way blend.

We also proposed to risk adjust these flat dollar amounts to account for differences in severity and case mix between the ACO's assigned beneficiaries and the national assignable FFS population for each Medicare enrollment type. We noted that we had concerns that flat dollar amounts that are not risk adjusted could generate a relatively lower update for higher spending ACOs caring for medically complex populations because the amount of the update would be set based on per capita expenditures for the national assignable population (which are likely to be lower) instead of the ACO's own assigned beneficiary population. Risk adjusting the flat dollar amounts would provide a higher flat dollar amounts for ACOs serving medically complex populations. We did not propose to adjust the ACPT flat dollar amounts for geographic differences in costs or prices, as we believed that such an adjustment may inadvertently reward higher spending, less efficient ACOs with a high market share in their regional service area.

In the CY 2023 PFS proposed rule, we explained that in order to blend the risk-adjusted flat dollar amounts with the corresponding two-way blend for each enrollment type, which would continue to operate on a relative basis, we would first need to re-express the risk-adjusted flat dollar amounts on a relative basis by dividing by the ACO's historical benchmark expenditure amount. This would be done separately for each Medicare enrollment type.

Using hypothetical values, the steps below illustrate how we would set the annualized growth rate(s) and calculate the ACPT flat dollar amount(s) (re-expressed as a relative value) that would be included in the three-way blend.

Step 1: Calculate annualized growth rate(s) for agreement period.

For step 1, OACT would calculate one or more annualized growth rates for the ESRD population (the ESRD ACPT) and one or more annualized growth rates for the aged/disabled population (the Aged/Disabled ACPT). Specifically, for each population OACT would project per capita spending growth for Parts A and B Medicare FFS spending as described earlier in this section between BY3 and each performance year of the agreement period. These annualized growth rates may either be calculated as a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period, or as two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period if CMS determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve.

Step 2: Express the growth rate(s) for each performance year as flat dollar amounts (the ACPT).

For step 2, we would multiply BY3 truncated national per capita FFS expenditures calculated by OACT for the assignable FFS population for a given enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries), by the applicable growth rate to calculate the flat dollar amount of growth for each performance year. As previously described in this section, we would use ESRD growth rate(s) for the ESRD population and non-ESRD aged/disabled growth rate(s) for the disabled, aged/dual eligible, and aged/non-dual eligible populations. Thus, for example, if the truncated national assignable per capita expenditures for a given enrollment type were $13,000, and the projected growth rate for that enrollment type in that year was 5 percent per year,[325] the flat dollar amounts would be:

PY1 flat dollar amount = $13,000 × (1.050 − 1) = $650, and

PY5 flat dollar amount = $13,000 × (1.276 − 1) = $3,588 [326]

Step 3: Risk adjust the flat dollar amounts.

In step 3, we would multiply the flat dollar amounts for each performance year, for each enrollment type, by the ACO's mean BY3 prospective HCC risk score [327] for that enrollment type. For consistency with other Shared Savings Program risk adjustment calculations, the risk score used would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Risk adjusting the flat dollar amounts would allow for a higher update for ACOs serving a population that is more medically complex than the national average. If the ACO's BY3 risk score was 1.025, the risk-adjusted flat dollar amounts would be:

PY1 flat dollar amount = $650 × 1.025 = $666, and

PY5 flat dollar amount = $3,588 × 1.025 =$3,678

Step 4: Re-express risk-adjusted flat dollar amounts as relative factors.

The fourth and final step before calculating the three-way blended update factor would be to re-express the risk-adjusted flat dollar amount for each enrollment type on a relative basis such that it can be combined in a weighted average with the current two-way blend. We would do this by dividing the risk-adjusted flat dollar amounts computed in Step 3 for a given enrollment type by the ACO's historical benchmark expenditures for that enrollment type. The resulting amount would represent the final ACPT portion of the blended update factor for that enrollment type. If the historical benchmark expenditures for the enrollment type were $12,000, the final ACPT portion of the blended update factors for this enrollment type would be:

[325] Although not specified in the CY 2023 PFS proposed rule, we wish to clarify that for this illustration the ACPT was assumed to roughly match the annual growth rate projected for FFS USPCC Non-ESRD Part A + Part B spending from 2024 to 2025 in table II–2 of the CY 2023 Medicare Advantage (MA) Rate Announcement. The ratio of $1,186.14 divided by $1,132.07 rounds to five percent growth in spending currently expected for the first year that the ACPT would be incorporated into ACO benchmarks under our proposal. In practice, the ACPT may differ from the USPCC because of adjustments to exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, and include payments associated with hospice claims, and because it accounts for an extended 5-year performance period. Refer to Announcement of CY 2023 MA Capitation Rates and Part C and Part D Payment policies, available at *https://www.cms.gov/files/document/2023-announcement.pdf*.

[326] For a given performance year ''X'' in an agreement period, the growth rate is calculated by raising the annual growth rate to the power of X (that is, multiplying the annual growth rate by itself X times). Thus, for PY5 in this example, the annual growth rate of 1.276 is computed by raising 1.05 to the power of 5 (that is, multiplying the single year growth rate of 1.05 by itself 5 times).

[327] We have also used the terms ''CMS–HCC prospective risk scores'' and ''CMS–HCC risk scores'' (see, for example, the December 2018 final rule, 83 FR 68007 through 68013) to refer to such risk scores. While we choose to use the term ''prospective HCC risk scores'' within this section of this final rule for consistency with the terminology used in the regulations (see, for example, §§ 425.601, 425.605, and 425.610), we consider these terms to be interchangeable.

PY1 final ACPT portion of the blended update factor = ($666/$12,000) + 1 = 1.056, and

PY5 final ACPT portion of the blended update factor = ($3,678/$12,000) + 1 = 1.306

The values in this step would then be combined with the two-way blend to compute the three-way blended update factor. The ACPT would constitute one-third of the total blend, while the remaining two-thirds would consist of the existing two-way blend.

To illustrate how we would compute the three-way blend, and how it would compare with the two-way blend, we assumed for the same hypothetical ACO for a given enrollment type that the regional expenditure growth between BY3 and PY1 is 2.5 percent, that national assignable FFS expenditure growth is 3 percent and that the ACO's assigned beneficiaries represent 20 percent of the assignable population in the ACO's regional service area. For simplicity, we assumed the ACO faces a risk ratio of 1.0. The current two-way blended update factor would be calculated as:

Two-way blend = (National Update Factor × National Weight) [328] + (Regional Update Factor × (1 − National Weight)); or

Two-way blend = (1.030 × 20 percent) + (1.025 × 80 percent) = 1.026.

Updating the ACO's benchmark with the two-way blended update factor alone would yield a value of $12,312 (that is, $12,000 × 1.026 = $12,312).

To calculate the three-way blend by incorporating the PY1 ACPT factor of 1.056 (from earlier in the example) we would use the following weighted average:

Three-way blend = [PY1 ACPT × (⅓)] + [PY1 Two-Way Blend × (⅔)]; or

Three-way blend = [1.056 × (⅓)] + [1.026 × (⅔)] = 1.036.

Applying the three-way blended update factor to the historical benchmark would yield an updated benchmark of $12,432 for the enrollment type (that is, $12,000 × 1.036 = $12,432). In this example, the ACO's benchmark update factor increases by 1.0 percentage point, corresponding to an increase of $120 per capita, which increases the ACO's potential for shared savings and reduces the potential for shared losses, if applicable.

In the CY 2023 PFS proposed rule, we stated that including the ACPT as a component of a three-way blend could provide a degree of certainty that benchmarks would not be lowered as a result of ACOs reducing FFS spending growth, and thereby increase the incentive for such savings and strengthen incentives for ACOs to enter and remain in the Shared Savings Program. However, we also acknowledged that incorporating the ACPT into a three-way blended update factor would have the potential for mixed effects. For example, it may also lower an ACO's benchmark relative to the current approach if external factors lead to higher program spending growth than originally projected at the start of an ACO's agreement period. This could, for example, cause an ACO in a two-sided model that would not have been responsible for shared losses under the two-way blend to owe shared losses under the three-way blend or cause an ACO that would have owed shared losses under the two-way blend to owe a larger amount of shared losses under the three-way blend.

Additionally, we noted that the three-way blend could potentially have negative implications for an ACO based on the Shared Savings Program's policy regarding monitoring of ACO financial performance described in § 425.316(d). Under this policy, if an ACO's performance year expenditures exceed its updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model or the minimum loss rate (MLR) under a two-sided model, CMS may take pre-termination actions against the ACO. For a subsequent occurrence for another performance year in the same agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement.

Consequently, we explained our belief that a guardrail would be needed to ensure the use of the three-way blend would not result in lower benchmarks than the current national-regional blend in a way that poses higher financial risk for ACOs under two-sided models, or that could jeopardize an ACO's continued participation in the Shared Savings Program under the financial performance monitoring policy described in § 425.316(d), or both.

We proposed to institute this guardrail as follows: if an ACO generates losses for a performance year that meet or exceed its minimum loss rate (MLR) (for two-sided model ACOs) or negative MSR (for one-sided model ACOs) under the three-way blend, we would recalculate the ACO's updated benchmark using the national-regional blended update factor (two-way blend). If the ACO generates a smaller amount of losses using the two-way blend, we would use this smaller amount to determine the ACO's responsibility for shared losses, if applicable, and in determining the ACO's financial performance for monitoring purposes under § 425.316(d). If the ACO generates saving using the two-way blend to update its benchmark but does not generate savings under the three-way blend, the ACO would neither be responsible for shared losses (if in a two-sided model) nor eligible for shared savings for the applicable performance year, even if the savings generated exceed the ACO's MSR. ACOs in these scenarios would publicly report their performance in accordance with § 425.308(b)(4) based on the recalculated amounts determined using the two-way blend. However, an ACO that generated savings under the two-way blend, but was not eligible to earn a shared savings payment, would be required to report zero shared savings for the performance year. We noted that we believed this guardrail would protect ACOs from the most negative potential outcomes of the proposed three-way blend, while still insulating the Trust Funds.

To illustrate how the guardrail would be applied, we considered a second hypothetical ACO participating at Level E of the BASIC track for which the updated benchmark calculated using the three-way blend was $12,760. We assumed that the ACO's per capita performance year expenditures were $12,980 and that the ACO had selected a symmetrical MSR/MLR of 1.5 percent. Using the three-way blend, the ACO would have per capita losses of −$220, or −1.7 percent of its updated benchmark which would be above ACO's selected MLR of −1.5 percent. Applying the fixed shared loss rate of 30 percent under Level E, the ACO would, in absence of the guardrail, be liable for shared losses (on a per capita basis) of −$66 and would face potential pre-termination actions or involuntary termination (depending on the ACO's financial performance in prior years of its agreement period). However, with the guardrail in place, we would re-assess the ACO's performance using the two-way blend. If the two-way blend produced an updated benchmark of $12,804, the ACO's new per capita losses amount would be −$176, or −1.4 percent of its updated benchmark which would be within the ACO's selected MLR of −1.5 percent. This ACO would therefore not be responsible for shared losses for the performance year and would not face any negative consequences under the financial performance monitoring policy. If the

[328] Weight for the national growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3 (refer to § 425.601(a)(5)(iv)(A)).

two-way blend instead produced an updated benchmark of $13,183, the ACO would have measured per capita savings of $203, or 1.54 percent of its updated benchmark. As previously explained, under the proposed approach, the ACO would no longer be responsible for shared losses nor face pre-termination action or termination based on its financial performance. However, although the savings amount would exceed the ACO's MSR of 1.5 percent, the ACO would not be eligible for shared savings under the proposed policy.

Under the proposal to set the ACPT for the duration of the ACO's agreement period, we explained that we would not adjust the ACPT due to external factors such as geographic price changes, efficiency discounts, or other retrospective updates occurring during the performance years throughout the agreement period. However, we acknowledged that a variety of circumstances could cause actual expenditure trends to significantly deviate from projections. Thus, we noted that we believed there would be circumstances that may warrant reducing the weight placed on the ACPT on an ad hoc basis. In particular, we noted that if we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered. For example, based on a review of projections detailed in the 2009 Medicare Trustees Report, an ACPT projected in 2009 (amidst the great recession and before passage of the ACA) would have ultimately overstated per capita spending growth from 2008 to 2013 by roughly 9 percentage points (which would have corresponded to a 3 percent upward bias to benchmarks when weighted as one-third of the blended update). We also noted that we were especially concerned that such unforeseen circumstances could result in an update factor that significantly differs from actual expenditure trends, and in turn could result in ACOs owing excessive shared losses or the Medicare Trust Funds paying out windfall shared savings. While we noted that the guardrail discussed previously would offer protection against some unexpected variances between the projected amount and actual expenditures to protect against shared losses, we also noted that we believed it would also be important for CMS to retain flexibility to reduce the impact of the prospectively determined ACPT portion of the three-way blend if unforeseen circumstances occur during an ACO's agreement period.

When determining an approach for adjusting the three-way blend if unforeseen circumstances occur, we considered CMS' experience with use of a prospective trend, calculated by OACT based on an adjusted USPCC amount, in the Next Generation ACO (NGACO) Model.[329] In the NGACO Model, CMS maintained the sole discretion to retrospectively modify the projected trend used in calculating the performance year benchmark (aggregate expenditure target) if CMS determined that exogenous factors, such as a natural disaster, epidemiological event, legislative change and/or other similarly unforeseen circumstance during the performance year, rendered the projected trend invalid. CMS used this discretion for the NGACO Model in response to the COVID–19 pandemic in PYs 2020 and 2021. For PY 2020, instead of applying the prospective trend, CMS offered NGACOs the choice between use of a retrospective national trend or a retrospective regional trend. For PY 2021, CMS applied a retrospective national trend to all NGACOs instead of a prospective trend.[330]

Based on the experience in the NGACO Model, we explained that we believed it would be appropriate, when unforeseen circumstances occur, to adjust the three-way blend to prevent drastic differences between actual and projected expenditure trends. Accordingly, we proposed that if unforeseen circumstances occur, we would retain discretion to decrease the weight applied to the ACPT in the three-way blend. Absent unforeseen circumstances, we would weight the two-way blend as two-thirds and the ACPT as one-third in calculating the three-way blend. However, if CMS determines an unforeseen circumstance has occurred that would warrant adjustments to these weights, then CMS would modify the three-way blend to reduce the weight that will apply to the ACPT and increase the weight of the two-way blend. We further proposed that CMS would have sole discretion to determine whether unforeseen circumstances exist that would warrant adjustments to these weights, as well as the extent to which the components of the three-way blend would be re-weighted. However, given that external factors that cause deviations from projected trends would continue to be reflected in the two-way blend component of the update factor, the impacts from unforeseen circumstances that either increase or decrease the two-way blend component would also then increase or decrease the three-way blend. We noted that this would likely mitigate the need to adjust the weight of the ACPT used in the three-way blend.

Based on initial modeling, we explained our belief that the proposed three-way blended update factor with the associated guardrail, in combination with the other benchmarking changes discussed in the proposed rule, including to apply a prior savings adjustment and mitigate the impact of negative regional adjustments on ACOs, would serve as a mid-term solution to ensuring the sustainability of ACOs' historical benchmarks as we consider moving toward an administrative benchmarking methodology, as discussed in section III.G.7. of the proposed rule.

To simulate the potential impact of the three-way blend, we examined ACO spending over a 5-year period (2014 to 2019) using ACO participant lists in effect for all 12- or 6-month performance years or performance periods beginning on January 1, 2019, and existing Medicare Part A and Part B USPCC projections published in the 2014 Medicare Trustees report.[331] We also adjusted the Part A projections to remove IME, DSH, and uncompensated care payments, to better reflect how the proposed ACPT would be calculated in practice. For the purposes of this simulation, we used 2014 per capita spending as the historical benchmark for each ACO in lieu of a 3-year base period. We then simulated updating each ACO's historical benchmark for each of the 5 subsequent years using the existing two-way blended update factor methodology (in accordance with § 425.601(b)) and incorporating the simulated flat dollar ACPT amounts into a three-way blended updated factor. We compared the simulated benchmark updates determined using this three-

[329] CMS, ''Next Generation ACO Model, Calculation of the Performance Year Benchmark: Performance Year 2021'' (Section 2.1.7, ''Prospective Base Year Trend''), available at *https://innovation.cms.gov/media/document/ngaco-py6-bnechmark-meth.*

[330] CMS, ''Next Generation ACO Model: Frequently Asked Questions'' (May 2021), available at *https://innovation.cms.gov/media/document/ngaco-2021-faqs.* Refer to question 18.

[331] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'', available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2014.pdf.*

way blend to updates simulated using the existing two-way blend. These simulations showed that, on average, ACOs were better off over the course of the 5-year agreement period using the three-way blend than using the current two-way blend. That is, in a given year, an ACO's benchmark on average increased more when the annual update was calculated using the proposed three-way blend. Incorporating the ACPT into a three-way blended update factor during the model period resulted in an average benchmark increase of $19 per capita, with an average of 62 percent of all ACOs across all years modeled receiving a larger benchmark increase compared with the current two-way blend. ACOs with high market penetration within their regional service area (ACOs whose assigned beneficiaries constitute at least 30 percent of the assignable beneficiary population within the ACO's regional service area) had similar results to those with lower market penetration (61 percent vs 63 percent, respectively), with both groups receiving larger benchmark increases from the three-way blend. ACOs operating in markets where the Shared Savings Program as a whole has higher penetration (at least 50 percent of the assignable beneficiaries in an ACO's regional service area are assigned to any Shared Savings Program ACO) were, on average, better off under the three-way blend. We observed that, on average over the 5-year period used in our modeling, approximately 65 percent of ACOs operating in markets with high Shared Savings Program penetration had a larger benchmark increase under the three-way blend compared with the two-way blend. Additionally, an average of 50 percent of ACOs with at least 25 percent of assigned beneficiaries being dually eligible for Medicare and Medicaid received a higher benchmark update under the three-way blend, as well as 65 percent of ACOs with at least 20 percent of assigned beneficiaries being disabled and 55 percent of ACOs operating in rural areas. As discussed in the CY 2023 PFS proposed rule, these results simulate a change in how the benchmark update is calculated holding everything else constant. That is, these results do not reflect any additional savings that may have materialized had a three-way blend that includes the ACPT been in place during the 5-year period included in our modeling. However, we also explained that introducing the ACPT into a three-way blend may incentivize ACOs to achieve additional savings, and that the three-way blend would then insulate a portion of the benchmark update from the impact of those savings as actual spending trends downward from initial projections. As a result, a higher percentage of ACOs may benefit from the three-way blend than is reflected in these simulations.

In the proposed rule, we noted our belief that incorporating the prospective trend into the benchmarking methodology by including the ACPT in a three-way blended update factor would be an important step towards an administrative benchmarking approach. ACOs may have a greater incentive to enter and continue participation in the Shared Savings Program when their benchmarks are further decoupled from their ongoing observed FFS spending while continuing to reflect a measure of the ACO's efficiency relative to its region. This approach may also serve to anchor and stabilize benchmarks to the extent that the ACPT projected growth component is an effective counterbalance when there are changes in an ACO's penetration in its regional service area that affect the weights given to the national and regional expenditure components of the current two-way blended update factor. However, we recognized that some interested parties may still have concerns and prefer a different approach to address impacts that may result from ACO market penetration. In section III.G.5.c.(6) of the proposed rule (87 FR 46183 through 46186), we sought comment on two potential alternatives to the package of benchmarking policies we were proposing to adopt. We explained that both of the alternatives presented in section III.G.5.c.(6) would attempt to limit the impact of an ACO's own assigned beneficiaries on regional factors used in the benchmarking methodology.

Because the proposed three-way blended update factor would be used in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act, we explained that this proposal would require us to continue to use our authority under section 1899(i)(3) of the Act. That provision grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model.

In the proposed rule, we explained our belief that by combining an external, prospective factor calculated based on the USPCC, as a component in the benchmark update, the proposed ACPT/national-regional three-way blended update factor would decouple an ACO's benchmark to a certain degree from ongoing observed FFS spending which is currently reflected in ACO benchmarks under the methodology specified under § 425.601. We noted that this approach may serve to anchor and stabilize benchmarks to the extent that the ACPT projected growth component is an effective counterbalance to the savings achieved by ACOs participating in the Shared Savings Program, which reduce the update factor under the current two-way national-regional blended update, including as a result of increasing market penetration by efficient ACOs in their regional service area. The proposed guardrail would protect ACOs from larger shared losses (or potentially from the negative implications of financial monitoring) but would not allow ACOs to move to a position of sharing in savings. Additionally, the proposal that CMS would retain discretion to reweight the components of the three-way blend to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances that result in drastic differences between the ACPT and actual national per capita FFS expenditure growth for assignable beneficiaries for a given performance year, would protect against ACOs owing excessive shared losses or the Medicare Trust Funds paying out windfall shared savings. We explained our belief that this combination of additional incentives and safeguards may encourage ACOs to enter and continue participation in the Shared Savings Program.

As discussed in section III.G.5.d. of the proposed rule (87 FR 46186 through 46188), we also proposed to determine the assignable population of beneficiaries used in calculating county-level FFS expenditures, and in other factors based on the assignable population in the ACO's regional service area, using the assignment window that corresponds to the ACO's selected assignment methodology to improve the precision of the calculations. As we explained in the CY 2023 PFS proposed rule, this modification would address a favorable bias in calculations for ACOs under prospective assignment, resulting in an estimated decrease in regionally

adjusted historical benchmarks for these ACOs estimated to range from 0.2 percent–1.9 percent based on modeling using historical benchmarks for ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019 (compared to leaving the bias uncorrected). If left uncorrected, the bias could potentially grow over time as more ACOs are subject to higher weights in the calculation of the regional adjustment. The proposed change in methodology for identifying the assignable beneficiaries used in calculating factors based on regional FFS expenditures would also improve the precision of the calculation of the blended national-regional growth rates within the benchmark update.

Considering the combination of these factors, in the proposed rule we explained our belief that the changes to the methodology for updating the benchmark that we proposed pursuant to section 1899(i)(3) of the Act would improve the quality and efficiency of items and services furnished under the Medicare Program. More specifically, we noted that we believed the introduction of the prospectively set ACPT into the blended benchmark update factor would increase the incentive for ACOs to achieve savings by partially insulating ACOs from the impact of those savings on future benchmark updates. We also noted that our belief that this change would encourage ACOs to enter and remain in the Shared Savings Program, which would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs have an incentive to perform well on quality measures in order to maximize the shared savings they may receive, and in the case of ACOs participating under the ENHANCED track to minimize any shared losses owed (as described in section III.G.4. of the proposed rule). In addition, as discussed in the Regulatory Impact Analysis for the proposed rule (87 FR 46427), we projected that this proposed approach for use of an ACPT/national-regional three-way blended update factor, in combination with other proposed changes to the statutory payment model in the CY 2023 PFS proposed rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, would not increase program expenditures relative to those under the statutory payment model. We explained that we would continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We proposed that the update factor based on a three-way blend of the ACPT and blended national-regional growth rates and the associated guardrail would be applicable to agreement periods beginning on January 1, 2024, and in subsequent years. We proposed to specify the use of the three-way blend, the associated guardrail, and the discretion for CMS to adjust the weight of the ACPT in the three-way blend in the event of unforeseen circumstances in paragraph (b) of a proposed new provision at § 425.652, which would govern the process for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. We also proposed to specify within § 425.652(b) the other components of the update factor, namely the calculation of the national and regional components of the blend which would follow the same approach currently specified under § 425.601(b), although with conforming changes to reflect the use of a three-way blend. Further, we proposed to specify the calculation of the ACPT in a new provision at § 425.660.

We sought comment on the proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. We also sought comment on the specific elements of the approach, including our proposal to calculate the ACPT on a risk-adjusted flat dollar basis, to institute a guardrail to protect ACOs, and to retain discretion to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances.

The following is a summary of the public comments received in response to our proposal to incorporate a prospective, external factor in the growth rates used to update the historical benchmark and our responses:

Comment: Commenters addressing our proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, generally favored an approach that would attempt to insulate a portion of the annual update from the cost efficiencies resulting from the ACO's historical performance and thereby mitigate the ratchet effect. However, commenters offered varying perspectives on whether the proposed approach or an alternative approach would best achieve these objectives.

Many commenters generally supported an approach under which CMS would prospectively set a component of the ACO's updated historical benchmarks. Some commenters expressed support for the proposed approach to use a three-way blended update factor. One commenter explained that the proposed ACPT would positively impact the patient mix ACOs serve by offsetting regional factors that make it difficult for ACOs to achieve shared savings and serve to disincentivize ACOs from providing care to certain beneficiary populations. Commenters also explained that the approach would provide greater stability to the benchmark value and allow ACOs to better predict their benchmarks and have greater visibility into the benchmark calculation (although as discussed elsewhere within this section of this final rule, some commenters urged for increased transparency on the calculation of the ACPT). Another commenter explained that the proposed ACPT would enable ACOs to effectively operate in under-resourced communities, close gaps in health equity and address social determinants of health. Yet another commenter explained that an ACPT would help maintain fairness within the Shared Savings Program, from which both ACOs and the government benefit.

More generally, some commenters believed that use of a prospective, external factor in the benchmarking methodology would be a step toward a longer-term administrative benchmarking approach, as discussed further in section III.G.7 of this final rule. Several commenters explained that the ratchet effect, and CMS' goal of having all Medicare FFS beneficiaries in an accountable care arrangement by 2030 make the current benchmarking strategies untenable. These commenters explained that the ACPT would serve as a positive short-term step to ameliorating these issues while CMS works to refine its administrative benchmarking strategy.

Response: We appreciate the commenters' support for the proposal under which we would place one-third weight on the ACPT and two-thirds weight on the existing two-way

national-regional blend used to update the ACO's historical benchmark. We are finalizing this proposal, which we believe will address dynamics under which savings achieved by ACOs participating in the Shared Savings Program reduce the two-way national-regional blended update, including as a result of increasing market penetration by efficient ACOs in their regional service area. We believe use of the ACPT, calculated as a risk-adjusted flat dollar amount set near the start of the ACO's 5-year agreement period, will decouple an ACO's benchmark to a certain degree from ongoing observed FFS spending currently reflected in ACO benchmarks and will thereby serve to anchor and stabilize benchmarks. We continue to believe the national-regional blend, comprising two-thirds of the update factor (with the majority of the two-way blend consisting of the regional trend for most ACOs, since most ACOs have relatively low market penetration), plays an important role in the update factor by ensuring benchmarks account for expenditure growth in the ACO's regional service area.

Further, we believe that finalizing the proposed three-way blended update factor, and other changes to the Shared Savings Program benchmarking methodology and participation options (including to make AIPs available to eligible ACOs, and to smooth the transition to performance-based risk) that we are finalizing as described in sections III.G.5 and III.G.2 of this final rule (respectively), are important steps forward in advancing Medicare's value-based care strategy of growth, alignment, and equity. A key component of this strategy is to address the underlying dynamics of the current benchmarking methodology, including the existing two-way national-regional blend, and ensure there is sufficient incentive for participation among ACOs serving underserved communities, or high-cost, medically complex populations.

Comment: A few commenters urged CMS not to finalize use of a prospective, external factor in updating ACO historical benchmarks. Several commenters urged CMS to take additional time to evaluate or pilot test the potential impact of the proposed approach before fully implementing it within the Shared Savings Program.

Many commenters expressed concerns about the proposed approach and recommended modifications to the approach if CMS were to move forward with incorporating a prospective, external factor in updating historical benchmarks, or provided alternative suggestions for modifying the benchmarking methodology. Commenters' concerns tended to center on the unknown accuracy of the projected amount, the potential for mixed effects of the approach under which ACOs may receive lower benchmarks under the three-way blend compared to the existing two-way blend, and a preference among some commenters for use of regional FFS trends in benchmark calculations. Some commenters urged CMS to adopt an alternative approach to calculating regional FFS expenditures, in addition to or instead of use of a prospective, external factor in updating the ACO's historical benchmark. We summarize and respond to these commenters' concerns and suggestions elsewhere within this section of this final rule.

Response: We decline commenters' suggestions to forgo finalization of the proposed approach to incorporate a prospective, external factor in the growth rates used in updating the benchmark, and we are finalizing the proposal to apply this approach to update ACO benchmarks for agreement periods beginning on January 1, 2024, and in subsequent years. We believe the three-way blended update factor is one of several timely and appropriate changes to the Shared Savings Program's benchmarking methodology designed to ensure the availability of robust benchmarks that create sufficient incentives to encourage ACOs to enter and remain in the Shared Savings Program. We believe that finalizing the three-way blended update factor in this final rule, as part of a package of benchmark changes, is crucial to supporting the agency's goal of having all Medicare FFS beneficiaries in an accountable care arrangement by 2030. These important changes will help ensure that ACOs' past success does not limit opportunities to achieve and sustain success over time, thus strengthening participation incentives and ultimately expanding the Shared Savings Program's reach. We further believe that incorporating the ACPT into the update factor could maintain accurate benchmarks in light of rapid growth in the number of Shared Savings Program ACOs and the percentage of Medicare FFS beneficiaries assigned to ACOs. Based on modeling in the Regulatory Impact Analysis (section VII of this final rule) that showed significant expected growth in benchmark spending under the program, we project, on average, up to 4 million additional beneficiaries could be assigned to Shared Savings Program ACOs in the 10 years between 2024–2034, as a result of the changes we are finalizing to the Shared Savings Program's policies with this final rule, representing a significant increase in market penetration by ACOs. We believe the three-way blended update factor, which decouples one-third of an ACO's benchmark from ongoing observed FFS spending, will provide for a more sustainable update methodology than the two-way blend alone, particularly as market penetration by Shared Savings Program ACOs increases.

We decline to delay implementation of the ACPT as part of the three-way blended update factor, and we decline to allow for additional time to test the approach, as suggested by commenters. The timing of implementing the three-way blended update factor, among other changes to Shared Savings Program policies we are finalizing with this final rule, is consequential. ACOs entering and continuing their participation in the Shared Savings Program under 5-year agreement periods beginning in upcoming years, such as for the agreement periods spanning 2024–2028, 2025–2029, and 2026–2030, will be pivotal to ensuring Medicare FFS beneficiaries are in a care relationship with accountability for quality and total cost of care in order to meet the agency's 2030 goal.

Moreover, as described elsewhere in this section of this final rule, our proposals were informed by consideration of suggested modifications to the benchmarking methodology from ACOs and other interested parties, and by our experience with Innovation Center ACO Models. The development of our proposal to use the ACPT as part of a three-way blended update factor was informed by consideration of commenters' suggestions from earlier rulemaking, including suggestions received in response to comment solicitations on the Shared Savings Program benchmarking methodology in the CY 2022 PFS proposed rule (86 FR 65295 through 65306). The development of our proposed approach was also informed by our experience with the NGACO Model and with the Global and Professional Direct Contracting Model (to be redesigned and renamed as the ACO REACH Model beginning January 1, 2023) which uses a prospective trend calculated by OACT based on an adjusted USPCC amount. However, we anticipate evaluating and monitoring the impact of the ACPT on ACO historical benchmarks, and would address any necessary refinements to the approach through future notice and comment rulemaking.

Comment: Some commenters that expressed concerns about the proposed

approach encouraged CMS to engage with ACOs and other interested parties to further develop and evaluate the ACPT.

Response: We welcome and encourage an ongoing dialogue between CMS, ACOs and other interested parties about approaches to improving the Shared Savings Program's benchmarking methodology, including the policies we are establishing in this final rule.

Comment: The progression of the Shared Savings Program's benchmarking policies was an important backdrop for commenters' consideration of the adequacy of the proposed three-way blended update factor. A few commenters recounted the initial use of factors based on national FFS expenditures to update the benchmark, followed by use of factors based on regional FFS expenditures, and most recently the use of a factor that is a blend of national expenditure and regional expenditure components, with some commenters noting that the current two-way blended update factor does not adequately account for the influence of an ACO's savings in relation to its own benchmark or the influence of other ACOs in its region on its regional expenditures.

Commenters took opposing positions on the best approach to address concerns with the current benchmarking approach, with some favoring incorporating an external factor based on projected national cost trends and others urging CMS to maintain or increase the role of a regional component in the benchmark update. Many commenters urged CMS to put in place safeguards to mitigate the potential for negative impacts of the benchmarking methodology on ACOs. Commenters' concerns centered on the potential negative impact of the proposed three-way blend on ACOs' ability to generate shared savings and the amount of savings, as compared to the existing two-way blend, as well as concerns about whether the existing two-way blend offers sufficient incentive for ACOs to participate in the program and generate savings. A few commenters urged CMS to pace the phase-in of changes to the benchmarking methodology in a way that safeguards against negative impacts on ACOs that could create disincentives for ACOs to enter or remain in the Shared Savings Program.

Commenters opposed to increasing the relative weight of national spending growth in the benchmark update, thereby reducing the relative weight on regional spending trends, cited concerns that the proposed ACPT and three-way blend would not adequately account for geographic variation in spending growth that is outside of an ACO's control. As one commenter explained, echoing concerns raised by others, the proposed three-way blend would constitute a ''step backward'' from accounting for regional variation in ACO benchmarks.

Some commenters explained their belief that comparing an ACO to its region is a fairer and more accurate approach to assessing performance than comparing to national growth rates. Several commenters specified that regional spending trends help account for local changes or shocks to spending growth for which ACOs should not be held accountable.

Several commenters noted that because there are persistent and significant variations in regional spending trends compared to national trends, regional trends would serve as a more accurate measure of how spending would have changed absent the ACO's response to Shared Savings Program incentives. Some commenters explained that using a national trend factor would result in higher benchmarks and thereby benefit ACOs in regions with comparatively slower spending growth, and result in lower benchmarks and thereby harm ACOs in regions with comparatively faster spending growth, leading to selective participation. For example, commenters explained that efficient, low-cost providers, including ACOs, that operate in regions where spending exceeds the ACPT would be harmed by having their already low spending targets further reduced over time. Another commenter also stated more generally that such selective participation could arise as ACOs observe projection errors that reveal the ACPT to be higher relative to actual spending trends. Although perhaps indicative of an inadvertent error, we note that several commenters also suggested (to the contrary), that if an ACO is in a region where spending growth falls below that of the USPCC, it would receive smaller update factors under CMS's proposed use of the ACPT. Some of these commenters cited their own analyses to support this notion that regional trends vary substantially and are persistent over time. One commenter expressed concern that ACOs with higher market penetration may tend to have faster regional growth rates and thus receive lower benchmarks under the three-way blend compared to the current two-way blend, and ACOs under these circumstances may be hesitant to enter the Shared Savings Program.

Given the aforementioned concerns, commenters requested various modifications to the proposed approach to incorporating an externally set prospective trend, or suggested CMS use alternative approaches to update the historical benchmark, including the following.

- Several commenters suggested keeping the current two-way blend weighting approach and substituting the historical national spending trend component with the proposed ACPT. For example, one commenter cited their belief that spending growth rates vary substantially and systematically across geographic areas and expressed concern that adding the ACPT would effectively reduce the weight given to regional spending growth in the annual benchmark updates. The commenter provided an analysis of risk-adjusted spending trend variations at the CBSA and county levels from 2015 through 2020 to support these conclusions. Their results suggested that the variation in the difference between county and national cumulative growth rates increases as the performance year grows farther from the baseline year, and they concluded from these and related findings that ACOs in some regions would experience sustained differences in annual expenditure growth from the national average growth rate. The commenter stated that basing the ACPT on the national trend and reducing the weight on the regional trend would then create winners and losers solely based on geography and create greater incentives for selective participation and provider consolidation.
- Several commenters suggested that the ACPT project regional rather than national spending growth.
- One commenter suggested CMS consider additional adjustments to mitigate the impact of regional spending variation in the three-way blend, for example by using case mix and geographic adjustments, but did not specify what these approaches could entail.
- A few commenters expressed their preference for use of only regional spending trends in benchmarking instead of either the current two-way blend or the proposed three-way blend.

Response: One common thread throughout many commenters' concerns was that observed regional spending trends are persistent over time and vary substantially across geographic regions, and so reducing the relative weight assigned to regional spending trends in the proposed three-way blend might disadvantage ACOs in areas with a faster spending growth rate compared with the current two-way blend.

To assess commenters' concerns, CMS analyzed whether ACO regional service

area per capita spending growth rates were predictably above or below national spending growth over an extended historical period. The analysis used FFS per capita spending published by CMS over the 2007 to 2016 time series broken down by Hospital Referral Region (HRR) geographic level.[332] HRRs provide a reasonable approximation of how counties can be weighted together to produce various ACO service areas. Comparing individual HRR excess growth in per capita spending relative to the national average for a base period covering 2007 to 2010 compared to a quasi-performance period of 2011 to 2016 indicated that about 47 percent of HRRs flipped from positive excess growth in the first period to negative excess growth in the second period or vice-versa. Among the 53 percent of HRRs that remained above or below national average growth in both periods the cause was likely related to relative spending at baseline. For 173 HRRs with positive excess relative growth in both periods the average starting per capita spending level was on average 13 percent below the national average, whereas for the 133 HRRs with below-national average growth in both periods the average starting per capita spending level was on average 7 percent above the national average. For comparison, the average starting per capita spending level was on average only 3 percent below the national average for the 47 percent of ACOs that flipped from one side of national growth to the other across the two periods. By utilizing a risk-adjusted flat-dollar method, the ACPT contribution to the three-way update is therefore expected to be reasonably equitable by providing a higher relative update for ACOs with (or in regions with) low spending at baseline (the type of HRR that tended to show excess growth historically). Modifying the analysis above using risk-adjusted absolute growth in per capita expenditures confirmed that the average starting per capita spending levels converged to within 4 percentage points for all three categories of HRRs described above (that is, HRRs that stayed higher than average growth over both periods, HRRs that remained below-average growth over both periods, and all remaining HRRs that flipped from one side of national average growth to the other from the first period to the next). Furthermore, the correlation in HRRs' average excess growth between the 2 multi-year periods (after employing risk adjustment and using absolute growth) was 0.18 when including all HRRs and only 0.05 after excluding three outliers with very high starting spending levels (McAllen and Harlingen, both in Texas, and Miami, Florida), effectively implying no relationship between an HRR's excess trend in the first period to the second. Importantly the use of the ACPT in a three-way blended update factor will also provide an update component that will be protected from ratcheting downward as the Shared Savings Program is expected to grow and protected from ACOs' impacting spending at the regional and national levels.

Over a 5-year agreement period, we recognize some ACOs may be disadvantaged or advantaged in the short term by benchmark updates that give greater weight to a national update factor. However, we believe that the net impact of these deviations will be modest in the context of offsetting considerations, for example: the three-way blend only incorporates the ACPT at a one-third weight and maintains the current two-way blend for the majority weight of the benchmark trend calculation, allowing for a significant proportion of the benchmark update to reflect expenditure growth in an ACO's regional service area, particularly as many ACOs have a relatively small amount of penetration within their market; the ACPT itself is expected to project spending above realized spending as ACOs generate savings, thereby providing a stable, predictable component of the update factor that will be beneficial for ACOs; a guardrail will protect ACOs from experiencing additional shared losses due to the three-way blend; and positive regional adjustments will continue to provide a benchmarking advantage for more efficient ACOs. Further, in light of these offsetting factors, we also believe that overall the benefits of use of the ACPT in updating the benchmark, for attracting and retaining ACOs in the Shared Savings Program and in turn savings potential, outweigh the potential negative impact on some ACOs' update amount as a result of this approach. We appreciate commenters' concerns about potential detrimental effects of this policy and will monitor how the three-way blend affects ACOs' benchmarks as it is implemented, and would address the need for any potential modifications to the approach through future notice and comment rulemaking.

We decline to adopt commenters' suggestions to maintain the current two-way blend and replace the current national component with the proposed ACPT, or to use only regional trends to calculate ACO benchmarks. We continue to believe that the existing two-way national-regional blend serves an important role in reducing the influence of the ACO's assigned beneficiaries on the benchmark update, and serves as an alternative to removing the ACO's assigned beneficiaries from the assignable population,[333] which we believe is an untenable solution. (Refer to section III.G.5.c.(6) of this final rule for additional discussion of the alternative option under which the ACO's assigned beneficiaries would be removed from the assignable population used to calculate regional FFS expenditures.)

Continued use of the two-way blend as a component of the three-way blended update factor maintains a degree of symmetry with the two-way blend used to trend forward expenditures for BY1 and BY2 to BY3 in establishing the ACO's historical benchmark. Furthermore, maintaining the current national-regional two-way blend remains an important safeguard during this initial introduction of the ACPT as part of the three-way blend. We will utilize the current two-way blend as the basis for the ACO's update factor as part of the guardrail to protect ACOs against higher financial risk under the three-way blend, and it is also integral to our approach to addressing unforeseen circumstances that impact the accuracy of the ACPT, by reducing the weight on the ACPT within the three-way blend and increasing the weight on the two-way blend. However, CMS will continue to monitor the application of the ACPT in benchmark updates and in the future may explore potential modifications to how the external projected growth rate is incorporated. Any such modifications would be made through notice and comment rulemaking.

We decline to adopt commenters' various suggestions to have the ACPT project regional instead of national trends. Calculating ACO region-specific ACPTs would require projecting spending growth at the county level, based on our current approach to defining an ACO's regional service area according to § 425.20, which is infeasible because assumptions for multi-year spending growth are made on a population level (that is, on a national

[332] Data, Medicare Geographic Variation—by National, State & County, downloaded from *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-geographic-comparisons/medicare-geographic-variation-by-national-state-county*.

[333] For example, in establishing this approach we explained that it could serve as an alternative option to excluding an ACO's own assigned beneficiaries from the population used to compute regional expenditures. See for example, 83 FR 68024.

basis, Medicare-wide) and not on a geographic basis.

We also decline at this time to adopt the commenter's suggestion that we make geographic adjustments to the ACPT because we believe the commenters' concerns are at least partly mitigated by the three-way blend maintaining the existing two-way blend, which incorporates regional trends. However, we note that in the request for information on administratively set benchmarks in section III.G.7 of the CY 2023 PFS proposed rule, we discussed our consideration of an approach under which we would incorporate adjustments into the ACPT to account for changes in relative price levels across counties.

Regarding the commenter's suggestion that we apply case mix adjustments to the ACPT, we note that the approach we proposed, and are finalizing, to calculate the ACPT as a risk-adjusted flat dollar amount will account for differences in severity and case mix between the ACO's assigned beneficiaries and the national assignable FFS population for each Medicare enrollment type. As we explained in the CY 2023 PFS proposed rule, risk adjusting the flat dollar amount will provide higher flat dollar amounts for ACOs serving medically complex populations.

Comment: Some commenters addressed more specifically the potential role of the proposed three-way blend in addressing concerns about ratchet effects on benchmark update factors resulting from high ACO market penetration.

Some commenters expressed their belief that the proposed three-way blended update factor was an incomplete solution to addressing the impact of ACO market penetration on historical benchmark expenditures, and suggested that CMS address these impacts by making additional adjustments to Shared Savings Program's benchmarking methodology. Some commenters, mostly commenters that also expressed a preference for use of regional spending trends in benchmarking, suggested removing ACOs' assigned beneficiaries from regional FFS expenditures used in calculating benchmarks. Commenters varied in whether they suggested these changes in addition to or instead of the proposed three-way blended update factor, or in addition to suggested alternative approaches. A few commenters also suggested that CMS use a broader geographic region to determine regional FFS expenditures as part of alternative suggestions, which included maintaining the existing national-regional blended update factor instead of implementing the proposed three-way blend. We refer readers to section III.G.5.c.(6) of this final rule, where we summarize and respond to comments on related alternatives. Further, some commenters believed the three-way blend would provide an inadequate solution when savings generated by ACOs with higher market shares subsequently ratchet down these ACOs' regional benchmarks.

Several commenters indicated there may not be an urgent need for the proposed three-way blend, for example pointing to ACO market share being at or below 40 percent of the national FFS population and that few ACOs are heavily penetrated in their regional service area. Another commenter made a more general statement that using a prospective trend factor dilutes the impact of ACO market share on the benchmark but fails to address the root cause of the ratchet effect and is therefore an inadequate solution. A few of these commenters pointed to these factors as reasons for CMS to delay implementation of the three-way blend within the Shared Savings Program, or to consider alternative approaches to address the underlying issue.

Response: While we agree with commenters that many ACOs have relatively small penetration in their regional market area, we disagree that this would be a reason to forestall addressing ratchet effects within the Shared Savings Program's benchmarking methodology through use of the three-way blended update factor. As discussed elsewhere within section III.G.5 of this final rule, ACOs and other interested parties have continued to raise concerns about benchmarking dynamics under which ACOs compete against themselves as their spending reductions are reflected in the regional spending trends that determine a portion of their benchmarks. Additionally, even in areas where a single ACO may represent a small portion of the assignable beneficiaries in its regional service area, the collective effects of other ACOs within the regional service area may also influence regional trends. We believe the use of the three-way blended update factor is an important step towards a more sustainable benchmarking methodology that offers sufficient incentives to encourage entry into and continued participation by ACOs in the Shared Savings Program, accounting for variation in ACOs' market share and the level of penetration of the ACOs collectively within a region. Furthermore, we anticipate participation in the Shared Savings Program will grow as CMS makes strides towards its goal of having all Medicare FFS beneficiaries in an accountable care arrangement by 2030.

Comment: A few commenters addressed the potential impact of the benchmarking policies on health care market dynamics. One commenter generally suggested that regional benchmarks help drive competition within regions. Several commenters indicated that emphasizing national spending trends in a three-way blended update factor would create a stronger incentive for ACOs to consolidate within regional markets as ACOs seek greater influence on their region's spending to help them remain under the national trend. The commenters indicated that these incentives exist because ACOs that have higher market penetration would face benchmarks where national spending trends, observed and projected, account for more than a one-third weight. Another commenter explained that the proposed three-way blended update factor could create a significant financial disincentive for independent practices and physicians in certain regions to move into and stay in the Shared Savings Program. This commenter urged CMS not to finalize the proposal, but instead to work with stakeholders to assess benchmarking changes that would better achieve CMS' goals and be more equitably applied.

Response: We are not persuaded by commenters' concerns that the use of an ACPT within a three-way blended update factor could create consolidation incentives within regional markets. As we have described in earlier rulemaking (see for example, 83 FR 68049), overall payment reform has been associated with little acceleration in consolidation of health care providers that surpasses trends already underway, although there is some evidence of potential defensive consolidation in response to new payment models.[334] Anecdotally, ACOs provide physician practices with a way to stay independent and offer a viable alternative to merging with a hospital.[335] We believe the three-way blend would likely do little to substantially increase any existing incentives for provider consolidation as

[334] See, for example, Neprash HT, Chernew ME & McWilliams JM. Little Evidence Exists to Support the Expectation That Providers Will Consolidate to Enter New Payment Models. Health Affairs. 2017; 36(2): 346–354. doi:10.1377/hlthaff.2016.0840. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0840.*

[335] See for example, Mostashari, F. The Paradox of Size: How Small, Independent Practices Can Thrive in Value-Based Care. Ann Fam Med. 2016; 14(1):5–7. doi:10.1370/afm.1899. Available at *https://www.annfammed.org/content/14/1/5.long.*

compared to the two-way blended update factor. To the contrary, we believe the changes to the Shared Savings Program's participation options and financial methodology we are finalizing with this final rule have the potential to attract and retain ACOs that vary in their composition of providers/suppliers, their efficiency relative to their region, their experience with accountable care initiatives, and in the needs of the populations they serve. In particular, participation by new, low revenue ACOs may be fostered by the availability of advance investment payments to eligible ACOs (discussed in section III.G.2.a of this final rule), a smoother transition to two-sided risk (discussed in section III.G.2.b of this final rule), and the increased opportunities for low revenue ACOs participating in the BASIC track to earn shared savings (discussed in section III.G.5.f of this final rule). Additionally, combining with another ACO or adding new providers/suppliers to the ACO will not necessarily increase an ACO's market share in a localized geographic area, as these actions may actually grow the ACO's defined regional service area. Lastly, the one-third weighting given to the ACPT may reduce incentives for ACOs to consolidate compared to the current two-way blend because consolidation would have limited to no impacts on an external, national prospectively set update factor.

Comment: One commenter explained its belief that the proposed fixed weight of one-third applied to the ACPT component of the three-way blended update factor is not appropriate when there are great variations in expenditures between counties that ACOs serve and in the level of an ACO's market penetration in its respective region. This commenter instead suggested that CMS consider applying a ''dynamic'' weight for the ACPT, such as the approach used to calculate the weights within the national-regional blended growth rate, or another, statistically sound formula.

Response: We decline at this time to adopt the commenter's suggestion to adjust the weight given to the ACPT component of the three-way blend based on each ACO's level of market penetration, as is done for the national component of the current two-way blend. As we discuss elsewhere in this section of this final rule, a key aim of incorporating a prospectively projected growth factor into the annual benchmark update is to provide ACOs with a degree of certainty regarding these updates for the duration of their agreement period, while simultaneously insulating a portion of the benchmark update from the impact of any savings achieved by ACOs participating in the Shared Savings Program. The ''dynamic'' weight suggested by the commenter would reduce the level of certainty the ACPT would provide to ACOs because the weight applied to that portion of the three-way blend could fluctuate on an annual basis, and ACOs would not find out the final weight applied to a given performance year until several months after that performance year ended. Additionally, we continue to believe that a variable weight similar to what is applied in the current two-way blend is not necessary for the ACPT portion of the three-way blend because the growth factor used for the ACPT is projected at the beginning of the agreement period and would not be impacted by an ACO's performance, unlike impacts that could occur on the regional portion of the two-way blend for ACOs with high market penetration. CMS will continue to monitor the three-way blend and may explore potential modifications in the future to how the external projected growth rate is incorporated. Any such modifications would be made through notice and comment rulemaking.

Comment: MedPAC was generally supportive of the proposed three-way blend but had reservations about the potential for USPCC projections to overestimate growth in national per capita spending, which MedPAC explained could result in benchmarks that fail to adequately incentivize ACOs to provide care efficiently and lead to shared savings payments that are larger than warranted. MedPAC suggested that the benchmark growth rate should be lower than the USPCC. MedPAC noted another concern with basing part of the benchmark growth rate on USPCC is that the spending measure includes several types of spending that are not under the control of ACOs and should not be included in benchmark growth rates, such as IME and DSH payments. Further, MedPAC recommended excluding shared savings payments and other value-based payments made to ACOs or providers from the ACPT. MedPAC explained that including those payments in the benchmark growth rate would act to increase benchmarks by essentially ''double counting'' those savings, which would result in less pressure on ACOs to reduce spending growth. According to MedPAC, not only would this undermine the goals of the Shared Savings Program, but the higher spending in FFS would carry through to Medicare Advantage benchmarks, resulting in less pressure on private plans to bring down spending growth in that part of the Medicare program.

Another commenter raised concerns that the three-way blend would not allow benchmarks to increase beyond actual spending growth rates if the ACPT takes into account expected spending reductions from ACOs over the projection period. Instead of implementing the three-way blend, the commenter suggested that CMS broaden the geographic regions used to compute the regional component of the existing national-regional blend and consider increasing that growth rate by a fixed percentage-point amount (such as 0.25 percentage points).

Response: We appreciate the commenters' concerns regarding the incorporation of expected savings from ACO participation in calculating the ACPT. The FFS USPCCs, long-running annual projections, are highly analogous to the ACPT. To the extent that ACO participation in the Shared Savings Program has impacted spending in the past, these net savings are implicitly incorporated into the baseline claims data used to generate Medicare spending projections for purposes of the USPCC on a net basis (after accounting for additional outlays such as shared savings payments). This is because, unlike the current two-way blend that measures growth in claims-based spending alone, the USPCC is (and the ACPT in the future will be) sourced from Medicare spending (and expected growth in spending) encompassing total FFS Medicare outlays which include non-claims-based payments such as shared savings payments. As the MedPAC comment letter pointed out, Medicare spending projections tended to be higher than actual growth over the period since the Shared Savings Program was first implemented, a track record suggesting that future ACPT projections are unlikely to be specifically biased against ACOs if they did not show evidence of such bias during the period the program was initially ramped up. To the extent that OACT identifies a need for a direct adjustment to the USPCC for net Shared Savings Program savings, we would revisit the calculation of the ACPT and such potential adjustment in future notice and comment rulemaking.

Comment: A few commenters suggested that CMS protect ACOs from potential forecasting deviations that might arise with the ACPT due specifically to high-cost technological, therapeutic or pharmaceutical advancements over the course of an agreement period.

Response: Medicare USPCC spending projections explicitly account for known

new technologies, for example when coverage determinations are announced for treatments undergoing clinical trials. In the longer run projections that are necessary for creating the ACPT (which includes five performance years) there is generally an assumption made for a component of trend related to new technologies that are not yet known.[336] This assumption may be informed by the average impact of such activity over the historical period prior to the creation of the projection. To the extent that specific high-cost therapeutics are introduced during an agreement period but after the ACPT was established, the generic assumption for growth in new technologies would in theory account for associated new spending. In addition, as described elsewhere in this section of this final rule, we believe that the proposed guardrail protecting ACOs from incurring additional shared losses under the three-way blend and the proposal to reduce the weight of the ACPT component of the three-way blend if projections diverge from actual expenditure growth due to unforeseen circumstances will effectively mitigate any remaining concerns about projection error impacting the benchmark updates, including as a result of spending for new technologies or high-cost therapeutics that go beyond the projection assumptions.

Comment: One commenter asked whether the financial impacts of the COVID–19 pandemic would be reflected in the ACPT for 2019 and beyond.

Response: The first ACPT release will be published in 2024 for agreement periods beginning on January 1, 2024, and will provide a projected annualized growth rate (or rates) relative to the 2023 benchmark year, which will be BY3 for agreement periods starting in 2024. To the extent that Medicare projections made at that time anticipate lingering effects from the COVID–19 pandemic then they would be reflected in the ACPT as well.

Comment: One commenter questioned whether the inputs into the ACPT consider the rapid increase in Medicare Advantage enrollment.

Response: The ACPT will reflect any expected changes in the average demographics of the Medicare FFS population, which would include the effect of any growth that may be expected in the overall proportion of beneficiaries electing enrollment in Medicare Advantage.

Comment: Some commenters expressed concerns about the accuracy of the ACPT, particularly over the proposed 5-year timeframe. A few commenters suggested that CMS initially use a shorter projection window to gain experience with the three-way blend, such as a 1-year, 2-year or 3-year projection. Commenters cited a number of reasons for updating the prospective calculation more frequently than every 5 years.

Some commenters referenced the significant impact of the COVID–19 pandemic on healthcare utilization and how patients interact with the healthcare system, and indicated it may be challenging to accurately project trends over the next several years. Most of these commenters encouraged CMS to evaluate the impacts of the pandemic on healthcare spending and service utilization and work with ACOs and other interested parties to develop a methodology that sufficiently addresses these concerns. These commenters tended to suggest CMS initially use a short-term trend of 1 to 2 years rather than 5 years to allow CMS time to evaluate and to refine its methodology without locking ACOs into a 5-year trend factor, which several commenters indicated may significantly under- or overpredict spending growth and changes in utilization over the agreement period. Several of these commenters suggested that CMS could consider gradually lengthening the amount of time over which the trend factor is applied as it refines its methodology.

Commenters offered a variety of other reasons for suggesting use of a projection window of less than 5 years. One commenter recommended that CMS update the ACPT annually, similar to the methodology used in the ACO REACH Model. Another commenter recommended that CMS start with a 3-year projection because that is the evidence base for the USPCC. One commenter noted that a 5-year projection period is unprecedentedly long for a prospective trend in the insurance industry. Another commenter expressed concern that the projection may be less accurate in the later years of a 5-year agreement period, and it may make sense for CMS to review the projection annually to adjust for unforeseen changes.

One commenter recommended that the proposed ACPT be piloted before use and prospectively set for 1 year rather than 5, with only positive retrospective adjustments to account for clinical developments such as broad coverage of a new high-cost drug.

More generally, one commenter explained that health care spending trends are affected by many factors that are outside of ACOs' control and hard to predict in advance, including: the emergence of new medical technologies and practice patterns; changes in population health, such as those due to changes in health behaviors or the emergence of new diseases; and macroeconomic developments, which may, for example, affect trends in provider input costs and thus Medicare's payment updates.

Response: As we described in section III.G.5.c.(3) of the proposed rule (87 FR 46163), we selected a 5-year projection horizon to align with the 5-year agreement periods used under the Shared Savings Program. The ACPT factors would remain unchanged throughout the ACO's agreement period in order to provide ACOs with a degree of certainty surrounding a portion of their benchmark updates, while simultaneously insulating a portion of the benchmark update from any potential impacts of their own savings. Updating the projections over the course of the agreement period or using shorter projection windows would remove the benefit of certainty. Indeed, many commenters expressed appreciation that the approach would provide greater stability to the benchmark value and allow ACOs to better predict their benchmarks and have greater visibility into the benchmark calculation.

We disagree with the commenters' suggestion that a 5-year projection window is unprecedented, as OACT routinely projects expenditures for this length of time (and longer) as part of the Medicare Trustees Report. We also note the USPCCs announced in the first quarter of a given year include projections for a total of 4 years (including the year of the announcement), not 3 years.

We recognize that some commenters prefer shorter projection windows because they have concerns about the potential inaccuracies of a longer projection due to the possibility of unforeseen events, such as was experienced with the COVID–19 PHE. We agree with commenters that the COVID–19 PHE has had important implications for utilization patterns and costs of care for Medicare beneficiaries. In the March 31, 2020 COVID–19 IFC (85 FR 19267 and 19268) and the May 8, 2020 COVID–19 IFC (85 FR 27573 through 27587) we adopted several

[336] For example, 2022 Medicare Trustees Report describes new technology contributing to hospital case mix growth in the 10-year projections on page 122 and contributing to the volume and intensity growth assumption for the long-range projections on page 169. The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'', available at *https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf*.

modifications to policies under the Shared Savings Program in response to the PHE, including excluding all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19 from certain Shared Savings Program calculations (for more information about the program changes in response to the COVID–19 PHE, refer to 87 FR 46198 and 46199). We note that we have proposed to first implement the ACPT and the three-way blend for agreement periods beginning in 2024, which would potentially allow for post-pandemic trends to inform the projections.

We also acknowledge and appreciate commenters' concerns that emergence of new, high-cost technologies can be difficult to predict. As we have discussed elsewhere in this section, Medicare spending projections explicitly account for known new technologies, such as when coverage determinations are announced for treatments undergoing clinical trials. Similarly, in the longer run Medicare spending projections that are necessary for creating the ACPT (which includes 5 performance years) there is generally an assumption made for a component of trend related to new technologies that are not yet known.

In addition, we believe that the proposed guardrail protecting ACOs from incurring additional shared losses under the three-way blend and the proposal to reduce the weight of the ACPT component of the three-way blend if projections diverge from actual expenditure growth due to unforeseen circumstances will effectively mitigate the commenters' concerns about projection error impacting the benchmark updates. Given these considerations, we are finalizing the 5-year projection window as proposed. However, we will continue to monitor the degree to which national expenditures differ from the projections following each performance year over the course of a 5-year projection window to determine whether any changes to the ACPT and the three-way blend are needed. Any such changes would be made through notice and comment rulemaking.

Comment: Of the commenters that addressed the proposal to express the ACPT as a flat dollar amount rather than on a relative basis, one commenter supported the proposed flat dollar approach. One commenter opposed the flat dollar approach to incorporating the ACPT into the three-way blend because it would not take into account regional differences in Medicare prices and spending, citing concerns that the approach would disadvantage ACOs in regions with higher costs and disincentivize participation in those areas.

Another commenter suggested that the projected national growth rates be used directly in the three-way blend rather than the proposed flat dollar amount, arguing that ACOs with high cost populations (such as a higher percentage of dually eligible beneficiaries) would be unfairly disadvantaged by the three-way blend. The commenter pointed to concerns that the proposed methodology under which CMS would divide the risk-adjusted flat dollar amounts by the ACO's historical benchmark expenditures for that enrollment type to express the flat dollar amount as a relative factor that can be combined with the current two-way blend to compute the three-way blended update would cause the risk-adjusted flat dollar amount to be divided by a disproportionately higher dollar amount for such ACOs, resulting in a lower final ACPT rates. To remedy these concerns, the commenter suggested alternative approaches that would all incorporate the ACPT on a relative rather than flat-dollar basis. Under the commenter's suggested approaches, the projected update would be similar for ACOs with otherwise higher or lower baseline spending.

Response: We appreciate the commenter's suggestions for alternative approaches to incorporating the ACPT into the three-way blend. In the proposed rule (87 FR 46164), we described retrospective modeling we had conducted to examine whether the ACPT should be included in the three-way blend on a relative or flat dollar basis. We found that the risk-adjusted flat dollar amount, on average, resulted in the most favorable benchmark update across ACOs because it was calculated using national per capita expenditures for the assignable population, which typically exceeds per capita expenditures for an ACO's own assigned beneficiaries. In contrast, the alternative options proposed by the commenter would result in a relatively smaller growth rate, on average, being incorporated into the three-way blend, which would lead to smaller benchmark increases on average across ACOs.

We disagree with the commenter's suggestion that ACOs with higher costs would necessarily receive a lower benchmark update under the flat-dollar approach. As proposed, the flat dollar amount used in the one-third ACPT portion of the three-way blend would be risk adjusted to account for differences in severity and case-mix of beneficiaries assigned to each ACO, and the other two-thirds of the three-way blend would still be a percentage reflecting the two-way blend of the national and regional update factors that would tend (all other things equal) to benefit high spending groups.

Comment: Many commenters requested that CMS implement a guardrail to protect ACOs from reductions in shared savings in addition to the proposed guardrail to protect against increases in shared losses under the three-way blend compared to the two-way blended update factor. (Herein, for ease of reference, we refer to such an approach as a ''two-sided guardrail.'') Commenters believed it would be necessary to protect ACOs from reductions in shared savings under the three-way blend for a number of reasons.

Several commenters emphasized the importance of shared savings as a source of revenue for ACOs, which (for instance) ACOs use to reinvest and sustain important initiatives. One commenter explained that given the significant investments that ACOs make in staffing, care coordination, infrastructure, and new workflows, it is not sufficient to have the guardrail simply protect against shared losses when an ACO would have earned shared savings under the current update methodology. One commenter specified that ACOs may be hesitant to invest in new initiatives or expand existing initiatives under a benchmark update approach where an ACO is ineligible for shared savings that it would have otherwise received under the two-way blend.

Some commenters noted it would be necessary to guard against reduced shared savings, as well as greater shared losses resulting from downward effects on the benchmark through use of the three-way blend in cases where the ACPT differs from observed national or regional trends. For example, some commenters indicated that a two-sided guardrail would ensure that ACOs are not penalized by unforeseen results or unintended consequences from use of the ACPT under the three-way blend. A few commenters explained that a two-sided guardrail would help to avoid penalizing ACOs in regions with high spending growth with lower benchmarks, since high regional growth rates can be caused by a host of local market factors (for example, opening of new tertiary services) beyond an ACO's control.

Some commenters pointed to the need to ensure no ACOs are negatively impacted by the use of a three-way blend in light of unknowns about the accuracy of a 5-year prospective trend. More specifically, a few commenters indicated that a two-sided guardrail

would be needed until CMS and the ACO community are confident that the ACPT and the three-way blend is the most appropriate way to update the benchmark. One commenter suggested implementing a two-sided guardrail for at least the first agreement period under the new policy. One commenter, expressing concern that ACOs with high-cost populations (such as a higher percentage of dually eligible beneficiaries) would be disadvantaged under the ACPT calculation as proposed, urged that CMS protect ACOs against receiving lower benchmarks by updating the benchmark using the higher of the proposed three-way blend or the current two-way blend.

Commenters recommended that CMS allow ACOs to, either automatically or by choice, receive the higher of the two benchmarks calculated under the current two-way blend and the proposed three-way blend, enabling them to avoid both additional shared losses and any lost shared savings they might observe under the proposed changes. Several commenters indicated there would be minimal additional burden placed on CMS under such an approach because CMS would already calculate the two-way trend as a component of the three-way trend.

Response: We appreciate commenters' support for the proposal to establish a guardrail on shared losses. We continue to believe this approach is necessary to safeguard ACOs from incurring additional shared losses purely as a result of the transition to the three-way blend, and we are finalizing this guardrail as proposed.

We decline commenters' suggestions to provide ACOs with the higher of the three-way blended update factor or the two-way national-regional blended update factor, to allow ACOs to maximize savings under their benchmark. We believe that such a two-sided guardrail would create multiple opportunities for individual ACOs to earn additional shared savings payments, rewarding ACOs in circumstances when they may not have improved care or efficiency, which would inflate shared savings payments from the Trust Funds when ACPT projection error favors ACOs. Because a two-sided guardrail would increase total shared savings payments for ACOs participating in the Shared Savings Program without corresponding reductions in spending, including one would jeopardize CMS' ability to satisfy the requirements of section 1899(i)(3) of the Act for use of other payment models. We also decline commenters' suggestion to allow ACOs to choose between the two-way or three-way blend. While we acknowledge commenters' point that both the two-way and three-way blend must be calculated as part of determining the three-way blend, we are concerned that allowing ACOs such a choice could result in increased shared savings payments based on selective participation under more generous benchmarks rather than from ACOs redesigning their care processes to lead to improved care for their assigned beneficiaries and lower growth in expenditures.

Comment: A few commenters recommended limiting the degree to which the benchmark increase could be impacted by the transition to the three-way blend from the current two-way blend. Specifically, one commenter indicated that a two-sided guardrail would defeat the purpose of the proposed methodology, and that a different alternative approach was needed to account for variation between regional and national trends beyond the ACO's influence under the three-way blended update factor. The commenter suggested using the two-way blended update factor if the three-way blend deviated from the two-way blend by more than 20 percent of an ACO's savings rate. Several other commenters made a more general suggestion to establish a maximum downward adjustment to ACO benchmarks due to switch to the three-way blend.

Response: We appreciate commenters' concerns that ACOs benchmark updates may be adversely impacted by the transition to the three-way blend. However, we believe that when taken together, the policies already included in the proposal for the ACPT and the three-way blend described in the proposed rule, which we are finalizing as proposed, offer sufficient protection against significant impacts arising from the shift to a three-way blended update factor. As discussed, the ACPT accounts for one-third of the three-way blend. A majority of the blend will continue to be based on actual expenditure growth, and CMS will have discretion to reduce the weight given to the ACPT if unforeseen circumstances cause the national growth to deviate substantially from the projected growth rates. A guardrail will also protect ACOs from incurring additional shared losses as a result of the use of the three-way blend. We believe these policies, when paired with the changes to the regional adjustment and the addition of a prior savings adjustment, as described elsewhere in this final rule, will offer ACOs sufficient protection against any negative impacts to their benchmark updates associated with the transition to the three-way blend.

Comment: Commenters generally supported including a framework to adjust the ACPT in the event of unforeseen circumstances that cause growth rates to diverge substantially from projected trends. However, several commenters suggested that CMS define what constitutes an ''unforeseen circumstance'' and what situation might require notice and comment rulemaking to adjust the weight of the ACPT in the three-way blend. Some commenters pointed to potential uncertainty for ACOs regarding when an adjustment for unforeseen circumstances might occur, as well as the potential magnitude of such an adjustment. Another commenter explained that CMS would likely face considerable resistance from ACOs if it attempted to reduce the weight on an overly generous ACPT after the fact. However, the commenter further noted that if CMS failed to reduce that weight, the fiscal cost of this proposal would remain large.

More generally, one commenter encouraged CMS to have a mechanism in place to adjust the ACPT growth rate projections when the actual growth rate differs from the projections, but did not specify whether this was in reference to the proposed approach to adjusting the weight placed on the ACPT as a result of unforeseen circumstances, or another approach. Several commenters encouraged CMS not to retrospectively adjust the ACPT downwards.

Response: We are finalizing our proposal that CMS would retain discretion to determine whether an unforeseen circumstance exists that warrants a reduction to the weight of the that would apply to the ACPT in the three-way blend. In the proposed rule, we acknowledged that a variety of circumstances could cause actual expenditure trends to significantly deviate from projections made at the start of the agreement period, which could result in an update factor that significantly differs from actual expenditure trends, and in turn result in ACOs owing excessive shared losses or the Medicare Trust Funds paying out windfall shared savings. As discussed in the CY 2023 PFS proposed rule, we anticipate that the types of events that could result in the need for CMS to exercise its discretion to reduce the weight placed on the ACPT could include an economic recession, pandemic, or other factors. We believe that it is important to maintain a degree of flexibility to best respond to the unforeseen circumstances as they may arise. Therefore, we decline at this time to adopt commenters' suggestions to

codify specific criteria for determining when an unforeseen circumstance occurs, such as through establishing a definition for unforeseen circumstances.

However, we clarify that we anticipate determining whether an unforeseen circumstance warrants adjustment of the weight placed on the ACPT component of the three-way blend by considering whether it has a material impact across the entire Shared Savings Program. In reducing weight on an overly generous ACPT, we appreciate the need, as reflected in the commenter's concern, to balance the interests of ACOs and protecting the Trust Funds from related costs. We may consider whether it would be appropriate to develop a materiality threshold to provide further clarity for ACOs and CMS of the magnitude of the change that would warrant reduction of the weight placed on the ACPT, and may revisit this issue in future notice and comment rulemaking.

In response to commenters' concerns that we may adjust the amount of the ACPT downward during an ACO's agreement period, we note that we are finalizing our proposal to establish the ACPT at the outset of an agreement period, based on one or more annualized growth rates. Under this approach we would not adjust the ACPT projections over the course of the agreement period. Rather, we would only reduce the weight that would be given to the ACPT in the three-way blend when necessary to mitigate unforeseen circumstances.

Comment: Some commenters urged CMS to provide transparency into the calculation of the ACPT. One commenter encouraged CMS to provide ACOs with guidance and education about the new benchmarking approach before implementing it in 2024. Another commenter explained that there are many unknowns with the prospective trend proposal that potentially impact ACO financial stability and predictability. To help mitigate unforeseen impacts of this new blend, the commenter requested that CMS provide greater detail and transparency regarding the national, regional, and ACPT calculations, as well as the definition of region. One commenter requested that CMS provide additional details of modeling or other analyses of the ACPT and three-way blended update factor.

Response: We will consider these suggestions as we develop future education and outreach plans. We anticipate including the amount of the ACPT for an ACO's agreement period in the ACO's final historical benchmark report, which is made available to ACOs approximately 6 months into the first performance year of the ACO's agreement period. We note this is a somewhat more protracted timeline than we originally anticipated for publicizing the final ACPT value, as described in the CY 2023 PFS proposed rule. However, this will allow time for three months of claims run-out and for final HCC risk scores for benchmark year 3 and other inputs needed for ACPT production to be available. We also anticipate updating the Shared Savings Program's publicly available specifications documents, programmatic resources and materials, and the aggregate reports provided to ACOs to include information about how we calculate and apply the ACPT.

Comment: Commenters suggested alternatives to the proposed implementation timeline for transitioning to the use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. Some commenters recommended that CMS allow currently participating ACOs, including ACOs entering an agreement period beginning on January 1, 2023, to elect for the three-way blended update factor to apply beginning in PY 2024, so that the ACOs do not have to enter a new agreement period for the revised approach to apply. Several commenters noted that 2023 starters that complete a 5-year agreement period and renew to continue their participation in the Shared Savings Program would not be under the revised benchmark update methodology until 2028. A few commenters expressed concern that ACOs interested in entering the Shared Savings Program for a 2023 start date may look to defer their entry to 2024 in order to benefit from these policies. One commenter, suggesting ACOs be allowed to opt in to use of the three-way blend, recommended that CMS provide ACOs with the ACPT prior to the start of the agreement period.

A few commenters suggested that CMS apply the three-way blended update factor to all ACOs, including those within existing agreement periods, beginning with PY 2024. These commenters also indicated that such an approach would avoid certain administrative burdens on ACOs and CMS, resulting from applying differing methodologies to distinct groups of ACOs or from ACOs terminating their current agreements and entering into new agreements for 2024 in order to benefit from the proposed changes.

In contrast, a few commenters suggested that CMS implement a more gradual phased transition to the three-way blend. For example, one commenter recommended allowing ACOs, whose final performance year of their current agreement period is PY 2023, to defer the transition to the three-way blend for up to one full agreement period to allow these ACOs to better understand the financial impact of the use of the ACPT.

Response: We believe commenters' suggested approaches to allow ACOs to opt in to the application of the three-way blend during an agreement period with a start date before 2024, or to allow ACOs with start dates on or after 2024 to delay adoption of the approach, could lead to selective participation, and prove operationally challenging to implement. Accordingly, we decline commenters' various suggestions for alternative approaches to the timing of applicability of the ACPT, and we are finalizing as proposed that the three-way blended update factor will apply to ACOs entering agreement periods beginning on January 1, 2024, and in subsequent years.

The three-way blended update factor is one of multiple changes we are finalizing to the Shared Savings Program's financial methodology and participation options, to be applicable for agreement periods beginning on January 1, 2024, and in subsequent years. We believe this timing will provide ACOs with sufficient time to consider the policies we are finalizing in this final rule, and prepare to apply to enter or continue their participation in the Shared Savings Program, as well as for CMS to prepare to implement these significant changes. Given the voluntary nature of participation in the Shared Savings Program, we agree with commenters that ACOs will likely carefully weigh the timing of their program entry, or renewal (in the case of currently participating ACOs), relative to the timing of applicability of the Shared Savings Program's requirements, including the modifications to the benchmarking methodology we are finalizing in this final rule.

We acknowledge that ACOs in the process of completing the application cycle for the 2023 start date, which concludes in early December 2022, will have limited time to evaluate the final policies adopted in this final rule prior to deciding whether to enter the Shared Savings Program (if eligible) for an agreement period starting on January 1, 2023. Further, we recognize that 2023 starters, and currently participating ACOs that entered an agreement period in earlier years, may wish to pursue the option to early renew for a new

agreement period beginning on January 1, 2024, by terminating their current agreement and immediately entering a new agreement period, so that they would have the opportunity to participate under the revised benchmarking methodology. (Refer to paragraph (2) of the definition of ''renewing ACO'' in § 425.20, and the application procedures set forth in § 425.224.) We note that early renewing, like renewing upon completion of an agreement period, will result in rebasing of the ACO's historical benchmark, and will affect the ACO's eligibility for certain participation options (refer to section III.G.2. of this final rule), as well as the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (refer to § 425.600(f)).

Lastly, in response to the commenter that suggested we allow ACOs whose final performance year of their current agreement period is PY 2023 to defer transition to the three-way blend for an agreement period, we note, as an initial matter, that under the policy adopted in the December 2018 final rule, which extended the length of the agreement periods to 5 performance years (or 6 performance years for ACOs that started an agreement period on July 1, 2019), there are currently no ACOs participating in the Shared Savings Program whose agreement period would conclude on December 31, 2023, unless the ACO's agreement is terminated early. Furthermore, we do not believe it would be appropriate to allow ACOs to defer transition to the three-way blend as such an approach would create perverse incentives for ACOs to game benchmarking policies we are phasing-out (namely use of the two-way blend instead of the three-way blend) in combination with other modified benchmarking policies and participation options that would be applicable to ACOs entering agreement periods beginning on January 1, 2024, and in subsequent years.

After consideration of the public comments, we are finalizing without modification our proposal to update an ACO's historical benchmark based on a three-way blend of the ACPT and blended national-regional growth rates, for agreement periods beginning on January 1, 2024, and in subsequent years. We are also finalizing as proposed the modifications to our regulations to incorporate the use of the three-way blend. The use of the three-way blend, the associated guardrail, and the discretion for CMS to adjust the weight of the ACPT in the three-way blend in the event of unforeseen circumstances are specified in paragraph (b) of a new provision at § 425.652, which would govern the process for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. We also specify within § 425.652(b) the other components of the update factor, namely the calculation of the national and regional components of the blend, which follows the same approach specified under § 425.601(b), with conforming changes to reflect the use within a three-way blend. Further, we specify the calculation of the ACPT in a new provision at § 425.660. We anticipate evaluating and monitoring the impact of the ACPT on ACO historical benchmarks, and would address any necessary refinements to the approach through future notice and comment rulemaking.

(4) Adjusting ACO Benchmarks To Account for Prior Savings

(a) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment that applied when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2016, to account for the average per capita amount of savings generated during the ACO's prior agreement period.[337]

The prior savings adjustment adopted in the June 2015 final rule (80 FR 32788 through 32791) was designed to adjust an ACO's benchmark for its second agreement period to account for the average per capita amount of savings generated by the ACO across the 3 performance years of its first agreement period. This average per capita amount also accounted for the ACO's quality performance in each performance year under its first agreement period. We limited the adjustment to the benchmark for the second agreement period to the average number of assigned beneficiaries (expressed as person years)[338] under the ACO's first agreement period in order to help ensure that the adjustment did not exceed the amount of net savings generated by the ACO during the first agreement period due to ACO participant list changes that may increase the number of assigned beneficiaries in the second agreement period (80 FR 32789). In calculating the adjustment, we used data from the ACO's finalized financial reconciliation reports for the performance years which corresponded to the benchmark years for the ACO's second agreement period. As described in the June 2015 final rule, the calculation included the following steps (80 FR 32789):

- *Step 1:* Determine whether the ACO generated net savings. For each performance year we determined an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. However, the ACO's total updated benchmark expenditures minus total performance year expenditures could not exceed the performance payment limit for the relevant track. If the sum of the per capita amounts for the 3 performance years was positive, the ACO would be determined to have net savings and we would proceed with Steps 2 and 3. If the sum of the per capita amounts for the 3 performance years was zero or negative, we did not make any adjustment to the ACO's rebased benchmark to account for any savings the ACO may have generated under its prior agreement period.
- *Step 2:* Calculate an average per capita amount of savings reflecting the ACO's final sharing rates based on quality performance. We averaged the performance year per capita amounts determined in Step 1 to determine the average per capita amount for the agreement period. We also determined the ACO's average final sharing rate, based on an average of the ACO's quality performance in each performance year of the agreement period. Therefore, the average per capita amount of savings would account for

[337] The relevant provision was originally finalized at § 425.602(c) in the June 2015 final rule (80 FR 32842). In the June 2016 final rule, we removed paragraph (c) from § 425.602 and included this provision within paragraph (b) of § 425.603 (81 FR 37968, 38014).

[338] To calculate person years: We sum the number of Shared Savings Program-eligible months for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, January 2022), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1* (Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

those situations where an ACO's sharing rate for a performance year was set equal to zero (based on the ACO's failure to meet the quality performance requirements in that year). We then calculated an average per capita amount of savings which was the product of the average performance year per capita amount and the average sharing rate based on quality performance.

- *Step 3:* Add the average per capita amount of savings determined in Step 2 to the ACO's rebased historical benchmark. The additional per capita amount was applied to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period.

As we explained in the CY 2023 PFS proposed rule (87 FR 46169), reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. Furthermore, we explained our belief that returning dollar value to benchmarks through a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark. We also noted that when applying two adjustments in establishing the benchmark—a prior savings adjustment and a regional adjustment—there are number of considerations related to the potential interactions between these adjustments. We proposed that these interactions would determine the extent to which efficient ACOs would receive positive regional adjustments to their benchmark and the extent to which less efficient ACOs could use their savings from a prior agreement period to offset a negative regional adjustment, which could help foster their continued participation in the Shared Savings Program.

(b) Revisions

In section III.G.5.c.(4).(b) of the CY 2023 PFS proposed rule (87 FR 46169 through 46179), we proposed to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years and that were reconciled for one or more of the 3 performance years immediately preceding the start of their agreement period. We considered a variety of approaches to calculating the prior savings adjustment and preferred an approach that would resemble the policy implemented for renewing ACOs entering a second agreement period in 2016 but that included additional steps to account for subsequent changes in Shared Savings Program policies. Specifically, these steps would account for the impact of the regional adjustment on the ACO's benchmark and attribute prior savings to re-entering ACOs.[339]

In the June 2016 final rule (81 FR 37962 through 37965), we explained our belief that it was important to forgo the adjustment to account for shared savings generated by the ACO under its prior agreement period when transitioning to a benchmark rebasing methodology that incorporates an adjustment for regional FFS expenditures. We anticipated that for ACOs generating savings, a rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO's rebased benchmark for its subsequent agreement period. At the time, we disagreed with comments suggesting that we either maintain the adjustment for prior savings or broaden its scope to make it more generous because we believed that maintaining an adjustment for prior savings alongside a regional adjustment could allow benchmarks to become overly inflated for some ACOs (particularly those benefiting from the regional adjustment). We also believed that continued application of the adjustment for prior savings would further tie an ACO's benchmark to its past performance rather than making it more reflective of FFS spending in the ACO's region, which was an important aim of revisions to the rebasing methodology in the June 2016 final rule (81 FR 37965).

In the CY 2023 PFS proposed rule, we explained our belief that based on our experience with rebasing under the current benchmarking methodology, it would be timely to re-introduce a prior savings adjustment to ensure rebased benchmarks continue to serve as a reasonable baseline when benchmark years correspond to performance years of the ACO's preceding agreement period. However, we explained our belief that the rebased benchmarks of ACOs that are lower spending compared to their regional service area and that generated savings in their benchmark years could become overinflated if we were to allow for both a prior savings adjustment and a positive regional adjustment. To prevent this from occurring, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate.

Additionally, we believed it would be appropriate to use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. This would permit ACOs that have generated savings in prior years to receive a relatively higher benchmark than under the current approach, which would incorporate a negative regional adjustment. We recognized that there are interactions between this proposed approach and the proposal to reduce the amount of the negative regional adjustment described in section III.G.5.c.(5) of the proposed rule. We accounted for these interactions in developing the proposed methodology for determining the prior savings adjustment.

In order to calculate the prior savings adjustment, we proposed to calculate the simple average of per capita savings or losses generated by the ACO during the 3 performance years that immediately precede the start of the ACO's current agreement period, and therefore, constitute the benchmark years of the current agreement period. The per capita savings for each performance year would be determined as the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. We noted that we would use all savings generated during each of the prior 3 performance

[339] According to § 425.20, re-entering ACO means an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions: (1) Is the same legal entity as an ACO, as defined according to § 425.20, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—(i) An ACO whose participation agreement expired without having been renewed; or (ii) An ACO whose participation agreement was terminated under §§ 425.218 or 425.220. (2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

years in the prior savings adjustment, not just savings that met or exceeded the ACO's MSR for that prior performance year. This would include savings generated by ACOs that were participating in an agreement period under the BASIC track that did not meet the MSR but would meet the expanded criteria to qualify for shared savings as proposed in section III.G.5.f. of the proposed rule. An ACO would be eligible for the prior savings adjustment if the ACO generates positive average prior savings across the 3 performance years immediately preceding the start of its current agreement period. If an ACO is not eligible to receive a prior savings adjustment, the ACO would receive the regional adjustment to its benchmark.

In calculating an ACO's average per capita prior savings over the 3 performance years immediately preceding the start of its agreement period, we believed a safeguard would be needed to ensure that ACOs that achieved savings for a performance year that serves as a benchmark year for the current agreement period, but were ineligible to receive a shared savings payment due to noncompliance with Shared Savings Program requirements, are not subsequently eligible to have a portion of those savings included in their historical benchmark. Without such a safeguard, we would be rewarding an ACO, despite its noncompliance, through a higher benchmark in its subsequent agreement period. This would conflict with the sanction imposed on the ACO for its noncompliance during the performance year(s) of its prior agreement period. Accordingly, we proposed that if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements, we would set at zero the per capita amount of savings for the affected performance year(s) when calculating the prior savings adjustment.

There are a variety of reasons that could result in an ACO's ineligibility to receive a shared savings payment due to noncompliance. In accordance with §§ 425.605(c)(2), and 425.610(c)(2), an ACO does not qualify to receive shared savings for a performance year if it failed to meet the quality performance standard as specified under § 425.512 (also refer to section III.G.4.b. of this final rule for modifications to the use of quality performance in determining shared savings and shared losses) or otherwise did not maintain its eligibility to participate in the Shared Savings Program. Furthermore, and to clarify the related explanation from the proposed rule, an ACO will not receive any shared savings payments during the time it is under a corrective action plan (CAP) for avoidance of at-risk beneficiaries, and is not eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries) (§ 425.316(b)(2)(ii)).

We proposed to apply a prior savings adjustment in establishing the historical benchmark for re-entering ACOs that meet the eligibility criteria for the adjustment. Under § 425.20, a re-entering ACO means an ACO that is not a renewing ACO and that is either the same legal entity as an ACO that previously participated in the program or a new legal entity that has never participated in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118 of the same ACO in any of the 5 most recent performance years prior to the agreement start date. For new ACOs that are identified as a re-entering ACO, we proposed to calculate the average per capita prior savings based on the prior performance of the ACO in which 50 percent or more of the ACO participants previously participated. We attribute various aspects of this prior ACO to the re-entering ACO for purposes of determining its eligibility to participate in the Shared Savings Program (§ 425.224), and to determine the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (§ 425.600(f)). We noted that we believed it would also be appropriate to attribute to the re-entering ACO the prior savings of this prior ACO. Therefore, in calculating the average per capita prior savings for ACOs identified as re-entering ACOs, we would include the per capita savings or losses of the prior ACO in the 3 performance years immediately preceding the start of the re-entering ACO's agreement period. This calculation would exclude from the prior savings adjustment any savings generated for performance years in which the prior ACO was ineligible to share in savings because of noncompliance with Shared Savings Program requirements. This safeguard would help to ensure that we would not reward ACOs for circumstances that may have led to their termination from the program, including circumstances that may have led to the formation of a new ACO.

We proposed to apply a proration factor to the prior savings adjustment to account for situations where an ACO's assigned beneficiary population is larger in the benchmark years when calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year, than the ACO's assigned beneficiary population was when the ACO was reconciled for the 3 performance years preceding the start of its current agreement period. Although this proration approach was not described with much specificity in the earlier rulemaking, we explained that this proration factor would be calculated and implemented in a manner that would be mathematically equivalent to the cap on the prior savings adjustment that was adopted in the June 2015 final rule (80 FR 32789).

Mathematically, to apply this proration factor we would calculate a ratio between: (1) the ACO's average person years for the 3 performance years that constitute the benchmark years for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods) and (2) the average person years in the 3 benchmark years for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year. Increases in beneficiary assignment would therefore result in a ratio less than 1, while decreases in assignment would result in a ratio greater than 1. This ratio would be capped at 1 to avoid increasing the per capita prior savings adjustment if the average number of beneficiaries assigned to the ACO across the 3 benchmark years of its current agreement period is lower than the average number of beneficiaries assigned during the 3 performance years immediately preceding the start of the ACO's current agreement period. This proration factor would be multiplied by the average positive per capita prior savings for the 3 performance years immediately preceding the start of the ACO's current agreement period to produce the pro-rated average per capita prior savings. We explained that prorating for growth in assignment would ensure that the prior savings adjustment does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute the benchmark years for its current agreement period.

We noted that there are a number of factors affecting the size of the ACO's assigned population between when CMS determined assignment for the performance year under the prior agreement period, and when CMS

determines assignment for the corresponding benchmark year of the ACO's current agreement period, thereby necessitating the calculation of the proration factor at the start of the ACO's new agreement period. Specifically, changes in the size of the ACO's assigned beneficiary population could be due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E. These circumstances also could arise during the course of an ACO's agreement period, and thereby also affect benchmark year assignment. Therefore, we proposed that for the second and each subsequent performance year during the term of the current agreement period, we would redetermine this proration factor under § 425.652(a)(9)(iv) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period, for the aforementioned reasons.

We further proposed to account for circumstances when an ACO was not reconciled for one or more of the 3 performance years immediately preceding the start of its current agreement period in the calculation of average per capita prior savings and the proration factor. ACOs that renew their agreement periods early or are a re-entering ACO may not be reconciled for one or more of the 3 years preceding the start of their current agreement period depending upon the timing of the expiration or termination of their prior agreement period and the start of their new agreement period. We proposed that if an ACO (or the prior ACO, if the ACO is identified as a re-entering ACO) was not reconciled during any of the 3 performance years immediately preceding the start of its current agreement period, the ACO would receive zero savings or losses in the calculation of average per capita prior savings for the relevant year(s). We noted that we believed this would be appropriate because the purpose of the prior savings adjustment is to return to an ACO's benchmark a portion of the savings experienced by beneficiaries assigned to the ACO during the 3 performance years immediately preceding the start of its current agreement period and CMS has no way to determine whether the ACO would have generated savings or losses during performance years it was not reconciled for. Excluding these years entirely from the calculation of average per capita prior savings would unduly increase the weight on the other year(s) included in the prior savings adjustment calculation for which the ACO received financial reconciliation results.

In contrast, we believed it would be appropriate to exclude years for which the ACO (or the prior ACO, if the ACO is identified as a re-entering ACO) was not reconciled when calculating the proration factor. The purpose of the proration factor is to account for situations where an ACO's assigned beneficiary population calculated at financial reconciliation in the 3 years preceding the start of the ACO's agreement period (numerator) is smaller than the ACO's assigned beneficiary population identified for those same years using the ACO's certified ACO participant list and assignment methodology for the current performance year (denominator).

If an ACO was not reconciled for one or more of the 3 performance years immediately preceding the start of its current agreement period, it would naturally have zero assigned beneficiaries determined at financial reconciliation for such years, which would factor into the numerator of the proration factor if such years were considered. However, the ACO would have positive beneficiary counts in the 3 years preceding the start of its current agreement period generated using the ACO's certified ACO participant list and assignment methodology for the current performance year, which would factor into the denominator of the proration factor if such years were considered. Thus, if the numerator and the denominator were both calculated as averages over 3 years, incorporating years for which the ACO was not reconciled in the calculation of the proration factor would artificially decrease the proration factor and lead to a smaller pro-rated average per capita prior savings for the ACO. Alternatively, if the numerator were calculated as an average that excludes performance years for which the ACO was not reconciled (that is, as an average across less than 3 years, including only those years an ACO was reconciled for) and the denominator was calculated as an average that included all 3 years preceding the beginning of the ACO's agreement period, the direction of the impact on the proration factor would depend on whether the number of assigned beneficiaries calculated using an ACO's current certified ACO participant list and assignment methodology in the benchmark years for which the ACO was not reconciled exceeds the number of assigned beneficiaries in the other benchmark years, and by how much. Therefore, we saw no compelling reason to include any of the 3 performance years immediately preceding the start of an ACO's agreement period for which the ACO was not reconciled in the numerator or the denominator of the proration factor and proposed to remove such years from the calculation of the proration factor. This would ensure that the proration factor compares average person years determined for prior performance years at financial reconciliation (numerator) to average person years determined using the ACO's current certified ACO participant list and assignment methodology (denominator) across a consistent set of years preceding the start of the ACO's agreement period.

For instance, if an ACO were only reconciled in 2 of the 3 performance years immediately preceding the start of its current agreement period, the proration factor would be calculated as a ratio between: (1) the ACO's average person years for the 2 performance years for which the ACO was reconciled (regardless of whether these performance years occurred over one or multiple prior agreement periods); and (2) the average person years in the 2 benchmark years of the ACO's current agreement period which correspond to these same 2 performance years, calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year. Tables 65 and 66 provide examples of the proration factor calculation when an ACO was not reconciled for one of the 3 performance years preceding the start of its agreement period. We did not propose parallel adjustments to the calculation of the proration factor if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements. We noted that we believed this would be appropriate because if an ACO was ineligible to share in savings in one of these years due to a noncompliance issue, we could still use the ACO's assigned beneficiary person years calculated at financial reconciliation in each of the 3 years preceding the start of the ACO's agreement period in the numerator of the proration factor, and could calculate the proration factor using the same method we would use for other ACOs that were reconciled in each of the 3 performance years immediately

preceding the beginning of the agreement period.

We proposed to calculate the final prior savings adjustment separately depending on whether an ACO is higher or lower spending relative to its regional service area. In order to avoid overinflating the benchmarks of ACOs that are lower spending relative to their regional service area by granting them both a prior savings adjustment and a positive regional adjustment, we believed it would be appropriate to apply the higher of the prior savings adjustment and the regional adjustment. In contrast, for ACOs that are higher spending relative to their region, we believed it would be appropriate to apply the prior savings adjustment to offset their negative regional adjustments partially or in full.

For an ACO that is lower spending than its regional service area, we proposed that the ACO would receive an adjustment equal to the higher of the following: (1) its positive regional adjustment; and (2) a prior savings adjustment equal to the lesser of—(i) 50 percent of its pro-rated positive average per capita prior savings and (ii) 5 percent of national per capita FFS expenditures for assignable beneficiaries. The national assignable per capita FFS expenditure cap used in this calculation would be expressed as a single per capita value by weighting the national per capita FFS expenditure averages for assignable beneficiaries of each Medicare enrollment type according to the ACO's person-year based enrollment proportions. The regional adjustment used in this calculation would be the ACO's regional adjustment determined as specified in the proposed new provision at § 425.656 (which would include the proposed modifications to the methodology for determining the regional adjustment as outlined in section III.G.5.c.(5) of the proposed rule) and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values. We believed that the cap on the prior savings adjustment at 5 percent of national per capita FFS expenditures for assignable beneficiaries would be necessary to ensure the amount of the prior savings adjustment does not inflate an ACO's benchmark to the point where the ACO is likely to generate shared savings without decreasing expenditures. The cap at 5 percent of national per capita FFS expenditures for assignable beneficiaries would align with the existing cap on positive regional adjustments (see § 425.601(a)(8)(ii)(C)). Further, we noted that the existing 5 percent cap on regional adjustments is adjusted to exclude episodes of care for treatment of COVID–19 in accordance with § 425.611(c)(2)(iii). Consistent with this current approach, we proposed to adjust the cap on prior savings adjustments to exclude episodes of care for treatment of COVID–19, and to specify this adjustment through modifications to the regulation at § 425.611(c)(2)(iii).

We proposed to apply the 50 percent scaling factor to the pro-rated positive average per capita prior savings because we believed it would be important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under its prior agreement period(s). We noted that the earlier version of the prior savings adjustment adopted in the June 2015 final rule also included a provision to scale the average per capita prior savings by a factor related to the sharing rate. Under this former policy, the ACO's average per capita prior savings were multiplied against its average final sharing rate across the prior agreement period. The average final sharing rate was determined using an average of the ACO's quality performance in each performance year of the prior agreement period (80 FR 32789). As proposed, the policy of applying a 50 percent scaling factor to the pro-rated positive average per capita prior savings would be a simplification of the older approach. The sharing rates vary within the Shared Savings Program's tracks/levels. Within an ACO's agreement period under the BASIC track's glide path, differing sharing rates will apply depending on the ACO's level of participation. Under the BASIC track, the maximum sharing rate is 40 percent under one-sided model Levels A and B, and 50 percent under two-sided model Levels C, D, and E (§ 425.605(d)). Under the ENHANCED track the maximum sharing rate is 75 percent (§ 425.610(d)). We also noted several proposals described in the proposed rule would affect the sharing rates: the proposal to apply sharing rates not to exceed one-half of the maximum amount within each Level of the BASIC track for eligible low revenue ACOs (section III.G.5.f. of the proposed rule); and the proposal to use a sliding scale in determining shared savings based on the ACO's quality performance for ACOs that meet the proposed alternative quality performance standard (section III.G.4.b. of the proposed rule). For simplicity, we believed it would be appropriate to apply a consistent scaling factor in calculating the prior savings adjustment when an ACO is lower spending relative to its regional service area. We believed that a 50 percent scaling factor would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track, and also takes into account the opportunity for ACOs to earn shared savings on a sliding scale under the proposed alternative quality performance standard.

For ACOs that are higher spending relative to their regional service area, we proposed to calculate the final adjustment to the benchmark by adding the pro-rated average per capita prior savings to the ACO's negative regional adjustment calculated as proposed in section III.G.5.c.(5) of the proposed rule and in the proposed new regulation at § 425.656. If this sum is positive, we proposed that the ACO would receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the positive sum and 5 percent of national per capita FFS expenditures for assignable beneficiaries. We proposed to apply the 50 percent scaling factor to the positive sum of the ACO's regional adjustment and the pro-rated average per capita prior savings instead of to the total pro-rated average per capita savings in order to strengthen incentives for ACOs to remain in the program by increasing the portion of the pro-rated average per capita savings that would be added to the negative regional adjustment in determining the final adjustment to the benchmark. The cap on the adjustment at 5 percent of national per capita FFS expenditures for assignable beneficiaries would mirror the proposed methodology described previously for determining the prior savings adjustment for ACOs with a positive regional adjustment. If the sum of the ACO's negative regional adjustment and its pro-rated average per capita prior savings is negative, the ACO would receive a reduced negative regional adjustment equal to the negative sum. In this case, the prior savings adjustment would not be subject to a 50 percent scaling factor because we believed that it would be appropriate to give the ACO the full benefit of generated prior savings when doing so would still not result in an overall positive adjustment to the benchmark that would be likely to inflate the ACO's benchmark. We believed this approach would also strengthen the incentive for ACOs that are higher spending than their regional service area to remain in the program and continue generating savings. We noted that we were also proposing to

reduce the current 5 percent cap on negative regional adjustments to 1.5 percent (as specified in section III.G.5.c.(5) of the proposed rule). We explained that if that proposal was finalized, the sum of the pro-rated average per capita prior savings and the negative regional adjustment would, necessarily, be less than 1.5 percent of national per capita FFS expenditures for assignable beneficiaries.

We proposed to use the following steps to calculate the prior savings adjustment:

• *Step 1:* Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period. For each performance year we would determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS would apply the following requirements in determining the amount of per capita savings or losses for each performance year:

++ The per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.

++ If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with Shared Savings Program requirements, the per capita savings for that year would be set to zero.

++ For a new ACO that is identified as a re-entering ACO, per capita savings or losses would be determined based on the per capita savings or losses of the ACO in which the majority of the ACO participants in the re-entering ACO were participating.

• *Step 2:* Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS would use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

++ If the average per capita value is less than or equal to zero, the ACO would not be eligible for a prior savings adjustment. The ACO would receive the regional adjustment to its benchmark.

++ If the average per capita value is positive, the ACO would be eligible for a prior savings adjustment.

• *Step 3:* Apply a proration factor to the per capita savings calculated in Step 2 equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. If the ACO was not reconciled for one or more of the 3 years preceding the start of the ACO's current agreement period, the person years from that year (or years) would be excluded from the averages in the numerator and the denominator of this ratio. For a new ACO that is identified as a re-entering ACO, the person years of the ACO in which the majority of the ACO participants of the re-entering ACO were participating would be used in the numerator of the calculation. This ratio would be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology.

• *Step 4:* Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment, determined as specified in the proposed new regulation at § 425.656, expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

++ If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings value and determine the final adjustment as follows:

—If the sum is positive, the ACO would receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment and 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment would be applied as a flat dollar amount [340] to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—If this sum is negative, this would constitute the amount of the negative regional adjustment applied to the ACO's historical benchmark. The adjustment would be applied as a flat dollar amount to the historical benchmark expenditures for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ If the regional adjustment, expressed as a single value, is positive, the ACO would receive an adjustment to the benchmark equal to the higher of the following:

—The positive regional adjustment amount. The adjustment would be applied separately to the historical benchmark expenditures for each of the following populations of beneficiaries according to the methodology for calculating the regional adjustment (as proposed under § 425.656(c)): ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings value and 5 percent of national per capita FFS expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment would be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

In the CY 2023 PFS proposed rule, we noted that an implication of using an ACO's prior performance to calculate the prior savings adjustment is that at

[340] In the CY 2023 PFS proposed rule, we referred to use of a ''flat rate'' in this description. However, for clarity and consistency with the proposed regulatory text at § 425.652(a)(8)(iii)(A)(*1*), we believe it is more appropriate to refer to this quantity as a ''flat dollar amount,'' a term that is also used in certain descriptions of the application of the prior savings adjustment to historical benchmark expenditures by Medicare enrollment type in this section of this final rule. This clarification of terminology does not reflect a methodological change.

the time we determine the preliminary historical benchmarks, an ACO entering a new agreement period that completed a performance year that corresponds to BY3 of its new agreement period will not have prior savings data yet available for that year. In this case, we would anticipate completing financial reconciliation for that performance year midway through the first performance year of the ACO's new agreement period. Accordingly, to determine the preliminary historical benchmark for the first year of the ACO's new agreement period, we would calculate the prior savings adjustment using zero savings in BY3. We would then update the calculation at the time when we calculate the ACO's final historical benchmark to incorporate any applicable BY3 savings. As a result, we acknowledged that production and release of final historical benchmarks may need to be delayed until after the calculation and release of financial reconciliation results for the preceding performance year.

Tables 65 through 68 present hypothetical examples to demonstrate how the adjustment for prior savings would work in practice. For purposes of this final rule, we have made minor updates to the versions of these tables that appeared in the CY 2023 PFS proposed rule for clarity and specificity. Numerically and conceptually the tables in this final rule are equivalent to the corresponding tables in the CY 2023 PFS proposed rule (87 FR 46175 through 46178, Tables 55–58).

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TABLE 65: ACO with Negative Aggregate Regional Adjustment, Sum of Regional Adjustment, and Pro-rated Average Prior Savings is Positive

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021 $0 (Not Reconciled) PY 2022: $1,400 PY 2023: $1,500
Step 2: Calculate Average Per Capita Prior Savings	($0 + $1,400 + $1,500) / 3 = $966.67
Step 3: Calculate and Apply Proration Factor	Assigned beneficiary person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 0 (Not included in proration factor because ACO was not reconciled) PY 2022: 5,000 PY 2023: 7,000 Assigned beneficiary person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 11,000 (Not included in proration factor because ACO was not reconciled) BY 2022 (BY2): 9,000 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period, excluding years for which the ACO was not reconciled [(5,000 + 7,000)/2] / [(9,000 + 7,000)/2] = 0.75, capped at 1 Proration factor = 0.75 Apply proration factor to average per capita prior savings: $966.67 x 0.75 = $725.00
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $-100 Sum of regional adjustment and pro-rated average per capita prior savings: -$100 + $725.00= $625.00 5 percent of national per capita FFS expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $625.00 x 50% and $600 = $312.50 Per capita benchmark expenditures after regional adjustment and prior savings adjustment: ESRD: $90,000 + $312.50= $90,312.50 Disabled: $13,000 + $312.50= $13,312.50 Aged/dual: $20,000 + $312.50= $20,312.50 Aged/non-dual: $11,000 + $312.50= $11,312.50

TABLE 66: ACO with Negative Aggregate Regional Adjustment, Sum of Regional Adjustment, and Pro-rated Average Prior Savings is Negative

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: $0 (Not Reconciled) PY 2022: $250 PY 2023: $150
Step 2: Calculate Average Per Capita Prior Savings	($0 + $250 + $150) / 3 = $133.33
Step 3: Calculate and Apply Proration Factor	Assigned beneficiary person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 0 (Not Included in proration factor because ACO was not reconciled) PY 2022: 6,000 PY 2023: 10,000 Assigned beneficiary person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 8,000 (Not Included in proration factor because ACO was not reconciled) BY 2022 (BY2): 6,000 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period, excluding years for which the ACO was not reconciled [(6,000 + 10,000)/2] / [(6,000 + 7,000)/2] = 1.23, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $133.33 x 1 = $133.33
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $-150 Sum of regional adjustment and pro-rated average per capita prior savings: -$150 + $133.33= -$16.67 Final adjustment is -$16.67 Per capita benchmark expenditures after regional adjustment and prior savings adjustment: ESRD: $91,000 - $16.67 = $90,983.33 Disabled: $12,000 - $16.67 = $11,983.33 Aged/dual: $19,000 - $16.67 = $18,983.33 Aged/non-dual: $10,000 - $16.67 = $9,983.33

TABLE 67: ACO with Positive Aggregate Regional Adjustment, ACO Receives Prior Savings Adjustment

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: -$100 PY 2022: $600 PY 2023: $900
Step 2: Calculate Average Per Capita Prior Savings	(-$100 + $600 + $900) / 3 = $466.67
Step 3: Calculate and Apply Proration Factor	Assigned beneficiary person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 8,000 PY 2022: 7,000 PY 2023: 9,000 Assigned beneficiary person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 6,000 BY 2022 (BY2): 5,500 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period [(8,000 + 7,000 + 9,000)/3] / [(6,000 +5,500 + 7,000)/3] = 1.30, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $466.67 x 1 = $466.67
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $50 5 percent of national per capita FFS assignable expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $466.67 x 50% and $600 = $233.34 Higher of regional adjustment and capped pro-rated average per capita prior savings: Higher of $50 and $233.34 = $233.34 Per capita benchmark expenditures after prior savings adjustment: ESRD: $92,000 + $233.34 = $92,233.34 Disabled: $13,000 + $233.34 = $13,233.34 Aged/dual: $19,000 + $233.34 = $19,233.34 Aged/non-dual: $10,000 + $233.34 = $10,233.34

TABLE 68: ACO with Positive Aggregate Regional Adjustment, ACO Receives Regional Adjustment

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: -$100 PY 2022: $600 PY 2023: $900
Step 2: Calculate Average Per Capita Prior Savings	(-$100 + $600 + $900) / 3 = $466.67
Step 3: Calculate and Apply Proration Factor	Assigned beneficiary person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 8,000 PY 2022: 7,000 PY 2023: 9,000 Assigned beneficiary person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 6,000 BY 2022 (BY2): 5,500 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period [(8,000 + 7,000 + 9,000)/3] / [(6,000 +5,500 + 7,000)/3] = 1.30, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $466.67 x 1 = $466.67
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $250 5 percent of national per capita FFS expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $466.67 x 50% and $600 = $233.34 Higher of regional adjustment and capped pro-rated average per capita prior savings: Higher of $250 and $233.34 = $250 Per capita benchmark expenditures after regional adjustment: ESRD: $92,000 + $880= $92,880 Disabled: $13,000 + $310= $13,310 Aged/dual: $19,000 + $850= $19,850 Aged/non-dual: $10,000 + $200= $10,200

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In the CY 2023 PFS proposed rule, we explained our belief that incorporating an adjustment for prior savings, when the adjustment for prior savings would be more advantageous for ACOs than the regional adjustment, would limit the negative ratchet effects of benchmark rebasing. Under the existing benchmarking methodology, the savings an ACO achieves in one agreement period can reduce its rebased benchmark for the subsequent agreement period either directly by reducing the historical spending that forms the basis for its rebased benchmark or indirectly by reducing regional expenditures in the ACO's regional service area leading to negative (or smaller positive) regional adjustments. Under the proposal to incorporate an adjustment for prior savings, ACOs that have demonstrated savings in the 3 years preceding the start of the agreement period would receive higher benchmarks under the following scenarios:

- ACOs with a negative regional adjustment would receive either a smaller negative regional adjustment or a positive adjustment for prior savings, depending on the relative size of the negative regional adjustment and their pro-rated average prior savings.
- ACOs with a positive regional adjustment whose pro-rated average prior savings multiplied by 50 percent are higher than their regional adjustment would receive a prior savings adjustment that is larger than their regional adjustment would have been under current policy. In contrast, ACOs whose positive regional adjustment is greater than 50 percent of their pro-rated average prior savings would not be impacted by the proposed adjustment for prior savings, and would continue to receive the (larger) regional adjustment.

We stated that we believed the proposal to take the greater of the regional adjustment and the adjustment for prior savings when the regional adjustment is positive, and to net out a negative regional adjustment with the prior savings adjustment when the regional adjustment is negative, would prevent the proposed policy from resulting in unduly large benchmarks. While no ACOs would receive a lower benchmark as a result of this policy, numerical modeling of the proposed policy performed for the proposed rule using data from ACOs beginning an agreement period in PY 2020 suggested that approximately 22 percent of all ACOs reconciled in one or more of their benchmark years would receive a higher benchmark under this policy. Among ACOs that would receive a higher benchmark, the average net effect on per capita benchmark expenditures would be approximately $130 applied as a flat dollar amount to the ACO's historical benchmark expenditures across each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

Since the issuance of the CY 2023 PFS proposed rule, we have performed additional modeling on the proposed prior savings adjustment using data from ACOs beginning an agreement period in PY 2022. The modeling methodology used for ACOs starting an agreement period in PY 2022 was equivalent to the methodology employed for PY 2020 starters. Table 69 summarizes the impact of the prior savings adjustment on ACOs beginning agreement periods on January 1, 2020 and January 1, 2022, and includes a greater level of detail than was included in the CY 2023 PFS proposed rule.

Table 69 is divided into several sections that correspond to the various criteria ACOs would be required to meet to receive the proposed prior savings adjustment. The first segment of the Table (rows [A] and [B]) identifies the total number of ACOs entering a new agreement period in the respective performance year (PY 2020 or PY 2022) and what proportion of all ACOs starting an agreement period in that performance year were reconciled in one or more benchmark years. Under our proposal, this is the first eligibility criterion ACOs must meet to receive the prior savings adjustment. The second segment of the Table (row [C]) identifies the proportion of ACOs, among those reconciled in one or more benchmark years, that had positive prorated average prior savings among the ACOs that were reconciled in one or more of their benchmark years, which is the second criterion under our proposed methodology. As proposed, the third criterion that ACOs must meet to receive the prior savings adjustment after identification as being reconciled for one or more benchmark years and having generated positive prorated average prior savings involves comparing the prior savings adjustment with the ACO's aggregate regional adjustment. All ACOs that receive a negative aggregate regional adjustment and have positive prorated average prior savings would receive some benefit from the prior savings adjustment. However, ACOs that receive a positive aggregate regional adjustment and have positive prorated average prior savings would only receive a benefit if the prior savings adjustment is greater than the positive aggregate regional adjustment the ACO otherwise would have received. The third section in Table 69 (row [D]) identifies the proportion of ACOs that were simulated to actually receive the prior savings adjustment among ACOs that were reconciled in one or more benchmark years. The fourth segment in Table 69 (row [E]) summarizes the positive impact of the prior savings adjustment relative to the aggregate regional adjustment the ACO would otherwise have received for ACOs that were simulated to receive the prior savings adjustment.

TABLE 69: Modeled Impact of Prior Savings Adjustment on Benchmarks for 2020 and 2022 Starters

	PY 2020	PY 2022
Proportion of ACOs Reconciled in One or More Benchmark Year		
[A] Count of Total ACOs Entering a New Agreement Period in the PY	153	206
[B] Proportion of ACOs Reconciled in One or More Benchmark Years (Percentage among ACOs in [A])	123 (80.4%)	153 (74.3%)
Among ACOs Reconciled in One or More Benchmark Years, Proportion with Demonstrated Savings		
[C] Proportion of ACOs with Positive Pro-rated Average Prior Savings Among ACOs Reconciled in One or More Benchmark Years (Percentage among ACOs in [B])	94 (76.4%)	118 (77.1%)
Among ACOs Reconciled in One or More Benchmark Years, Proportion that Receive Benefit from Prior Savings Adjustment		
[D] Proportion of ACOs Whose Final Adjustment Includes Adjustment for Prior Savings Among ACOs Reconciled in One or More Benchmark Years (Percentage among ACOs in [B])	27 (22.0%)	43 (28.1%)
Among ACOs Reconciled in One or More Benchmark Years, Net Benefit of Prior Savings Adjustment		
[E] Net Benefit to Benchmarks from Prior Savings Adjustment Relative to Aggregate Regional Adjustment Otherwise Received ($) (Calculated among ACOs in [D])		
Minimum	2.70	0.19
25th Percentile	23.54	51.83
Median	75.75	85.92
Average	132.84	104.73
75th Percentile	144.66	133.62
Maximum	964.22	511.89

In the CY 2023 PFS proposed rule, we explained that when the historical benchmark is adjusted for changes in severity and case mix between BY3 and the performance year as proposed under § 425.652(a)(10) and updated for growth in expenditures between BY3 and the performance year as proposed under § 425.652(b), the portion of the historical benchmark attributable to the prior savings adjustment would also be updated for changes in severity and case mix and growth in expenditures at the enrollment type level. This is consistent with the way in which the regional adjustment that is currently calculated under § 425.601(a)(8) (and would be calculated under proposed § 425.656), is updated at the time of financial reconciliation to reflect changes in severity and case mix and growth in expenditures. If the portion of the benchmark attributable to prior savings were not updated for changes in severity and case mix and growth in expenditures, this could result in smaller benchmarks if the updates for severity and case mix and growth in expenditures are positive (which is typical in past experience). Thus, including the prior savings adjustment in these updates would tend to result in larger benchmarks for those ACOs that receive a prior savings adjustment to their benchmark. In the proposed rule, we explained that we believed this would be appropriate because the prior savings adjustment is based on reductions in expenditures in previous performance years. To the extent that updates to the benchmark for changes in severity and case mix and growth in expenditures suggest that the benchmark should be increased, we believed that it would be appropriate to increase the size of the prior savings adjustment proportionally. Similarly, in the less likely scenario that updates for severity and case mix and growth in expenditures are negative, we believed it would be appropriate to commensurately decrease the size of the prior savings adjustment.

We proposed that the methodology for calculating the average per capita prior savings amount, including the use of a proration factor to account for any upward growth in the ACO's assigned population in the benchmark years of the current agreement as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period(s), would be specified in a new provision at § 425.658 applicable for agreement periods beginning on January 1, 2024, and in subsequent years. As proposed, this section would also specify the approach to determining an ACO's eligibility for the prior savings adjustment. Further, we proposed to specify in § 425.652(a)(8) the approach for comparing the pro-rated average prior savings amount calculated under § 425.658 with the ACO's regional adjustment amount described in the proposed new provision at § 425.656(c), to determine the applicability of the prior savings adjustment, the regional adjustment, or a combination of these two adjustments. We also proposed to specify at § 425.652(a)(9) that for the second and each subsequent performance year during the term of the ACO's agreement period, we would redetermine the proration factor used in calculating the prior savings adjustment under § 425.658 to account for any changes in the ACO's assigned beneficiary population in the benchmark years due to the addition and removal of ACO participants or

ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology.

We sought comment on this proposal to adjust the ACO's historical benchmark for savings generated in the ACO's prior agreement period.

The following is a summary of the public comments received on the proposal to adjust ACO benchmarks to account for prior savings and our responses:

Comment: Commenters generally supported our proposal to adjust ACO benchmarks for prior savings, although some commenters described certain concerns about or suggested modifications to the calculation methodology, which we summarize elsewhere within this section of this final rule. More specifically, several commenters explained that high performing ACOs would no longer be penalized with lowered benchmarks for past savings and success if this proposal were implemented. Some of these commenters agreed with CMS's proposition that the proposal would provide an incentive for high performing ACOs to remain in the Shared Savings Program. Several commenters supported CMS's acknowledgement of the ''ratchet effect'' that occurs when ACOs that have generated prior savings receive rebased benchmarks and the introduction of proposals to minimize this effect. These commenters agreed that the prior savings adjustment would help to allow successful ACOs to continue to implement and refine existing programs that lower the cost of care and improve quality instead of finding additional ways to lower cost. One commenter also suggested that the proposal would help offset the related issue of ACOs in rural areas being disproportionately penalized for reducing spending due to having a high regional market share.

Response: We appreciate commenters' support for the proposal to adjust benchmarks to account for savings generated in prior agreement periods.

Comment: Many commenters that supported the proposal to introduce a prior savings adjustment also offered a variety of suggestions to broaden the policy's impact to make it more favorable to ACOs. These suggestions included making the scaling factor used to calculate the adjustment more generous, applying the average savings rate from an ACO's prior agreement period as an upward adjustment to the historical benchmark, increasing the cap on the prior savings adjustment, and including savings earned in other alternative payment models in the calculation of the prior savings adjustment. We summarize and respond to these commenters' suggestions elsewhere within this section of this final rule. One commenter also supported the prior savings adjustment but indicated that they are actively considering dropping out of the Shared Savings Program due to insufficient incentives to remain in the program. This commenter did not share specific suggestions to increase the scope of the prior savings adjustment.

Response: We appreciate these commenters' support of CMS's efforts to implement the prior savings adjustment and their recommendations to make the prior savings adjustment more favorable for ACOs, particularly for ACOs serving high-risk populations.

We believe that the proposed approach strikes an appropriate balance by mitigating the rebasing ratchet effect on an ACO's benchmark through returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while safeguarding the Medicare Trust Funds from excessive shared savings payments that could result from overly inflated benchmarks. As discussed previously in this section, following the publication of the proposed rule we conducted additional modeling on the anticipated impact of the prior savings adjustment. Using data from ACOs beginning agreement periods in PY 2020 to model the impact of the prior savings adjustment suggests that had the prior savings adjustment been in place as proposed in PY 2020, 22.0 percent of the ACOs reconciled in one or more benchmark year would have received a higher benchmark (see Table 69). Across all ACOs receiving a higher benchmark due to the prior savings adjustment, the median benchmark increase would have been approximately $76. For ACOs beginning agreement periods in PY 2022, CMS' modeling suggests that the prior savings adjustment, if implemented as proposed, would have been slightly more advantageous to ACOs. Modeling for PY 2022 suggests that 28.1 percent of ACOs reconciled in one or more benchmark year would have received a higher benchmark, while the median benchmark increase would have been approximately $86.

In light of these findings, we do not believe there is a compelling justification at this time to alter the proposed policy in order to make the prior savings adjustment more generous to ACOs.

Comment: Several commenters suggested that instead of using a 50 percent scaling factor to calculate the prior savings adjustment, CMS should consider using a higher scaling factor that may more closely match the maximum shared savings rate from an ACO's prior agreement period.

Response: We decline the commenters' suggestion to use a scaling factor that more closely matches the maximum shared savings rate from an ACO's prior agreement period. We continue to believe, as stated in the CY 2023 PFS proposed rule, that a 50 percent scaling factor would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track. Additionally, using a 50 percent scaling factor considers the opportunity for ACOs to earn shared savings on a sliding scale under the proposed alternative quality performance standard (also refer to section III.G.4.b. of this final rule for a discussion of modifications to the use of quality performance in determining shared savings and shared losses). If CMS were to use the maximum shared savings rate from an ACO's previous agreement period in calculating the prior savings adjustment, this scaling factor may be inflated relative to the shared savings rate ACOs actually receive using the sliding scale approach based on ACO quality performance under the alternative quality performance standard that we are adopting in this final rule.

Comment: One commenter noted that CMS should apply the actual average savings rate over the previous 3 years as the upward adjustment factor to the benchmark instead of implementing the prior savings adjustment as proposed, which involves multiplying per capita average prior savings by a scaling factor. The commenter noted that this alternative approach would be particularly beneficial for low cost ACOs.

Response: We decline the commenter's suggestion to use the actual average savings rate from an ACO's prior agreement period as the upward adjustment factor to the historical benchmark. We continue to believe, as stated in section III.G.5.c.(4) of the proposed rule, that as part of any adjustment for prior savings it is important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under its prior agreement period(s). Using the actual average savings rate as the upward adjustment factor to the historical benchmark would not

incorporate a measure of the sharing rate in computing the prior savings adjustment to the benchmark, and we believe that such an approach could contribute to overinflating benchmarks. If CMS were to return 100 percent of an ACO's per capita savings to its historical benchmark in subsequent agreement periods, ACOs would have minimal incentives to continue lowering spending after generating shared savings in a single agreement period. Additionally, the sharing rates vary within the Shared Savings Program's tracks/levels. Under the BASIC track, the maximum sharing rate is 40 percent under the one-sided model Levels A and B, and 50 percent under the two-sided model Levels C, D, and E (§ 425.605(d)). Under the ENHANCED track the maximum sharing rate is 75 percent (§ 425.610(d)). As we explained in the proposed rule (87 FR 46173), we believe it is most straightforward to apply a consistent scaling factor in calculating the prior savings adjustment and we believe that a 50 percent scaling factor is appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track.

Comment: Several commenters suggested that CMS modify the cap on the prior savings adjustment, which was proposed to be set at 5 percent of national per capita FFS expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. Commenters provided a variety of suggestions, including to risk adjust the 5 percent national FFS spending cap to make it a more accurate reflection of the complexity of an ACO's patient population. Many of these commenters also suggested that CMS should increase the cap by allowing ACOs to receive the greater of the 5 percent of national per capita FFS expenditures in BY3 for assignable beneficiaries or 50 percent of the pro-rated average per capita savings net of any negative regional adjustments. Some of these same commenters preferred an alternative approach to capping the prior savings adjustment wherein the cap would be adjusted according to an ACO's spending relative to its region. One commenter that was particularly concerned that the value of the prior savings adjustment may be relatively lower (we assume the commenter means as a proportion of the ACO's own historical benchmark expenditures) for ACOs serving medically complex populations specifically suggested that CMS use one of the following approaches to adjust the cap on the prior savings adjustment: (1) risk adjust the national per capita FFS expenditures for assignable beneficiaries used to determine the cap on the prior savings adjustment; (2) allow ACOs with higher percentages of underserved, high-risk populations to receive the greater of a percentage of their prior average per capita savings or a percentage of national FFS expenditures for the assignable population; or (3) replace the proposed cap based on national per capita FFS expenditures for assignable beneficiaries with a percentage of an ACO's most recent per capita benchmark from the prior agreement period (BY3). Within each of these options, this commenter suggested using a sliding scale to allow ACOs with larger average final sharing rates in their previous agreement period to receive a larger cap on the prior savings adjustment to encourage ACOs to assume greater risk over time. The commenter suggested that these alternatives would not meaningfully increase costs for the Shared Savings Program and would ''offset large adjustments to ACOs with higher than average benchmarks that would otherwise discourage these ACOs from continued participation in the program.'' Although the precise meaning of this statement is unclear, we believe that the commenter may have been suggesting that these proposed changes would compensate for large negative regional adjustments received by ACOs with high risk or medically complex beneficiary populations that are higher spending than their regional service areas.

Response: We appreciate commenters' concerns that the cap on the prior savings adjustment at 5 percent of national per capita FFS expenditures could be disadvantageous to some ACOs, particularly those with a large proportion of high-risk patients. However, we decline to adopt their suggestions for modifying the cap on the prior savings adjustment to make it more generous to ACOs, or for a subset of ACOs including ACOs serving a high proportion of high risk or medically complex beneficiaries, either through risk adjustment or other methods. Based on CMS's additional modeling of the prior savings adjustment conducted with ACOs beginning an agreement period in PY 2020 and PY 2022, less than 5 percent of ACOs receiving the prior savings adjustment would be impacted by the cap on the prior savings adjustment. In PY 2020, among ACOs that would have benefited from the prior savings adjustment but that would also have seen the prior savings adjustment limited by the cap, the mean reduction would have been 2.1 percent of their total historical benchmark. In PY 2022 the equivalent figure would have been 0.61 percent. Further, given that few ACOs were subject to the cap in our modeling, our modeling does not conclusively suggest whether ACOs with a large proportion of high risk beneficiaries would be disproportionately impacted by the cap. Based on this analysis, we believe that the proposed cap on the prior savings adjustment adequately prevents against over inflating benchmarks and would not disproportionately impact ACOs with a high proportion of high risk beneficiaries. However, we do intend to monitor the application of the prior savings adjustment and may adjust the cap in future rulemaking if evidence emerges that ACOs with relatively large high risk or medically complex patient populations are disadvantaged by the capping methodology.

Additionally, we interpret the commenters' suggestion that CMS should increase the cap by allowing ACOs to receive the greater of 5 percent of the national per capita FFS expenditures in BY3 for assignable beneficiaries or 50 percent of the pro-rated average per capita savings net of any negative regional adjustments to imply that all ACOs would receive a prior savings adjustment of 5 percent of national per capita FFS expenditures in BY3 for assignable beneficiaries. We decline to adopt this suggestion because doing so would result in a large prior savings adjustment for all ACOs regardless of their past performance. If commenters instead intended to imply that CMS should raise the cap on the prior savings adjustment to be the greater of 5 percent of national per capita FFS expenditures in BY3 and 50 percent of the pro-rated average per capita savings net of any negative regional adjustments, we decline to adopt this alternative for the same reasons we previously explained for declining to alter the cap on the prior savings adjustment, namely that our modeling of the proposed approach suggests that only a small percentage ACOs would have their prior savings adjustment capped and because this alternative approach may over inflate benchmarks.

We also decline to adopt the commenter's suggestion to modify the cap on the prior savings adjustment to further mitigate large negative regional adjustments received by ACOs because we believe the proposed approach already provides sufficient flexibility

with respect to the use of the prior savings adjustment to offset a negative regional adjustment. Under the proposed approach, for ACOs with negative aggregate regional adjustments, the cap of 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 would apply only when 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment is not only positive but also exceeds 5 percent of national per capita FFS expenditures. As a result, because the prior savings adjustment could not only fully offset a negative aggregate regional adjustment but also yield a positive adjustment up to the 5 percent of national per capita FFS expenditures cap, ACOs with negative aggregate regional adjustments could receive a net benefit from the proposed policy significantly greater than 5 percent of national per capita FFS expenditures relative to the benchmark they would have received in the absence of the proposed policy.

We also decline to adopt the commenter's suggestion to tie the cap on the prior savings adjustment to an ACO's final sharing rate from the previous agreement period. We believe this approach could selectively ameliorate ratchet effects for a subset of ACOs while providing little benefit for other ACOs, depending on their track in their prior agreement period. Accordingly, we believe that this alternative approach, when compared to the proposed approach of applying the same cap on the prior savings adjustment for all ACOs regardless of their previous agreement period track(s), would less equitably addresses the dynamics we set out to address through our proposal, as described in section III.G.5.c.(2) of this final rule, including ensuring accurate and reasonable benchmarks and addressing the effect of an ACO's prior success in the Shared Savings Program on its benchmark.

Comment: Several commenters encouraged CMS to expand the prior savings adjustment to include savings achieved through past and future CMS ACO initiatives, such as the NGACO Model and the Global and Professional Direct Contracting Model, including the redesign of that model as the ACO REACH Model.

Response: We decline the commenters' suggestion because we do not believe it would be appropriate or feasible to incorporate savings generated in other shared savings models within a prior savings adjustment under the Shared Savings Program at this time. There are significant methodological differences across models that would make blending savings estimates across models logistically infeasible and could produce inequities between cohorts of ACO that did or did not participate in other models previously. Additionally, pursuing this suggestion would entail developing a methodology for how to account for such savings based on an ACO's participation in other CMS ACO initiatives, which was not contemplated within our proposed approach.

Comment: Several commenters suggested that because the prior savings adjustment as proposed would only apply to renewing ACOs and re-entering ACOs entering a new agreement period beginning on January 1, 2024, and in subsequent years, CMS should make this methodology change available to all ACOs in existing agreement periods beginning in PY 2024. These commenters expressed concern that, in order to benefit from the adjustment for prior savings, ACOs within existing agreement periods would have to terminate their current agreements and enter into a new agreement period starting in 2024, causing undue administrative burden.

Response: We appreciate these commenters' concern that ACOs continuing in existing agreement periods with start dates prior to 2024 would not operate under a benchmark methodology that includes an adjustment for prior savings until they enter a new agreement period beginning on or after January 1, 2024. However, we do not believe it would be appropriate to institute the prior savings adjustment for such ACOs until they enter a new agreement period because doing so would disrupt the consistency of an ACO's benchmarking methodology within a single agreement period. These ACOs would be eligible to receive a prior savings adjustment for an agreement period beginning on January 1, 2024, and in subsequent years, upon renewing (including early renewing) to continue their participation in the Shared Savings Program or re-entering the Shared Savings Program after the termination or expiration of their prior participation agreement.

Additionally, a key aspect of applying the prior savings adjustment for future agreement periods is that an ACO's benchmark would be rebased upon the beginning of a new agreement period. We believe that making the prior savings adjustment available to ACOs without the requirement of beginning a new agreement period could create a selective gaming opportunity. ACOs could take advantage of the prior savings adjustment without receiving a rebased historical benchmark that incorporates the spending reductions from the performance years used to calculate the prior savings adjustment. Further, as we indicated in earlier rulemaking, while ACOs may early renew in order to opt into new Shared Savings Program methodologies, the accompanying requirement of receiving a rebased historical benchmark at the start of each new agreement period, among other factors, mitigates the concern that ACOs could selectively take advantage of new policies (83 FR 67906).

Comment: One commenter encouraged CMS to explore calculating the prior savings adjustment at the TIN-level as opposed to the ACO-level. While the commenter did not specify a methodology for calculating a TIN-level prior savings adjustment, the commenter suggested that a TIN-level adjustment would ensure that the prior savings adjustment accounts for changes in ACO participant lists between agreement periods and captures the full scope of savings generated by an ACO's participant TINs. This commenter noted that by not applying the previous savings adjustment at the TIN-level, ACO participants, and potentially any ACO that they join, could be negatively impacted by changes to ACO participant lists.

Response: At this time, we decline the commenter's suggestion to establish a TIN-level prior savings adjustment. This alternative goes beyond the scope of the proposed prior savings adjustment. Additionally, we have some concerns about a TIN-level prior savings adjustment. Our primary concern with instituting a TIN-level prior savings adjustment is that an ACO could receive benefits from prior savings generated by other ACOs that are unconnected to the ACO's actual prior performance. Such a methodology could reward ACOs for savings generated by another ACO if the ACO gains an ACO participant TIN that previously participated with another ACO. Such churn in ACO participant lists is allowable and anticipated under existing Shared Savings Program methodology. We note that under the proposal, for new ACOs that are identified as re-entering ACOs, we would calculate the prior savings adjustment based on the prior performance of the ACO in which 50 percent or more of the ACO participants previously participated. In this scenario an ACO would receive credit for savings generated by another ACO. However, we believe that the requirement that we would only consider the prior savings of the ACO in which 50 or more percent

of an ACO's ACO participants previously participated makes it reasonable, in this circumstance, to utilize the prior savings generated by a different ACO to calculate an ACO's prior savings adjustment. Additionally, instituting a TIN-level prior savings adjustment would involve significant additional complexity that is outside the scope of the proposal.

Related to the proposal to utilize the prior savings of another ACO to calculate the prior savings adjustment for re-entering ACOs, we note that as proposed, we would only identify the ACO in which 50 or more percent of the ACO's ACO participants previously participated at the beginning of an ACO's agreement period, consistent with our regulation at § 425.20. We intend to monitor ACOs identified as re-entering ACOs to determine how ACO participant list changes that occur during performance years within an agreement period may change the composition of the ACO relative to the initial composition that established the ACO as a re-entering ACO. As we continue to monitor the effects of this policy, we may revisit the applicability of the prior savings adjustment for re-entering ACOs in future rulemaking to ensure that the prior savings adjustment is calculated appropriately for re-entering ACOs.

Comment: MedPAC supported the proposed prior savings adjustment because it would provide a strong incentive for ACOs to improve efficiencies in care delivery, particularly among ACOs that serve beneficiaries with higher spending than their regional averages. MedPAC stated that a prior savings adjustment is a reasonable policy for mitigating ratchet effects until CMS can phase in a fixed administrative growth rate with a regional efficiency discount.

However, MedPAC raised several concerns about implementing proposals designed to combat ratcheting effects—specifically the prior savings adjustment and the ACPT—alongside the regional adjustment. Most of these concerns were rooted in a belief that the existing regional adjustment is too generous to ACOs. MedPAC explained that the regional adjustment, which allows ACOs to receive higher benchmarks without demonstrating efficiency gains during their Shared Savings Program participation, has coincided with an elevated level of selective participation into the Shared Savings Program that has put it at risk of being a net cost to the Medicare program. MedPAC stated that the regional adjustment used under the existing benchmarking methodology creates selective participation pressures by benefiting low-spending providers/suppliers and disadvantaging high-spending providers/suppliers, and presented evidence that positive regional adjustments have contributed to ACOs receiving inflated benchmarks and substantial shared savings payments without decreasing costs relative to what spending levels would have been in the absence of the Shared Savings Program. MedPAC included recommendations for alternatives to the positive regional adjustment for consideration by CMS. These include higher shared savings rates, protection from shared losses up to an amount equivalent to the regional adjustment, and prospective trend factors that could be slightly higher relative to an ACO's regional spending.

Given their criticism that the regional adjustment has generated ''illusory savings'' in the Shared Savings Program, MedPAC urged CMS to use the prior savings adjustment as a means of phasing out the regional adjustment. MedPAC expressed a belief that while the prior savings adjustment is a reasonable policy for mitigating ratcheting effects, implementing both policies together would be duplicative. MedPAC also expressed concern that the prior savings adjustment and the regional adjustment could interact in a way that would perpetuate a programmatic bias towards ACOs receiving a positive regional adjustment. In MedPAC's view, many ACOs would receive an inflated prior savings adjustment because the prior savings adjustment would be based on savings achieved using benchmarks already inflated by the regional adjustment. MedPAC's comments regarding interactions between the ACPT and the regional adjustment contain a similar concern. MedPAC asserted that without a downward adjustment to the positive regional adjustments currently received by the majority of ACOs, the ACPT would further subsidize these ACOs without generating real efficiency gains for the Medicare program.

Response: We appreciate the perspective that the regional adjustment has increased savings for certain ACOs, has coincided with increased selective participation in the Shared Savings Program, and could contribute to the over inflation of historical benchmarks if left in place alongside other policies designed to combat ratcheting like the prior savings adjustment and the ACPT. We decline to adopt MedPAC's specific proposed alternatives to the positive regional adjustment because they go beyond the scope of the policies proposed. With respect to the interaction between the prior savings adjustment and the regional adjustment, the design of the proposed approach includes guardrails that we believe will be sufficient to prevent ACO historical benchmarks from becoming overly inflated and enabling ACOs to earn shared savings payments without decreasing spending. Specifically, ACOs could only receive the greater of the prior savings adjustment and the regional adjustment under the proposed policy, we would apply a proration factor to help ensure that the prior savings adjustment does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute the benchmark years for its current agreement period due to growth in assigned beneficiaries, and the size of the final adjustment would be capped. With respect to interactions between the ACPT, the prior savings adjustment, and the regional adjustment more broadly, we note that each of these policies is designed to address different dynamics within the benchmark. However, we intend to monitor the collective impacts of these approaches on ACO benchmarks for evidence of over-inflation or negative impacts to the Trust Fund. We may address these issues in future rulemaking if necessary.

Comment: One commenter suggested that CMS provide additional modeling and/or analytical results on the impacts of the prior savings adjustment because the proposed calculations are complex. This commenter preferred removing an ACO's assigned beneficiaries from regional expenditures or expanding the regional service area to the more complicated prior savings adjustment.

Response: Since the issuance of the proposed rule we have conducted additional modeling of the impact of the prior savings adjustment that we believe clearly shows the potential for ACOs to benefit from the proposed policy. We refer readers to Table 69 and the related description of this modeling within this section of this final rule. We have provided detailed descriptions and examples in the proposed rule and this final rule on how the prior savings adjustment will be calculated, and we also anticipate updating the Shared Savings Program's publicly available specifications documents, programmatic resources and materials, and the aggregate reports provided to ACOs to include information about how we calculate and apply the prior savings adjustment. In section III.G.5.c.(6) of this final rule, we summarize and respond to comments on the alternative options we considered to address concerns about the effect of an ACO's assigned beneficiaries on regional FFS

expenditures in establishing, adjusting, updating, and resetting the ACO's historical benchmark.

Comment: One commenter supported our proposed prior savings adjustment because they believe it would tend to set persistently higher benchmarks for ACOs that decreased spending during prior participation in the Shared Savings Program. In the commenter's view, the prior savings adjustment would increase the attractiveness of Shared Savings Program participation for such ACOs. However, the commenter expressed concern that, as proposed, the prior savings adjustment may phase out across agreement periods too quickly to combat long-run ratchet effects. The commenter pointed out that, due to the use of a scaling factor to calculate the prior savings adjustment, if an ACO generates savings during an agreement period, a progressively smaller share of those savings would be returned to the benchmark in each successive agreement period. The result, in the commenter's view, is that although the prior savings adjustment would mitigate selective participation concerns in the short-run, in the long-run some ACOs will once again begin to face benchmarks that are too low to allow them to participate, recreating similar ratchet effects that exist under the current benchmarking methodology. The commenter offered an alternative approach under which, in any agreement period that follows an agreement period during which the ACO received a prior savings adjustment, a portion of the earlier prior savings adjustment would be retained regardless of how the ACO performed relative to its benchmark during the agreement period in which it received the prior savings adjustment. This fraction of the ACO's earlier prior savings adjustment, plus any additional prior savings from the ACO's previous agreement period, subject to a discount factor, would constitute the prior savings adjustment for the ACO's new agreement period.

The commenter also urged CMS to consider additional modifications to the Shared Savings Program financial methodology that would encourage efficient ACOs to serve more patients and inefficient ACOs to either become more efficient or serve fewer patients. In particular, the commenter urged CMS to consider modifications that would increase the financial costs to providers and suppliers of opting out of the Shared Savings Program such as reducing the FFS payment rates for non-participating providers and suppliers (which the commenter acknowledges would require legislative action). In the commenter's view, introducing financial penalties for opting out of the Shared Savings Program would enable CMS to move towards an ideal historical benchmarking methodology that places ACOs on a level playing field and reduces reliance on incentives like the prior savings adjustment which increase benchmarks for high cost ACOs.

Response: We appreciate this commenter's support for the proposed prior savings adjustment and their comments on the potential for the effect of the prior savings adjustment to phase out over the course of multiple agreement periods. However, we believe it is appropriate for the prior savings adjustment to fade out over time if the ACO maintains steady spending levels over subsequent agreement periods in order to retain an incentive for ACOs to become more efficient over time. Additionally, ACOs will still be eligible for the positive regional adjustment if they maintain or increase their efficiency relative to their region. The commenter's suggestion that CMS increase the financial costs to providers and suppliers for opting out of participating in the Shared Savings Program, such as by reducing FFS payment rates for non-participating providers and suppliers, is outside the scope of the proposal and would, as the commenter notes, require legislative action.

Comment: One commenter supported our proposal to calculate the final adjustment to an ACO's benchmark as the higher of the positive aggregate regional adjustment and the prior savings adjustment but noted that the policy did not sufficiently account for the impact of an ACO's prior success on future benchmarks. This commenter offered several alternative benchmarking proposals that would involve significant alterations to the regional adjustment and the proposed prior savings adjustment which the commenter claims would ''address the concerns of all new and renewing ACOs, regardless of regional efficiency.'' Under this commenter's suggestions, benchmark options would be flexible. New ACOs and those that are less efficient than their regions would receive purely historical benchmarks until becoming more efficient than their regions, and would receive positive regional adjustments thereafter. ACOs in a second or subsequent agreement period would receive the higher of a purely regional benchmark, a benchmark with 50 percent of prior gross savings added back in, and a benchmark based solely on historical expenditures.

Response: We are unsure how to interpret the commenter's alternative benchmarking proposals. However, we note that they go beyond the scope of the proposed prior savings adjustment and the other modifications we proposed to the Shared Savings Program's benchmarking methodology in the CY 2023 PFS proposed rule. Additionally, relating to the portion of the commenter's recommendations that we understand to recommend more generous alternatives, we believe that the commenter's suggested approach could result in overly generous benchmarks and additional costs to the Shared Savings Program.

After consideration of the public comments, we are finalizing as proposed the methodology for instituting a prior savings adjustment. This new policy will be specified in a new provision at § 425.658 applicable for agreement periods beginning on January 1, 2024, and in subsequent years. This provision also specifies the approach to determining an ACO's eligibility for the prior savings adjustment.

We received no comments directly addressing the proposed proration factor component of the prior savings adjustment calculation, as described in this section of this final rule. We are finalizing without modification our proposal to specify at § 425.658(b)(3)(ii) the application of a proration factor in the calculation of the prior savings adjustment to account for any upward growth in the ACO's assigned population in the benchmark years of the current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period(s). We are also specifying at § 425.652(a)(9) that for the second and each subsequent performance year during the term of the ACO's agreement period, we will redetermine the proration factor used in calculating the prior savings adjustment under § 425.658 to account for any changes in the ACO's assigned beneficiary population in the benchmark years due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology. We clarify, more generally, that we anticipate applying the provisions in § 425.652(a)(9) in a

manner that is consistent with how we have previously applied the existing provision at § 425.601(a)(9), which provides for the redetermination of certain benchmark calculations for the second and each subsequent performance year during the term of the ACO's agreement period to account for changes in the ACO's assigned beneficiary population in the benchmark years. Consistent with this approach, we would only redetermine the proration factor used in the prior savings adjustment calculation, as necessary, to account for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology. If none of these circumstances apply for the second or subsequent performance year, we would not redetermine the proration factor.

Further, we are finalizing in § 425.652(a)(8) the approach for comparing the pro-rated average prior savings amount calculated under § 425.658 with the ACO's regional adjustment amount described in the new provision at § 425.656(c), to determine the applicability of the prior savings adjustment, the regional adjustment, or a combination of these two adjustments.

(5) Reducing the Impact of the Negative Regional Adjustment

(a) Background

In earlier rulemaking we have discussed our use of the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area (81 FR 37962). We initially established a regional adjustment in a benchmark rebasing methodology that applied to ACOs entering a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019 (§ 425.603(c) through (g)), before modifying our policy to apply this adjustment program wide beginning with agreement periods starting on July 1, 2019, and in subsequent years (§ 425.601(a)(8)).

In accordance with § 425.601(a)(8), for ACOs in agreement periods beginning on or after July 1, 2019, we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark (referred to herein as the ''regional adjustment''). As we explained in the CY 2023 PFS proposed rule, the percentage that is applied in calculating the regional adjustment is currently determined in accordance with § 425.601(f) and depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of the applicable weights. For an ACO that has lower spending compared to its regional service area, the weight applied to the regional adjustment is 35 percent for the first agreement period in which the ACO is subject to a regional adjustment and 50 percent in the ACO's second and subsequent agreement periods subject to a regional adjustment. For an ACO that has higher spending compared to its regional service area, the weight is 15 percent for the first agreement period in which the ACO is subject to a regional adjustment, increasing to 25 percent, 35 percent, and 50 percent, for the second, third, and fourth and subsequent agreement periods that an ACO is subject to a regional adjustment, respectively.

As discussed in the proposed rule, we cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (referred to herein as positive or negative 5 percent of national per capita FFS expenditures for assignable beneficiaries, and as the ''symmetrical cap;'' terms which we consider to be synonymous).

Table 70 illustrates how the regional adjustment is calculated under the current policy. For this hypothetical ACO, assumed to be in its first agreement period subject to a regional adjustment, the ACO has lower spending than its regional service area for the ESRD and aged/dual eligible populations (that is, the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures is positive) and higher spending for its disabled and aged/non-dual eligible populations (that is, the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures is negative). The weighted average difference between the region and the ACO, which is used to calculate the ACO's regional adjustment, is determined first by multiplying the difference between average per capita FFS expenditures for the ACO's regional service area and the ACO's average per capita historical benchmark expenditures for each Medicare enrollment type by its respective enrollment type proportion and then summing across the four enrollment types. In this example, because the weighted average is negative (−$495), the ACO is considered to have higher (overall) spending than its regional service area. Thus, the weight used to calculate the regional adjustment for this ACO based on the schedule of weights described in § 425.601(f) is 15 percent. This regional adjustment percentage weight is applied to the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures for each enrollment type (whether positive or negative) to obtain the uncapped regional adjustment for each enrollment type. When comparing these uncapped values to the symmetrical cap of 5 percent of national per capita FFS expenditures for assignable beneficiaries, only the ACO's positive ESRD adjustment is constrained by the cap. The ultimate impact of the symmetrical cap is to increase the ACO's overall weighted average regional adjustment from −$74 to −$77.

TABLE 70: Hypothetical Example of Regional Adjustment Calculation under Current Policy

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Difference Between Average Per Capita Expenditures for ACO's Region and ACO's Historical Benchmark ($)	Weight	Uncapped Regional Adjustment ($)	5% of National Assignable Per Capita Expenditures ($)*	Capped Regional Adjustment ($)
ESRD	0.020	29,667	15%	4,450	4,299	4,299
Disabled	0.170	-1,120	15%	-168	591	-168
Aged/dual	0.110	2,827	15%	424	880	424
Aged/non-dual	0.700	-1,727	15%	-259	528	-259
Weighted Average		-495		-74		-77

*Values in column "5% of National Assignable Per Capita Expenditures ($)" reflect values from the performance year from July 1, 2019, through December 31, 2019 (referred to as 2019A).

In the CY 2023 PFS proposed rule, we explained that the current schedule of weights described in § 425.601(f)) and the positive or negative 5 percent cap on the regional adjustment described in § 425.601(a)(8)(ii)(C)) were finalized in the December 2018 final rule (83 FR 68017 through 68024). These policies were designed to address a dynamic where the regional adjustment could provide overly inflated benchmarks for ACOs that are relatively low spending compared to their region, while ACOs with higher spending compared to their region may find little value in remaining in the program when faced with a significantly reduced benchmark. We also explained our belief that these policies would make the benchmark more achievable for ACOs that care for medically complex patients and are high spending compared to their region, thereby encouraging their continued participation, while at the same time preventing windfall shared savings payments for ACOs that have relatively low spending levels relative to their region (83 FR 67822).

As discussed in the section entitled ''Overview of Considerations for Modification to the Benchmarking Methodology'' (section III.G.5.c.(2) of this final rule), we now believe that the existing negative 5 percent cap may not limit the negative regional adjustment enough to provide sufficient incentive for participation among ACOs serving high cost, medically complex populations. In the proposed rule, we noted that we have concerns that setting the cap on negative regional adjustments at negative 5 percent may limit opportunities for these beneficiaries, who arguably have the greatest need to receive coordinated care, as well as potential savings for the Trust Funds. Therefore, we noted that we believe it is important to further reduce the impact of negative regional adjustments, particularly for ACOs caring for high cost populations, including high-risk patients and beneficiaries dually eligible for Medicare and Medicaid, beyond what is allowed under the current regulation at § 425.601(a)(8)(ii)(C).

(b) Revisions

We proposed to institute two policy changes designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries:

- Reduce the cap on negative regional adjustments from negative 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries to negative 1.5 percent.
- After the cap is applied to the regional adjustment, gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases.

The choice of a negative 1.5 percent cap was informed by CMS' experience with use of a 2 percent cap on negative regional expenditure adjustments under the Global and Professional Direct Contracting Model (to be redesigned and renamed as the ACO Realizing Equity, Access, and Community Health (REACH) Model beginning January 1, 2023), as well as considerations related to the potential longer-term vision for use of an administratively set benchmark under which a negative discount for less efficient ACOs could be approximately 1.6 percent over the ACO's agreement period as described in the comment solicitation on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program in section III.G.7. of the proposed rule.

Under this proposal, we would continue to apply a cap equal to positive 5 percent of national per capita expenditures for assignable beneficiaries to positive regional adjustments for each enrollment type. Table 71 illustrates how the cap would be applied asymmetrically to positive and negative regional adjustments under this proposal.

TABLE 71: Hypothetical Example of Cap on Regional Adjustment

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Uncapped Regional Adjustment ($)	5% of National Assignable Per Capita Expenditures ($)	-1.5% of National Assignable Per Capita Expenditures ($)	Capped Regional Adjustment ($)
ESRD	0.020	4,450	4,299	-1,290	4,299
Disabled	0.170	-168	591	-177	-168
Aged/dual	0.110	424	880	-264	424
Aged/non-dual	0.700	-259	528	-158	-158
Weighted Average		-74			-7

The hypothetical ACO in this example had a mix of positive and negative regional adjustments across the four enrollment types. The ACO's uncapped ESRD adjustment is positive and above the positive 5 percent cap. Therefore, it falls from $4,450 to $4,299 when the cap is applied. The ACO's uncapped aged/non-dual eligible adjustment is outside the new negative 1.5 percent cap and thus falls from −$259 to −$158 when the cap is applied. The ACO's disabled and aged/dual eligible adjustments are both under the applicable caps and are unaffected. The ACO's overall weighted average regional adjustment (calculated by multiplying the adjustment for each enrollment type by the corresponding enrollment type proportion and then summing across the four enrollment types) falls from −$74 to −$7 when the cap is applied. Note that under the current policy with a symmetrical cap equal to 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries, only the ACO's ESRD adjustment would be constrained. The ACO's aged/non-dual eligible adjustment would remain at −$259 and the ACO's overall adjustment would actually become more negative (−$77) after capping (as shown in Table 71).

For negative regional adjustments, we also proposed to apply an offset factor based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) [341] and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types. Before taking this weighted average, the risk score for each enrollment type would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Specifically, the offset factor would be calculated as:

Offset factor = [A] + ([B] − 1)

This offset factor would be applied to negative regional adjustments after the negative 1.5 percent cap is applied. The offset factor would be subject to a minimum of zero and a maximum of one. We would apply the offset factor by subtracting its value from 1 and multiplying this difference by the negative regional adjustment for each Medicare enrollment type, calculated as:

Final regional adjustment = Negative regional adjustment × (1 − Offset factor)

The higher an ACO's proportion of dually eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment (that is, the negative weighted average regional adjustment would be fully offset). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

To illustrate how the offset would be calculated and applied, assume that the hypothetical ACO from Table 72 had a proportion of dually eligible beneficiaries of 0.220 and a weighted average prospective HCC risk score for BY3 of 1.389. The offset factor for this ACO would be calculated as:

Offset factor = 0.220 + (1.389 − 1) = 0.609

This factor would be applied as illustrated in Table 72 by multiplying the negative regional adjustment for each applicable Medicare enrollment type by 1 minus the offset factor or 0.391.

[341] In computing this proportion, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

TABLE 72: Hypothetical Example of Offset Factor Applied to Negative Regional Adjustments

Medicare Enrollment Type	Enrollment Proportion	Capped Regional Adjustment (Before Offset) ($)	Offset Factor	1 – Offset Factor	Final Regional Adjustment ($)
ESRD	0.020	4,299	N/A	N/A	4,299
Disabled	0.170	-168	0.609	0.391	-66
Aged/dual	0.110	424	N/A	N/A	424
Aged/non-dual	0.700	-158	0.609	0.391	-62
Weighted Average		-7			78

Here, the offset factor would be applied to the regional adjustments for the disabled and aged/non-dual eligible populations, as both are negative, but not to the regional adjustments for the ESRD and aged/dual eligible populations, which are both positive. Taking the weighted average across the enrollment types following application of the offset factor shows that the ACO's overall weighted regional adjustment goes from −$7 before the offset to $78 after the offset, a positive per capita impact of $85.

In the proposed rule, we noted that it would be possible for an ACO to benefit from one aspect of the proposed policy, but not the other. For example, ACOs that have negative regional adjustments that are below the negative 1.5 percent cap will not be affected by the proposed reduction to the cap but could still benefit from the proposed offset factor. Alternatively, an ACO whose negative adjustment is reduced by the negative 1.5 percent cap would receive no further benefit from the offset factor if it has a low proportion of dually eligible beneficiaries or a low risk score such that the offset factor equals 1.

We simulated the combined impact of the policy proposals using data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019. The results of this simulation are summarized in Table 73.

TABLE 73: Simulated Impact of Negative 1.5% Cap and Offset Factor to Negative Regional Adjustments

	Total ACOs	ACOs with Negative Weighted Average Regional Adjustment Under Current Policy	ACOs with Positive Weighted Average Regional Adjustment Under Current Policy
Number of ACOs			
Total	356	43	313
No Impact	146	3	143
Impacted	210	40	170
Impacted by -1.5% Cap Only	8	0	8
Impacted by Offset Factor Only	117	26	91
Impacted by Both	85	14	71
Per Capita Impact among Impacted ACOs			
Average	$25.66	$113.92	$4.89
Minimum	< $0.01	$0.57	< $0.01
Maximum	$789.22	$789.22	$72.40

Under the policy proposals, the negative regional adjustment for almost every ACO that had a negative regional adjustment in PY 2020 under current policy (40 out of 43 ACOs) would have been reduced (or eliminated), with an average per capita impact of approximately $114. ACOs with higher weighted average BY3 prospective HCC risk scores and higher proportions of dually eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. Four ACOs in the simulation had an offset factor of 1, meaning they received a full offset to their negative regional adjustments. An additional 170 ACOs that had a positive weighted average regional adjustment under the current policy but that had at least one enrollment type with a negative regional adjustment would also have benefitted from the combined policy. The average per capita impact among these ACOs was smaller at around $5. We believe that the impacts observed in our simulation are likely to grow larger as more ACOs progress further in the program and are subject to higher weights in the calculation of the regional adjustment, and as more ACOs that serve high cost and medically complex populations join the program.

We considered whether to make the changes applicable only to ACOs that would have had a negative weighted average regional adjustment under the current policy (that is, ACOs for which the regional adjustment has an overall negative impact on the per capita historical benchmark). However, we explained our belief that applying the lower cap and the offset factor at the enrollment type level would be more straightforward and would have the

opportunity to benefit ACOs that may be serving high risk populations in at least one, but not all Medicare enrollment types.

We sought comment on the proposed changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years. The proposed changes would be reflected in a proposed new provision at § 425.656. We also proposed to specify in paragraph (a)(8) of the proposed new provision at § 425.652, also applicable for agreement periods beginning on January 1, 2024, and in subsequent years, the approach for comparing the pro-rated average prior savings amount (described in proposed § 425.658(b)(3)(ii)) with the ACO's regional adjustment amount (described in proposed § 425.656(c)), to determine the applicability of the prior savings adjustment, the regional adjustment, or a combination of these two adjustments.

The following is a summary of the public comments received on our proposals to reduce the impact of the negative regional adjustment and our responses:

Comment: Many commenters supported the proposal to: (1) reduce the cap on negative regional adjustments from negative 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries to negative 1.5 percent, and (2) after the cap is applied to the regional adjustment, gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases.

Many commenters explained their support for the proposal, noting it will incentivize certain ACOs to join the program, such as those that are higher spending or care for underserved, complex, dually eligible, or high-cost beneficiaries. Several commenters supported the proposal stating that it will further incentivize higher spending ACOs to join the program, as well as increase participation from providers and suppliers who care for underserved and complex populations, which they stated addresses existing equity concerns. Several commenters noted that the policy will incentivize participation of ACOs that serve high-cost beneficiaries. One commenter agreed with CMS' concern that ACOs may be higher cost relative to their regions as a result of caring for the highest needs populations rather than being inefficient, and that the current negative regional adjustment policy impacts ACOs serving medically-complex, high-cost populations by creating barriers for existing ACOs to continue their participation in the Shared Savings Program, and for non-participating Medicare providers/suppliers caring for similar populations to join the Shared Savings Program. Another commenter stated that they support CMS' effort to ''tailor'' adjustments based on the specific population served by an ACO, such as through the population's average risk score or proportion of dually eligible beneficiaries, and recommended that CMS utilize the methodology which best advantages ACOs serving those acute, complex, and/or vulnerable populations.

A few commenters indicated that they believe the proposed modifications to limit the impact of the negative regional adjustment will help their ACO(s) specifically, stating they serve high-cost or medically complex populations. One commenter noted that their benchmark was ''penalized'' in their initial agreement period because they serve medically complex patients which resulted in their ACO having higher spending relative to its region. The commenter stated and that the proposed policy would help to mitigate this effect.

One commenter, who was supportive of the proposed policy, explained how they believe the current policy disincentivizes higher cost ACOs from joining the Shared Savings Program. The commenter noted that under the current benchmarking methodology CMS calculates an ACO's historical spending and then makes an adjustment based on the spending in the ACO's region. For ACOs that have spending that is higher than their region, the regional adjustment reduces their benchmark below their historical spending level, which the commenter states makes it more difficult for the ACO to achieve shared savings. As a result, the commenter noted ACOs with higher spending relative to their region are less likely to join the Shared Savings Program. The commenter added that more high spending ACOs exited the program than low spending ACOs when the regional adjustment was initially introduced. The commenter noted that current policy has led to selection bias against high spending ACOs, which may result in missed opportunities for generating savings to Medicare and constraining overall spending because these ACOs have the ''greatest potential'' for savings.

A few commenters cited their findings that the proposed policy would positively benefit 11 percent of currently participating ACOs. Another commenter cited CMS's estimate that the policy would benefit nearly all ACOs. One commenter stated their support for reducing the cap on negative regional adjustments to 1.5 percent, but noted that there is an argument that completely removing the negative adjustment would help maximize growth. The commenter did not indicate the type of growth they were referring to. However, the commenter noted that growth is not the only consideration and so agreed that the 1.5 percent cap balances growth with other considerations. Another supportive commenter recommended that CMS monitor the effects of the proposed policy on ACOs, especially ACOs that care for high cost or medically complex patients.

Response: We agree with commenters that the proposed policy would incentivize certain ACOs either to continue their participation in or to join the Shared Savings Program, and we are finalizing the proposal to modify the calculation of the negative regional adjustment with a modification to correct the description of the calculation.

For the reasons we provided in the CY 2023 PFS proposed rule, and as reflected in commenters' support for the proposed approach, we continue to believe reducing the impact of the negative regional adjustment will facilitate participation of ACOs in the Shared Savings Program, in particular ACOs with spending above their regional benchmark and those serving medically complex, high cost populations. Further, we have continued to evaluate our proposal since issuance of the CY 2023 PFS proposed rule, including performing additional modeling with benchmark data for ACOs with an agreement period beginning on January 1, 2022. This additional modeling yielded similar results to the PY 2020 modeling discussed earlier in this section with results presented in Table 73.

In the CY 2023 PFS proposed rule (87 FR 46161 and 46180), we noted that we had concerns that setting the cap on negative regional adjustments at negative 5 percent may limit opportunities for high cost, medically complex beneficiaries, who arguably have the greatest need to receive coordinated care, as well as potential savings for the Trust Funds. For example, in PYs 2017 through 2019, just over 80 percent of ACOs subject to a regional adjustment received a positive adjustment, indicating their spending was lower than spending in their regional service area. More recently, the

share of ACOs receiving a positive regional adjustment is closer to 90 percent. This pattern also holds true in our analysis of PY 2022 historical benchmarks, with 87 percent of ACOs starting an agreement period on January 1, 2022 receiving a positive regional adjustment. This pattern suggests selective participation behavior, where ACOs that have already achieved efficiency or that are serving beneficiaries with lower health risks are more likely to participate in the Shared Savings Program. Providers and suppliers with the greatest opportunity to reduce spending (those that are inefficient and high spending relative to their region and that would receive a negative regional adjustment if they formed an ACO) are less likely to participate under the current methodology, limiting savings for the Medicare program. In the proposed rule, we also noted that additional analysis has suggested that ACOs receiving the largest negative regional adjustments tend to be those serving beneficiaries with high average risk scores and/or high proportions of beneficiaries dually eligible for Medicare and Medicaid. This pattern was also observed in our more recent analysis of PY 2022 historical benchmarks among ACOs starting an agreement period on January 1, 2022. These findings suggest that these ACOs may be higher cost relative to their regions as a result of caring for high needs populations rather than being inefficient, and that ACOs serving medically complex, high cost populations may have more difficulty participating in the Shared Savings Program. However, we also note that, similar to the findings discussed in section III.G.1.a of this final rule, we have observed that the highest earning ACOs are those ACOs providing care for a higher proportion of aged/dual eligible Medicare and Medicaid beneficiaries and higher average risk scores than the lowest earning ACOs, further supporting the rationale for reducing the negative regional adjustment.

We believe the modifications to the calculation of the negative regional adjustment that we are finalizing in this final rule will generate higher benchmarks among ACOs with spending above their regional benchmark and those serving medically complex, high cost populations and will provide more achievable benchmarks to measure the performance of these ACOs. Additionally, because we decided not to limit the proposal only to those ACOs that have a negative weighted average regional adjustment, as discussed earlier in this section of the final rule, we believe this policy will also generate higher benchmarks for many ACOs with overall lower spending than their region, but that may have higher spending for one or more Medicare enrollment types. In section III.G.5.c.(5).(b) of the proposed rule, we discussed our simulation of the impact of the proposals to limit the impact of the negative regional adjustment using data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019 (summarized in Table 73 of this final rule). Based on this simulation, a majority of ACOs would have seen increased historical benchmarks in PY 2020 under this proposed policy compared to current policy. This was also observed in more recent simulations using data from PY 2022 historical benchmarks among ACOs starting a new agreement period on January 1, 2022.

We need to provide a correction to the methodology for the calculation of the offset factor that was described in the proposed rule, and update the values related to the PY 2020 simulation summarized in Table 73 of this final rule to reflect this correction. In the CY 2023 PFS proposed rule, we proposed to apply an offset factor based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) [342] and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types (87 FR 46181). The offset factor was specified in the proposed new regulation at § 425.656(c)(4) as the sum of the proportion of the ACO's BY3 assigned beneficiaries that are dual eligible for Medicare and Medicaid and the difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and 1. However, we need to correct this definition to address how the weight for each Medicare enrollment type would be calculated for purposes of determining the weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types. Accordingly, we are modifying the text of § 425.656(c)(4)(ii) in this final rule for consistency with this corrected approach. In calculating the weighted average prospective HCC risk score for BY3, the weight applied to the prospective HCC risk score for BY3 for each enrollment type would be equal to the product of the BY3 per capita expenditures for that enrollment type and the BY3 person years for that enrollment type. We note that the use of these weights to determine weighted average prospective HCC risk scores is similar to the proposal to use a weighted average risk ratio in setting the 3 percent cap on risk score growth as discussed in section III.G.5.e.(2) of this final rule. The correction we are making to the methodology used to calculate the offset factor is to ensure consistency between these two policies. We believe that weighting prospective HCC risk scores for BY3 using both BY3 per capita expenditures and BY3 person years is warranted to account for both the proportion of beneficiaries in each enrollment type, which is typically highest for the aged/non-dual eligible enrollment type, and per capita expenditures for each enrollment type, which tend to be highest in the ESRD and aged/dual eligible Medicare enrollment types. Additionally, we are modifying the text of § 425.656(c)(4)(i) in this final rule to say ''dually eligible for Medicare and Medicaid'' instead of ''dual eligible for Medicare and Medicaid'' for consistency of terminology used in this final rule and elsewhere in the regulations. This is not a substantive modification to the proposals included in the proposed rule.

In the simulation results presented in Table 62 of the proposed rule (87 FR 46182), and restated in Table 73 of this final rule, we calculated a weighted average prospective HCC risk score for BY3 where the weight applied to the prospective HCC risk score for BY3 for each enrollment type was equal only to the BY3 person years for that enrollment type, instead of the product of BY3 per capita expenditures for that enrollment type and the BY3 person years for that enrollment type. For this final rule, we have rerun this simulation to recalculate the weighted average prospective HCC risk score for BY3 across the four Medicare enrollment types after weighting each enrollment type by the product of BY3 per capita expenditures for that enrollment type and the BY3

[342] We note that in simulations of this policy proposal, when calculating ''[A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries)'', we used, for each beneficiary, the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid. This fraction of the year included months associated with episodes of care for the treatment of COVID–19. In operationalizing this proposal when finalized, this fraction would not include months associated with episodes of care for the treatment of COVID–19 (refer to § 425.611).

person years for that enrollment type. The updated results are reported in Table 74 of this final rule. The numbers of ACOs remain the same in the table; however, there are very small changes in dollar amounts provided in the ''Per Capita Impact among Impacted ACOs'' section of the table (all less than a dollar). The overall impact of this change to the methodology used to determine the offset factor was relatively small for all ACOs in the simulation, and led to changes in the impact of the simulation on the historical benchmark in both positive and negative directions (average change −$0.07, minimum −$6.13, and maximum $3.48).

TABLE 74: Simulated Impact of Negative 1.5% Cap and Offset Factor to Negative Regional Adjustments using Corrected Weighted Average Prospective HCC Risk Score for BY3, PY 2020

	Total ACOs	ACOs with Negative Weighted Average Regional Adjustment Under Current Policy	ACOs with Positive Weighted Average Regional Adjustment Under Current Policy
Number of ACOs			
Total	356	43	313
No Impact	146	3	143
Impacted	210	40	170
Impacted by -1.5% Cap Only	8	0	8
Impacted by Offset Factor Only	117	26	91
Impacted by Both	85	14	71
Per Capita Impact among Impacted ACOs			
Average	$25.58	$113.62	$4.87
Minimum	< $0.01	$0.56	< $0.01
Maximum	$789.22	$789.22	$71.59

In addition, since the issuance of the CY 2023 PFS proposed rule, we have simulated the impact of the proposed modifications to the negative regional adjustment using data from PY 2022 historical benchmarks among ACOs starting a new agreement period on January 1, 2022, and using the corrected weights to determine the weighted average prospective HCC risk score for BY3. Results of this simulation are provided in Table 75.

TABLE 75: Simulated Impact of Negative 1.5% Cap and Offset Factor to Negative Regional Adjustments, PY 2022

	Total ACOs	ACOs with Negative Weighted Average Regional Adjustment Under Current Policy	ACOs with Positive Weighted Average Regional Adjustment Under Current Policy
Number of ACOs			
Total	206	27	179
No Impact	77	1	76
Impacted	129	26	103
Impacted by -1.5% Cap Only	10	0	10
Impacted by Offset Factor Only	77	15	62
Impacted by Both	42	11	31
Per Capita Impact among Impacted ACOs			
Average	$12.24	$47.78	$3.27
Minimum	< $0.01	$0.15	< $0.01
Maximum	$779.94	$779.94	$29.89

In these PY 2022 simulation results (Table 75), the negative regional adjustment for almost every ACO that had a negative regional adjustment under current policy (26 out of 27 ACOs) would have been reduced (or eliminated). This is very similar to the PY 2020 simulation results (Table 74).

In the PY 2022 simulation, similar to the PY 2020 simulation, ACOs with higher weighted average BY3 prospective HCC risk scores and higher proportions of dually eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. These results also show that in both our PY 2020 and PY 2022 simulations, these policies generated higher benchmarks than the current policy for a majority of ACOs,

whether or not they had higher spending than their region. However, as shown in the PY 2022 simulations, among ACOs with a positive weighted average regional adjustment, the average impact on benchmarks was only around $3, or about 1 percent of the average positive regional adjustment of about $268. In comparison, among ACOs with a negative weighted average regional adjustment, the average impact on benchmarks was around $48, or about 52 percent of the average negative regional adjustment of about −$92. As discussed elsewhere in this final rule, we decided not to limit the proposal only to those ACOs that have a negative weighted average regional adjustment in order to provide the opportunity to benefit ACOs that may be serving high risk populations in at least one, but not all Medicare enrollment types. However, we note that those ACOs with a positive weighted average regional adjustment would likely receive only a minor benefit from this policy based on the aforementioned simulation results.

Comment: One commenter urged CMS to allow ACOs that are in the middle of an agreement period on January 1, 2024, the flexibility to opt into the proposed negative regional adjustment policy without having to early renew, a process which the commenter described as being onerous. Another commenter also asked CMS to expand the negative regional adjustment policy to apply to ACOs currently participating in the Shared Savings Program.

Response: We decline the commenters' suggestion and are maintaining our proposal that ACOs would be subject to the changes we are finalizing to the negative regional adjustment on an agreement period basis. The modified approach we are finalizing to the calculation of the negative regional adjustment will apply to ACOs entering a new agreement period beginning on or after January 1, 2024. Elsewhere in section III.G.5 of this final rule, we explain our concerns regarding applying benchmarking changes to ACOs within an agreement period in responding to similar suggestions. Among other reasons, such an approach would introduce considerable operational complexity into the program's benchmarking methodology, particularly as the modified approach to calculation of the negative regional adjustment is one of a package of changes we are finalizing to the benchmarking methodology to be applicable for agreement periods beginning on January 1, 2024, and in subsequent years.

We recognize that currently participating ACOs that entered an agreement period prior to January 1, 2024, may wish to pursue the option to early renew for a new agreement period beginning on January 1, 2024, by terminating their current agreement and immediately entering a new agreement period, so that they would have the opportunity to participate under the revised benchmarking methodology. (Refer to paragraph (2) of the definition of ''renewing ACO'' in § 425.20, and the application procedures set forth in § 425.224.) We note that early renewal, like renewing upon completion of an agreement period, will result in rebasing of the ACO's historical benchmark, and will affect the ACO's eligibility for certain participation options (refer to section III.G.2. of this final rule), as well as the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (refer to § 425.600(f)).

Comment: Many commenters supportive of the proposed policy had suggestions for additional policy changes that went beyond the scope of modifications we proposed to the regional adjustment methodology. One commenter suggested that high-cost ACOs may see the negative regional adjustment proposal as making the Shared Savings Program more attractive, but these ACOs may still not participate if regional trends are not accurately reflected in historical benchmark update factors.

Several commenters recommended that CMS further lower the negative regional adjustment cap based on the proportion of an ACO's population that is assigned based on primary care services furnished by specialists (Step 2 of the assignment methodology [343]). The commenters explained that even after accounting for their higher risk scores, beneficiaries assigned through specialists have higher costs than those who are assigned based on services furnished by primary care providers (Step 1 of the assignment methodology [344]) in the same given region.

Another commenter requested that CMS move ACOs with lower spending than their region to fully regional benchmarks over time (for example, by their second agreement period). The commenter also stated that CMS should allow ACOs with higher spending than their region to ''remain in historical benchmarks'' until they become efficient relative to their regions, then phase in the regional adjustment. The commenter noted that this additional modification would serve CMS' goal of encouraging increased participation in the program.

Another commenter requested that CMS consider two additional modifications to the regional adjustment policy: (1) extend the scope of the policy to apply a similar offset factor for positive regional adjustments; and (2) account for changes in an ACO's proportion of beneficiaries dually eligible for Medicare and Medicaid between its BY3 and the performance year when updating the ACO's benchmark to reflect changes in the cost of care for assigned beneficiaries with ''social needs,'' similar to what is done in risk adjustment to account for changes in severity and case mix between BY3 and the performance year.

MedPAC noted concern that risk adjustment may not be adequately accounting for an ACO's regional efficiency. They explained that regional adjustments to benchmarks rely heavily on the accuracy of risk adjustment and presented evidence that ''discrepancies'' in the CMS–HCC risk adjustment model may penalize ACOs that disproportionately serve high-needs populations. They added that ACOs can create favorable bias in regional adjustments by being selective about identifying physician practices that serve assignable beneficiaries with low risk-adjusted spending. They provided (in response to our proposals for adjusting benchmarks to account for an ACO's prior savings and reducing negative regional adjustments) their recommendations for phasing out the regional adjustment to an ACO's benchmark expenditures.

Response: At this time, we decline the commenters' suggestions as summarized in the comment summary above. These suggestions go beyond the scope of the modifications we proposed to the program's regional adjustment methodology. In regards to the commenters' concern that high-cost ACOs may still not participate in the program if they believe regional trends are not accurately reflected in historical benchmark update factors, we note that we believe that incorporating a prospective, external factor that is risk adjusted in the growth rates used to update the historical benchmark (see section III.G.5.c.(3) of this final rule) will help to mitigate this concern by decreasing the weight placed on the two-way blend of national and regional growth rates when updating an ACO's historical benchmark for each performance year in the ACO's agreement period. In regards to the

[343] Refer to § 425.402(b)(4).

[344] Refer to § 425.402(b)(3).

commenters' concerns that regional adjustments to benchmarks (that rely on the accuracy of risk adjustment) may penalize ACOs that disproportionately serve high-needs populations, we believe the proposal to reduce the cap on negative regional adjustments from negative 5 percent to negative 1.5 percent, and then gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases, will address this concern.

After consideration of public comments, we are finalizing our proposal to make changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years, with a modification to correct an error in the description of the methodology in the proposed rule and a non-substantive modification for consistency of terminology, both of which were discussed earlier in this section of this final rule. Under this final policy, we will apply a cap on the negative regional adjustment at negative 1.5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries, and after the cap is applied to the regional adjustment, gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases. We are also finalizing our proposal to specify the provisions related to the calculation of the regional adjustment to the benchmark in a new regulation at § 425.656. However, we are revising § 425.656(c)(4)(ii) to specify that when calculating the weighted average prospective HCC risk score for BY3 across the four Medicare enrollment type, the weight applied to the prospective HCC risk score for BY3 for each enrollment type is equal to the product of the BY3 per capita expenditures for that enrollment type and the BY3 person years for that enrollment type.

We are also finalizing without modification our proposal to specify in paragraph (a)(8) of § 425.652, also applicable for agreement periods beginning on January 1, 2024, and in subsequent years, the approach for comparing the pro-rated positive average prior savings amount (described in § 425.658(b)(3)(ii), and as discussed in section III.G.5.c.(4) of this final rule) with the ACO's regional adjustment amount (described in § 425.656(c)), to determine the applicability of a prior savings adjustment, the regional adjustment, or a combination of these two adjustments.

(6) Alternative Options for Addressing Concerns About the Effect of an ACO's Assigned Beneficiaries on Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

ACOs and other interested parties have expressed concerns with CMS' approach to determining regional FFS expenditures using a population of assignable beneficiaries that includes an ACO's assigned beneficiaries including, with respect to the impact on the calculation of the regional adjustment and the blended national-regional growth rate used to trend and update the ACO's historical benchmark, suggesting this policy results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which may tend to be ACOs located in rural areas. In the CY 2022 PFS proposed rule (86 FR 39291 through 39294), we sought comment on a number of potential approaches to addressing these concerns, as well as any unintended consequences that may result from removing an ACO's assigned beneficiaries from regional calculations. We summarized comments received in the CY 2022 PFS final rule (86 FR 65296 through 65302). In sections III.G.5.c.(3) through (5) of the proposed rule (87 FR 46158 through 46183), we proposed a package of three provisions: incorporating a prospective, external factor in the growth rates used in updating the benchmark; adjusting rebased benchmarks to account for an ACO's prior savings; and reducing the impact of negative regional adjustments on ACO benchmarks. We designed this package of proposed provisions to, among other things, address concerns associated with including an ACO's own beneficiaries in its regional FFS expenditures. For example, the proposed inclusion of the ACPT in the growth rates used to update the benchmark based on a three-way blend would reduce the impact of including an ACO's assigned beneficiaries in the regional component of the blend. Under the proposal to use the higher of a prior savings adjustment, a positive regional adjustment, or a combination of both, the proposed prior savings adjustment could increase the historical benchmark for an ACO whose regional adjustment could have been decreased by the inclusion of its own assigned beneficiaries in the regional expenditure calculation.

As discussed in the proposed rule (87 FR 46183 through 46186), we also considered alternative options to this package of three proposals that would more directly reduce the effect of the ACO's own beneficiaries on its regional FFS expenditures: (1) removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations; and (2) expanding the definition of the ACO's regional service area to use a larger geographic area to determine regional FFS expenditures. We noted that these related approaches were among the policies we discussed and on which we sought comment in the CY 2022 PFS proposed rule. We also noted that we considered whether to use a combination of these two alternative approaches under which we would expand the ACO's regional service area in combination with removing an ACO's assigned beneficiaries from the assignable beneficiary population used in calculating regional FFS expenditures. In evaluating these alternative approaches, we considered the comments we received in response to that comment solicitation (summarized in the CY 2022 PFS final rule) and considered the extent to which each alternative would address three core concerns (or dynamics) previously described in section III.G.5.c.(2) of the proposed rule (87 FR 46160) and summarized here:

- Mitigating the ratchet effect to ensure ACOs' rebased benchmarks remain accurate and serve as a reasonable baseline.
- Reducing a single ACO's or multiple ACOs' collective impacts on an ACO's regional expenditures, which are used to calculate the regional adjustment and the regional portion of the trend and update factors.
- Ensuring the benchmarking methodology results in benchmarks of sufficient value to encourage program entry and continued participation by ACOs, ACO participants, and ACO providers/suppliers serving medically-complex, high-cost populations.

We also noted that we considered the extent to which the alternatives could lead to other unintended consequences including introducing excessive benchmark volatility or creating incentives for market consolidation. We noted some of these alternatives may require use of our authority under section 1899(i)(3) of the Act to implement alternative benchmarking methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, including alternative

approaches to updating the historical benchmark. We explained that in order to use our authority under section 1899(i)(3) of the Act, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. We noted that as of the time the CY 2023 PFS proposed rule was issued, we had not performed an analysis of the extent to which the alternative approaches would meet the requirements of section 1899(i)(3) of the Act, when use of this authority would be necessary for implementing such approaches within the Shared Savings Program's financial methodology.

In the proposed rule, we described the alternative options that we considered in more detail, as well as our assessment of the ability of each alternative to address the three core concerns we articulated and the other factors considered. We sought comment on these alternative options noting that interested parties would have the opportunity to consider their merits relative to the package of policies we proposed in sections III.G.5.c.(3) through (5) of the proposed rule (87 FR 46158 through 46183). We also sought comment on certain operational factors that we would need to address with greater specificity if we were to finalize any of the alternatives. We noted that we would consider the comments received on these alternative options along with the comments on the proposed package of policies in the development of our final policy, and that we might consider adopting one or both of the alternatives in lieu of the package of policies we proposed in section III.G.5.c.(3) through (5) of the proposed rule.

Alternative 1: Removing an ACO's Assigned Beneficiaries From the Assignable Beneficiary Population Used in Regional Expenditure Calculations

Under the first alternative considered, which aligns with suggestions made by some ACOs and other interested parties, we would exclude an ACO's assigned beneficiaries from the population of assignable beneficiaries in the ACO's regional service area used to determine the regional FFS expenditures used in all benchmarking calculations including trending and updating the benchmark and calculating the regional adjustment. We noted in the proposed rule (87 FR 46184) that if we were to adopt this first alternative to remove the ACO's own assigned beneficiaries but not also adopt the alternative to expand the ACO's regional service area under a combined approach, the ACO's regional service area would remain as all counties where one or more beneficiaries assigned to the ACO reside (as defined under § 425.20). If we were to adopt a combined alternative, we would consider a modified definition of the ACO's regional service area. To remove an ACO's assigned beneficiaries from the regional expenditure calculation, we would use the mathematical approach described in the CY 2022 PFS proposed rule (86 FR 39292 and 39293), which relies on the premise that per capita risk-adjusted FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk-adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk-adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share [345] and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) × (ACO's regional market share)] + [(c) × (1 − ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, we would insert the applicable values for (a), (b), and regional market share (all data elements already computed under the current benchmarking methodology) into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) − [(b) × (ACO's regional market share)]}/(1 − ACO's regional market share).

By using such ACO- and regional-level values, this approach, performed separately by Medicare enrollment type, would avoid the need to calculate individualized ACO county-level risk-adjusted expenditures. As such, and by leveraging existing data elements, we noted our belief that this approach would pose relatively limited operational burden.

As described in the CY 2022 PFS final rule, some of the commenters responding to our initial comment solicitation indicated CMS' mathematical approach was ''directionally correct,'' relatively simple, and would work well in nearly every case while using data that CMS already produces (86 FR 65299 and 65300). However, in the CY 2022 PFS final rule we also noted that we share the concerns raised by several commenters that an approach to remove an ACO's assigned beneficiaries from the assignable population could incentivize ACOs to ''cherry-pick'' healthier, lower-cost patients and could unfairly penalize ACOs that specialize in more medically-complex, higher-cost patients, running counter to one of the core dynamics we seek to address (86 FR 65300 and 65301). Similarly, we indicated that we are also concerned that this approach would incentivize market consolidation, as ACOs may anticipate a benefit to maintaining the largest market share in the region if their own assigned beneficiaries are removed from the assignable population. Additionally, removing an ACO's assigned beneficiaries from the calculation of regional FFS expenditures could yield unstable estimates due to small sample sizes in areas with high program penetration and/or in rural areas. As a result, an approach that would remove an ACO's assigned beneficiaries from the assignable population used to calculate regional FFS expenditures could result in a situation where the ACO's assigned population is relatively healthier and less costly than the assignable beneficiary population in the regional service area, which in turn would result in higher benchmarks for ACOs and thereby greater shared savings payments and reduced shared losses. More generous benchmark updates resulting from this approach could jeopardize CMS' use of the statutory authority under section 1899(i)(3) of the Act to adopt such an alternative approach. In the CY 2023 PFS proposed rule, we stated our belief that these concerns would be relevant to whether we adopt this alternative alone or adopt a combined approach, under which we would both remove the ACO's own assigned beneficiaries from the regional expenditure calculation and expand the ACO's regional service area for purposes of that calculation. We noted that expanding the regional service area may also mitigate the concern about unstable estimates due to small sample sizes.

In the proposed rule (87 FR 46184) we noted that while we believed this first alternative would partially address one of our core concerns by removing an ACO's own impact on the regional expenditures used in its benchmark calculations, it would not directly address the collective impact of multiple ACOs that may be operating in the same regional service area. We

[345] What is referred to here as the ''ACO's regional market share'' is the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO, which is the weight that it is applied to the national component of the national-regional blend under § 425.601(a)(5)(iv) and (v).

further noted that under the proposed changes described in the proposed rule designed to increase participation in the Shared Savings Program, we would expect this issue to grow more prominent over the coming years.[346] Additionally, we noted that we believed removing an ACO's own assigned beneficiaries from the regional expenditure calculation would be less effective at mitigating the ratchet effect than our proposed package of policies. For example, while this alternative might address how the ACO's prior performance affects regional factors used for purposes of calculating an ACO's rebased historical benchmark, this alternative would not address the concern that actual assigned beneficiary expenditures used in establishing an ACO's rebased historical benchmark may already be reduced by the ACO's prior success in reducing expenditures for its own assigned beneficiary population. We stated that the proposed adjustment for prior savings described in section III.G.5.c.(4) of the proposed rule would more directly address this concern by adding a portion of the ACO's prior savings during the benchmark years back into the rebased benchmark. Further, the proposal to include the ACPT in a three-way blended update factor as described in section III.G.5.c.(4) of the proposed rule would more directly ''decouple'' the update factor from actual observed expenditures, including expenditure reductions that are a result of savings already achieved by the ACO, than simply removing the ACO's own beneficiaries from the regional expenditure calculation.

We explained that one option that had been suggested by commenters during prior rulemaking is to remove all Shared Savings Program assigned beneficiaries from the assignable beneficiary population used to calculate each ACO's regional expenditures. In the proposed rule (87 FR 46185) we declined to consider removing all Shared Savings Program assigned beneficiaries from the assignable beneficiary population used to calculate each ACO's regional expenditures, as we had concerns about the short- and long-term sustainability and soundness of such an approach given the Agency's goal to expand participation in accountable care. We noted our belief that under the current level of program participation, an approach that would remove all Shared Savings Program assigned beneficiaries from the assignable population for each ACO's regional service area would yield unstable estimates of regional FFS expenditures for some ACOs, even if we were to expand the definition of an ACO's regional service area. We also noted that over time, we would expect this issue to worsen as Shared Savings Program participation expands.

We noted in the proposed rule that if we were to seek to finalize the first alternative of removing an ACO's assigned beneficiaries from the calculation of regional expenditures either by itself or in the combination with expanding our definition of an ACO's regional service area in lieu of the proposed package of policies, we would potentially need to adjust the weights used in calculating the regional adjustment to the historical benchmark. Under the current regulations, for ACOs that have lower average spending than their regional service area, we use a weight of 35 percent in the first agreement period that an ACO is subject to a regional adjustment and a weight of 50 percent in the second and subsequent agreement periods the ACO is subject to a regional adjustment. If an ACO was serving an assigned population that is markedly healthier than other assignable beneficiaries in the ACO's regional service area, removing the ACO's assigned beneficiaries from the population used to compute regional expenditures would increase the magnitude of the regional adjustment, all else being equal. This could potentially lead to a dramatic increase in program costs as higher regional adjustments could translate to higher shared savings payments. Thus, we indicated that we would potentially need to consider reducing the weights used to calculate the regional adjustment to protect the Medicare Trust Funds. Determining the appropriate adjustment to the weights may be complicated by potential resulting consolidation. For example, assume for illustration purposes that the regional adjustment weights were reduced by 10 percentage points to bring the overall impact of regional adjustments back in line with the existing program design (that is, the weighting would be reduced from 35 to 25 percent in the first agreement period if positive, and from 50 percent to 40 percent in succeeding agreement periods if positive, etc.). If ACOs consolidate in order to concentrate the residual regional spending on fewer higher spending assignable beneficiaries, then the weights may need to be further reduced to offset the further increase in regional adjustments for consolidated ACOs.

Alternative 2: Expanding the Regional Service Area

The second alternative we considered in the proposed rule in place of the package of proposed policies would seek to reduce an ACO's influence on expenditures in its regional service area by expanding the ACO's regional service area. While we did not outline a specific approach to expanding an ACO's regional service area in the CY 2022 PFS proposed rule (86 FR 39294), we sought comment on basing regional expenditure calculations on larger geographic areas, such as using State-level data or Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/State expenditures). We also sought comment on what would constitute heavy market penetration by an ACO in its regional service area if we were to use an approach that would consider the ACO's level of penetration in determining whether to expand the ACO's regional service area.

For example, one potential approach to expanding the regional service area would be to define an ACO's regional service area to include all States in which at least one of the ACO's assigned beneficiaries resides and calculating regional expenditures as a weighted average of State-level risk-adjusted expenditures, with the weights reflecting the proportion of the ACO's total assigned beneficiaries residing in each State. This approach would therefore mimic the current calculation, but replace county-level data with State-level data.

Another possible approach would be to follow the existing methodology, but replace county-level risk-adjusted expenditure values with State-level risk-adjusted expenditure values for the corresponding State only for counties where an ACO has market share above a specified threshold, such as 50 percent. Such a blended approach would maintain greater geographic specificity than an approach that relies exclusively on State-level data, while still reducing the influence of an ACO's own beneficiaries in areas where the impacts may be most acute.

In its comment responding to our solicitation in the CY 2022 PFS proposed rule, MedPAC favored altering the calculation of regional spending by extending the ACO's regional service area to a larger market area (for example, CBSAs, health service areas, or hospital referral regions) in lieu of removing ACO assigned beneficiaries from the

[346] CMS has set forth a goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.

calculation of regional FFS expenditures, noting that expanding an ACO's regional service area would help to reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain categories of ACOs (for example, historically low spending ACOs). Other commenters on the comment solicitation in the CY 2022 PFS proposed rule also supported expanding the regional service area for the purposes of calculating regional FFS expenditures in cases where ACO market penetration is high, with some of those commenters suggesting this would mitigate concerns about the reference population being too small after removing the ACO's assigned beneficiaries. Some commenters specifically called for using a threshold of 50 percent market penetration in such an approach. For example, a commenter suggested expanding the regional service area to include all contiguous counties for ACOs that have high market penetration (for example, when an ACO's assigned beneficiary population in a county exceeds 50 percent), with allowances for a lower threshold under special circumstances. For a full summary of the considerations and comments received, refer to the CY 2022 PFS final rule (86 FR 65301 and 65302).

As discussed in the proposed rule (87 FR 46185), like MedPAC, we believed that adopting only this second alternative to expand the regional service area would reduce the impact of an ACO's own expenditures on its regional expenditures without introducing incentives for favorable patient selection or concerns about increased volatility that may result from the first alternative of excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures. However, like that first alternative, expanding the regional service area might not address concerns about ACOs' collective market penetration. We also noted our belief that this second alternative or a combined approach would do less to ''decouple'' the ACO's benchmark from observed FFS spending than the package of policies that we had proposed, and thus would likely be more limited in countering the ratchet effect. By contrast, the proposal to incorporate the ACPT into the growth rates used to update the benchmark would ensure that a portion of the update will remain unaffected by observed FFS spending. Furthermore, we noted in the proposed rule that we had concerns that use of a market penetration threshold may drive further market consolidation as ACOs seek to meet such a threshold.

We noted in the proposed rule that if we were to decide to finalize this second alternative or a combined approach in lieu of our proposed package of policies, there would be a number of operational factors that we would need to address with greater specificity, including, but not limited to: what alternative geographic area we would use, whether we would replace county-level data with data based on an alternate geographic area or use a blend, and, if using a blend, at what threshold it would be triggered, and what weights would be applied when aggregating expenditures across geographic areas.

On the balance, we noted that we believed the proposed package of policies described in sections III.G.5.c.(3) through (5) of the proposed rule would collectively be more effective at addressing the core concerns we articulated than the two alternatives described or a combined approach, and would avoid some of the alternatives' potential unintended consequences. However, we sought further comment on these alternatives, including various operational considerations we would need to specify if we were to finalize either alternative 1, alternative 2, or a combined approach. As stated previously, we noted that we would consider the comments received on these alternative options and the related operational considerations along with the comments on the proposed package of policies in the development of our final policies, and might consider adopting one or both of the alternatives discussed in this section in lieu of the package of proposed policies discussed in section III.G.5.c.(3) through (5) of the proposed rule.

The following is a summary of the public comments received on these alternative options for addressing concerns about the effect of an ACO's assigned beneficiaries on regional FFS expenditures in establishing, adjusting, updating, and resetting the ACO's historical benchmark and our responses:

Comment: A few commenters addressed the concerns we raised in the proposed rule about Alternative 1, under which we would remove an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations.

One commenter stated that they shared CMS' concerns outlined in the proposed rule regarding Alternative 1, noting that this approach is not adaptable or sustainable when CMS' objective is to grow participation in the Shared Savings Program with the goal of having all Original Medicare beneficiaries cared for by participants of value-based payment initiatives by 2030. Additionally, the commenter noted that as CMS nears this goal, eventually there will be regions where all Original Medicare beneficiaries are assigned to ACOs participating in the Shared Savings Program or entities participating in other value-based payment initiatives and it will not be possible to calculate regional expenditures under this alternative option. Another commenter disagreed with certain concerns CMS outlined in the proposed rule regarding the proposed Alternative 1, stating that the concerns were unfounded. Specifically, the commenter noted that there is no evidence to support CMS' concerns regarding potential beneficiary selection or market consolidation that would result from removing an ACO's assigned beneficiaries from the assignable population used in regional expenditure calculations. Additionally, the commenter stated that incentives for ACOs to consolidate currently exist in the program due to ACOs needing to compete against themselves, as well as each other, and that removing the ACO's assigned beneficiaries from regional calculations would not address the competition between ACOs but would eliminate the need for an ACO to compete against itself. Finally, the commenter described being less concerned than CMS that competition between ACOs in areas with multiple ACOs in a market is a major barrier to entry for ACOs, given that ACOs currently compete on trends, not on the absolute level of spending. The commenter noted that CMS creates county rates in Medicare Advantage in counties where the Original Medicare population is in the minority. The commenter noted that a counterfactual population would still be available for calculating regional trend factors within the Shared Savings Program even after removing the ACO's own assigned beneficiaries. It was unclear to this commenter why CMS can overcome the rate-setting issues in Medicare Advantage but not in the Shared Savings Program. The commenter also disagreed with CMS' concern that removing assigned beneficiaries would jeopardize the ability to use an alternative payment model adopted under section 1899(i)(3) of the Act.

Response: We appreciate the commenters' input on the concerns laid out in the proposed rule with the alternative options. We continue to share the concern of the first commenter that removing the ACO's own assigned beneficiaries from regional FFS

expenditure calculations will be problematic as ACO assigned beneficiaries account for a greater share of Medicare FFS beneficiaries over time. We disagree with the second commenter that we would retain valid counterfactual populations in all ACO regions after removing the ACO's assigned beneficiaries from the population of assignable beneficiaries in the region. We note that under the Medicare Advantage program, the counterfactual population used for county rate setting is the Medicare FFS population. The Shared Savings Program is already limited to the Medicare FFS beneficiary population; and removing the ACO's own assigned beneficiaries would further limit the number of beneficiaries in a counterfactual population. We believe that removing the beneficiaries from the region could leave highly penetrated ACOs with adjusted regional trends based on very small sample sizes where the resulting trend target could lack validity. For example, if the ACO's trend was 3 percent and the unadjusted regional and national trends were 5 percent, but the adjusted regional trend was 30 percent, then the target calculation under Alternative 1 would appear deeply problematic on its face.

We disagree with the second commenter that the concerns we laid out about beneficiary selection and market consolidation are unfounded. We continue to believe that a policy of removing an ACO's own assigned beneficiaries from the calculation of its regional FFS expenditures would create a strong incentive for both beneficiary selection and market consolidation. Removing an ACO's own assigned beneficiaries from the regional trend calculation would reward an ACO for serving an assigned beneficiary population whose spending grew slower between the benchmark period and the performance year than the spending of the remaining assignable FFS beneficiaries in the ACO's region. Additionally, removing an ACO's own assigned beneficiaries from the regional trend calculation would penalize an ACO for serving an assigned beneficiary population whose spending grew faster between the benchmark period and the performance year than the spending of the remaining assignable FFS beneficiaries in the ACO's region, which could make it harder for ACOs caring for medically complex and high cost beneficiaries to achieve shared savings and could cause such ACOs to drop out of the Shared Savings Program. These situations may occur, either intentionally or accidentally, through shifts in the types of services provided by ACO participants or shifts in the ACO professionals billing through those ACO participant TINs between the benchmark period and the performance year. That is, because the Shared Savings Program assignment methodology considers all primary care services billed under an ACO participant TIN that are furnished by an ACO professional with a primary specialty designation used in assignment, shifts in billing patterns or the populations served by any given ACO participant TIN could produce a biased residual trend at the regional level if an ACO's own assigned beneficiaries are not included in the respective benchmark and performance years. Removing the ACO's beneficiaries from regional FFS expenditures for purposes of calculating the regional trend could also incentivize consolidation so that an ACO could have more ACO-related spending excluded from its regional trend than if the ACO is only one of multiple ACOs in its market.

We also disagree with the commenter's statement that removing assigned beneficiaries would not jeopardize CMS's ability to use an alternative payment model under section 1899(i)(3) of the Act. Preliminary modeling indicates program outlays for shared savings could rise by roughly 15 to 40 percent or more initially under Alternative 1 (presuming use of the current two-way blended update factor) and could grow significantly beyond that if gaming via consolidation were to follow.

Comment: We received several comments in support of Alternative 1, Alternative 2, or a combination of the two.

The majority of commenters expressed support for Alternative 1, either by itself or as part of a combination of Alternative 1 and Alternative 2. Among these commenters, it was not always clear whether the commenter supported removing ACO-assigned beneficiaries from the regional FFS expenditures used in determining the regional component of the update factor (also referred to as the regional trend), from the regional FFS expenditures used in determining the regional adjustment, or both.

The majority of these commenters specified their preference for Alternative 1 over the proposed policy to incorporate a prospective, external factor (the ACPT) in growth rates used to update the historical benchmark. Among these commenters, most discussed how Alternative 1 would more directly or comprehensively address the ''rural glitch'' than the proposal to incorporate the ACPT as part of a three-way blended update factor. Another commenter indicated that they could not support CMS' proposal to address the rural glitch and that CMS should instead remove assigned beneficiaries from ''benchmark calculations.'' Some commenters who expressed a preference for Alternative 1 over the three-way blend that incorporates the ACPT offered an alternative suggestion to: (1) use the ACPT as the national component in the two-way blend; and (2) remove assigned beneficiaries from the regional component in the two-way blend. Another commenter preferred an approach that would combine Alternative 1 and Alternative 2 to remove the ACO's own assigned beneficiaries from the calculation of the regional trend, as well as to broaden the region when needed for ACOs with large market shares to allow for statistically valid non-ACO reference populations. One commenter who expressed a preference for Alternative 1 over the proposed three-way blend that incorporates the ACPT specified that while they supported removal of the ACO's assigned beneficiaries from the calculation of the regional trend, they did not support removal of the ACO's assigned beneficiaries for purposes of calculating the regional adjustment to the benchmark because they believe doing so could discourage participation by high-cost ACOs and work against the goal of equity.

One commenter indicated that they preferred Alternative 1, Alternative 2, or a combination of the two, over the prior savings adjustment proposal, asserting that the proposed formulas used in the latter seem quite complicated and the impact is unclear.

Some commenters that expressed general support for Alternative 1 did not expressly indicate a preference for that option over the other benchmarking proposals. These commenters stated generally that they supported CMS' removing the ACO's assigned beneficiaries from benchmark calculations. One commenter supported CMS' adopting either or both of the alternative policies to help mitigate the problems associated with including an ACO's own beneficiaries in benchmark calculations, particularly for ACOs that have a high market share in their region. One commenter stated that they agreed completely with the policy under the section heading ''Alternative Options for Addressing Concerns About the Effect of an ACO's Assigned Beneficiaries on Regional FFS

Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark'' in the proposed rule, but the commenter did not specify further.

Some commenters urged CMS to adopt Alternative 2 to expand the ACO's regional service area, but did not specify an approach to doing so. One of these commenters also supported the prior savings adjustment proposal and the proposal to reduce the impact of the negative regional adjustment, but did not comment on CMS' proposal for a three-way blended updated factor so it was unclear if the commenter preferred Alternative 2 over the proposed changes to the update methodology. Another commenter suggested that CMS expand the ACO's regional service area for purposes of computing the regional component of the existing national-regional blended update factor and incorporate a set increase in the growth factor each year, preferring this combination over the proposed three-way blend. Another commenter recommended that CMS broaden the region when needed to allow for statistically valid non-ACO reference populations for ACOs with large market shares.

One commenter mentioned that CMS could remove all Shared Savings Program assigned beneficiaries from regional expenditure calculations in order to remove competition among ACOs operating in the same market, but did not recommend doing so, as they do not believe competition is a major barrier to entry for ACOs given that ACOs currently compete on trends, not on the absolute level of spending.

Response: We appreciate commenters' sharing their perspectives on Alternative 1 and Alternative 2. We interpret comments expressing preference for Alternative 1 over a three-way blended update factor that incorporates the ACPT as specifically requesting that CMS remove an ACO's assigned beneficiaries from the regional component of the update factor. We interpret comments described as supportive of applying Alternative 1 for benchmark calculations as supporting the removal of an ACO's assigned beneficiaries from all benchmark calculations involving regional FFS expenditures, which includes not only the update factor, but also the regional adjustment.

As we stated in the proposed rule and have reiterated above, we are concerned that serious unintended consequences may arise from adopting Alternative 1. Specifically, we continue to believe that removing an ACO's assigned beneficiaries from the assignable beneficiary population used to compute regional expenditures would amplify the benefit to ACOs of selecting lower cost patients and avoiding higher needs groups and drive market consolidation, while still failing to mitigate the problem in cases where multiple ACOs work in combination to drive down regional spending. Furthermore, it would increase program spending to such a degree that compliance with the requirements of section 1899(i)(3) of the Act regarding the use other payment models would be violated. We also have these same concerns with an approach that would remove all Shared Savings Program assigned beneficiaries from regional expenditure calculations, which was an option we declined to consider in the proposed rule.

As Alternative 2 does not include removing the ACO's own assigned beneficiaries from regional FFS calculations, we do not believe that the same serious unintended consequences would arise from that option, nor did we receive comments suggesting as such. However, although Alternative 2 may not have the same serious unintended consequences, we believe that adopting Alternative 2 alone without also adopting the other policies in this rule, would not effectively address the ratcheting effect that could be created by multiple Shared Savings Program ACOs operating in the same market. One way ratcheting could occur is if beneficiaries assigned to any Shared Savings Program ACO make up a significant enough proportion of assignable beneficiaries in the ACO's regional service area to constrain regional FFS expenditures because expenditures among these Shared Savings Program assigned beneficiaries have already been reduced by ACO actions. Alternative 2, which would expand the regional service area, would not necessarily reduce the proportion of the assignable beneficiaries in the ACO's region that are assigned to Shared Savings Program ACOs. Rather, one ACO may see a reduced proportion of beneficiaries assigned to Shared Savings Program ACOs in its expanded region, while another may see an increased proportion. The change in the proportion depends on the degree of penetration of all Shared Savings Program ACOs in the ACO's expanded regional service area. Therefore, we remain concerned that Alternative 2 would not fully address the concerns raised by interested parties about ratcheting.

We continue to believe that the package of three benchmarking policies proposed in the proposed rule will adequately address concerns raised by interested parties about the ability of ACOs with high market penetration to generate shared savings. For the reasons discussed in the proposed rule, we believe that incorporating a prospective trend into the benchmarking methodology by including the ACPT in a three-way blended update factor would be an important step towards an administrative benchmarking approach. ACOs may have a greater incentive to enter and continue participation in the Shared Savings Program when their benchmarks are further decoupled from their ongoing observed FFS spending while continuing to reflect a measure of the ACO's efficiency relative to its region. This approach may also serve to anchor and stabilize benchmarks to the extent that the ACPT projected growth component of the three-way blend is an effective counterbalance when there are changes in an ACO's penetration in its regional service area that affect the weights given to the national and regional expenditure components in the current two-way blended update factor. Furthermore, as we discussed in the proposed rule, incorporating the ACPT, which is not influenced by actual performance by a single ACO, multiple ACOs in a region, or all ACOs nationally, as part of a three-way blend, will also address the wider issue of multiple neighboring ACOs pushing down the regional trend.

However, given the continued interest among interested parties in Alternative 2, and given that we do not have the same concerns about unintended consequences from expanding the definition of an ACO's regional service area, we believe that additional consideration of Alternative 2 is warranted. As we stated in the proposed rule, there are a number of operational factors that we would need to address with greater specificity before deciding to adopt such an approach, including, but not limited to: what alternative geographic area we would use, whether we would replace county-level data with data based on an alternate geographic area or use a blend, and, if using a blend, at what threshold it would be triggered, and what weights would be applied when aggregating expenditures across geographic areas.

We intend to continue to explore approaches for expanding the definition of the ACO's regional service area to use a larger geographic area to determine regional FFS expenditures that could be incorporated into the financial methodology in the future. We may revisit the issue of expanding the definition of the ACO's regional service area in future rulemaking.

d. Calculating County FFS Expenditures To Reflect Differences in Prospective Assignment and Preliminary Prospective Assignment With Retrospective Reconciliation

(1) Background

Under the current regulation at § 425.601, CMS uses risk-adjusted county-level FFS expenditures, determined based on expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to the relevant benchmark or performance year, to calculate factors used in establishing, adjusting and updating the ACO's historical benchmark. Specifically, we use these risk-adjusted county-level FFS expenditures to determine the ACO's regional service area expenditures, which are used to calculate the regional adjustment in accordance with § 425.601(a)(8) and the blended national-regional growth rates used to trend forward expenditures for BY1 and BY2 to BY3 dollars (§ 425.601(a)(5)), and to update the ACO's historical benchmark between BY3 and each performance year in the ACO's agreement period (§ 425.601(b)).

To calculate the risk-adjusted regional expenditure amounts under § 425.601(d) for each Medicare enrollment type, we first calculate risk-adjusted expenditures for the relevant benchmark year or performance year for assignable beneficiaries in each county in the ACO's regional service area in accordance with § 425.601(c). We then weight these county-level risk-adjusted expenditure amounts by the proportion of the ACO's assigned beneficiaries residing in each county, and sum across all counties in the ACO's regional service area. Additionally, we use county-level assignable beneficiary person years in combination with the ACO's assigned beneficiary person years by county to calculate an ACO's share of assignable beneficiaries in the ACO's regional service area as described in § 425.601(a)(5)(v). These shares are, in turn, used to determine the weights used in calculating the blended national-regional trend and update factors as described in §§ 425.601(a)(5)(iv) and (v) and 425.601(b)(4).

The assignable population of beneficiaries used to calculate the county level values described above is identified in accordance with the definition of ''assignable beneficiary'' under § 425.20. Specifically, an assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). When first proposing to incorporate regional and national factors based on the assignable beneficiary population in the February 2016 proposed rule (81 FR 5843 through 5845), we discussed our consideration of which assignment window to use to identify the assignable population used to calculate inputs to the program's financial calculations. Specifically, we considered using the 12-month period based on a calendar year, which aligned with the assignment window for preliminary prospective assignment with retrospective reconciliation, or an offset 12-month period, which aligned with the assignment window for prospective assignment (for example, October through September preceding the calendar year). We proposed, and ultimately finalized, use of the 12-month period based on the calendar year for all ACOs, regardless of the ACO's assignment methodology (81 FR 37985 through 37989).

In the February 2016 proposed rule (81 FR 5843 and 5844), and as restated in the June 2016 final rule (81 FR 37985 and 37986), we expressed our belief that it is important to calculate regional and national FFS factors consistently program-wide, so as not to advantage or disadvantage an organization simply on the basis of the assignment methodology that applied under its track. We also noted our belief that this consistency would help to ensure a level playing field in markets where multiple ACOs are present and would also simplify program operations. We indicated that we would monitor for observable differences in the health status (for example, as identified by prospective HCC risk scores) and expenditures of the assignable beneficiaries identified using the 12-month calendar year assignment window, as compared to assignable beneficiaries identified using the offset assignment window (for example, October through September preceding the calendar year) and would, if warranted, address the need for additional adjustments to account for the use of assignable beneficiaries identified using an assignment window that is different from the assignment window used to assign beneficiaries to the ACO through future rulemaking.

In addition to these inputs based on county-level assignable beneficiary data, the Shared Savings Program's financial calculations also use the assignable beneficiary population to calculate a variety of factors based on national FFS expenditures, including:

- National growth rates used to trend and update the benchmark (see § 425.601(a)(5)(ii) and § 425.601(b)(2));
- Thresholds used to truncate beneficiary expenditures (see §§ 425.601(a)(4), 425.601(c)(3), 425.605(a)(3) and 425.610(a)(4)(ii));
- Caps applied to the regional adjustment (see § 425.601(a)(8)(ii)(c)); and
- Mean risk scores used to renormalize ACO- and county-level risk scores (see discussion in 83 FR 68007 through 68013).

Having gained experience using factors based on the assignable beneficiary population since PY 2017, and based on our monitoring of differences in expenditure and risk scores among beneficiaries identified using an assignment window based on the calendar year versus an offset assignment window, we have concluded that there exists a systematic bias in the calculations using county-level expenditures that favors ACOs under prospective assignment. Based on historical data, we have observed that for a given calendar year, risk-adjusted expenditures for populations identified based on the offset assignment window are systematically lower than risk adjusted expenditures for populations identified based on the calendar year assignment window, all else equal. In the calculation of the regional adjustment, the favorable bias arises for ACOs under prospective assignment because we are comparing risk-adjusted expenditure levels between populations identified based on different assignment windows for BY3: the ACO's own assigned beneficiary population identified based on the offset assignment window, and expenditures for the assignable population of beneficiaries in the ACO's region identified based on the calendar year assignment window. This mismatch causes the ACO's spending to look ''low'' relative to the regional spending, leading to a larger positive (or smaller negative) regional adjustment than we would observe if the assignment windows used to identify the two populations were consistent.

Based on modeling using historical benchmarks for ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019, and after accounting for regional adjustment weighting and capping, we estimate that actual regionally adjusted historical benchmarks were 0.2 percent to 1.9 percent higher for ACOs under prospective assignment than they would have been if the regional adjustment had been calculated using risk-adjusted regional expenditures for assignable

beneficiaries identified using the offset assignment window used under prospective assignment. The median estimated bias was 1.0 percent. We believe the program-wide impact of this bias was likely low in the initial years that the regional adjustment was in effect because only a subset of ACOs were originally eligible for the regional adjustment (ACOs that renewed for a second agreement period starting in January 2017, January 2018, or January 2019), and a relatively small share of those ACOs were under prospective assignment (ACOs participating in Track 3 or the Track 1+ ACO Model). Starting with agreement periods beginning on July 1, 2019, all ACOs became eligible to receive a regional adjustment and to select their assignment methodology in accordance with §§ 425.226(a)(1) and 425.400(a)(4)(ii). With this latter change, the share of ACOs under prospective assignment grew considerably, from around 17 percent in PY 2019 to 38 percent in PY 2022. Because of this, we believe that the bias has a larger impact currently than in earlier years.

Additionally, while risk-adjusted expenditure trends have generally been consistent for prospectively and retrospectively determined assignable populations, this stable relationship was disrupted in the PHE for COVID–19 when decreased utilization led to expenditures for prospectively determined populations falling more sharply in CY 2020 than for retrospectively determined populations (due to an increase in the number of beneficiaries that did not utilize any care after being prospectively assigned to an ACO). This appears to have generated an additional 1.0 percentage point increase in measured savings (relative to total benchmark) for ACOs under prospective assignment in PY 2020 beyond the effect of the biased regional adjustment. However, we note that between CY 2020 and CY 2021 expenditures grew more quickly for prospectively determined populations, causing cumulative trends from years preceding the PHE for COVID–19 to CY 2021 to return to a roughly parallel state for the two populations. Although the disruption of expenditure trends between prospective and retrospectively assignable populations was temporary in this case, the disruption of stable expenditure trends during the PHE for COVID–19 highlights the possibility of future biases in the blended national-regional growth factor. If the blended growth factor is based on an assignable population with a different expenditure growth trend than the expected trend in expenditures of an ACO's assigned population, an ACO could receive an artificial increase or decrease in savings.

In the CY 2023 PFS proposed rule, we stated our belief that without correction the impact of this bias has the potential to grow costlier to the Trust Funds over time. For one, more ACOs will be subject to higher weights used in calculating the regional adjustment as they progress in the Shared Savings Program, which is expected to lead to larger regional adjustments and, by extension, larger biases than those estimated in our analysis using benchmark data from the 6-month performance year beginning July 1, 2019, in which most ACOs were subject to the lowest regional adjustment weights. Second, as more ACOs move to the ENHANCED track with its 75 percent sharing rate, aggregate savings against a favorably biased benchmark will be shared by ACOs at a higher rate. We also stated that preventing further influence of the bias would be important for ensuring good stewardship of Medicare Trust Fund dollars. Addressing this bias in Shared Savings Program calculations for ACOs under prospective assignment would also ensure a more level playing field for ACOs under both assignment methodologies and would improve the comparability of ACOs' performance under the Shared Savings Program irrespective of the ACO's chosen assignment methodology.

Further, if left unresolved, this bias would need to be taken into account as part of the regulatory impact analysis for evaluating proposed modifications to policies under the Shared Savings Program, and in considering whether CMS has met the requirements for use of other payment models under section 1899(i)(3) of the Act. The authority to use other payment models under section 1899(i)(3) of the Act is necessary for implementing key aspects of the Shared Savings Program's financial methodology, including the two-sided models and the blended national-regional growth factors used to update the historical benchmark (as discussed in section III.G.5.c.(3) of the proposed rule), as well as the proposal to provide AIPs to eligible ACOs (discussed in section III.G.2 of the proposed rule). This authority is contingent on the statutory requirement that other payment models adopted under section 1899(i)(3) of the Act must be determined to improve the quality and efficiency of items and services furnished to Medicare FFS beneficiaries and not to increase program spending relative to a baseline estimated for the Shared Savings Program were it not to employ modifications authorized under section 1899(i)(3) of the Act. A predictable favorable bias would increase program spending (particularly in combination with modifications like two-sided risk sharing that require authority from section 1899(i)(3) of the Act), and therefore, jeopardize CMS' ability to satisfy the requirements of section 1899(i)(3) of the Act for use of other payment models.

In the CY 2023 PFS proposed rule, we stated our belief that modification to the methodology for calculating regional FFS expenditures is necessary and timely to mitigate the observed favorable bias for ACOs under prospective assignment.

(2) Revisions

To remove the favorable bias and bring greater precision to the calculation of factors based on regional FFS expenditures, we proposed to modify the calculation of risk-adjusted regional expenditures used in the regional adjustment and in the regional component of the blended factors used to trend and update the benchmark (including, if finalized, the three-way blend proposed in section III.G.5.c.(3) of the proposed rule). As proposed, for agreement periods beginning on January 1, 2024, and in subsequent years, we would calculate risk-adjusted regional expenditures using county-level values computed using an assignment window that is consistent with an ACO's assignment methodology selection for the performance year under § 425.400(a). That is, for ACOs selecting prospective assignment, we would use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we would continue to use an assignable population of beneficiaries that is identified based on the calendar year assignment window. In the proposed rule, we noted our belief that removing the current mismatch in the assignment window used to determine the assignable population, and the assigned population for ACOs under prospective assignment would create a more equitable historical benchmark across assignment methodologies and help protect the Trust Funds. For consistency, we also proposed to use an assignable population identified using an assignment window that corresponds to an ACO's selected assignment methodology to calculate other factors based on county-level data, namely, the

weights used in computing the blended trend and update factors.

We did not propose to change the way we compute national factors that require identifying assignable populations. That is, all factors used in calculations that are based on the national assignable FFS population would continue to be computed using an assignable population identified based on the calendar year assignment window. As discussed in the proposed rule, this choice was driven by two factors. First, for simplicity, we favored using the same set of national values for all ACOs. Second, we did not believe the national factors, as currently computed, contribute to the current bias that we have observed, and which is the motivation for the proposed policy changes. While using a national assignable population based on an offset assignment window to compute the national component of trend and update factors could help to further protect against unanticipated biases in those calculations, the national component represents a small portion of the blend for most ACOs. Thus, the additional protection provided would be limited. However, we indicated that we intend to continue monitoring how national assignable expenditure trends hinge on the selection of assignment methodology and may return to this issue in future rulemaking if significant biases exist that may systemically impact the national component of the trend and update factors.

We also noted that we currently make available public use files (PUFs) containing the county level expenditures, risk scores and assignable beneficiary person years for each calendar year on the *data.cms.gov* website, specifically: (1) County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries PUF,[347] and (2) Number of ACO Assigned Beneficiaries by County PUF.[348] Interested parties are able to use these files to replicate the calculation of risk-adjusted regional expenditures or the weights used in the blended trend and update factors. We also provide ACOs with program reports that include information on the geographic distribution of their assigned beneficiary populations which can also be used along with the county-level data based on the assignable population for modeling purposes.

In the CY 2023 PFS proposed rule, we noted that if the proposal was finalized, we anticipated making two sets of county-level values publicly available for each calendar year: we would continue to provide county-level data on the assignable population identified based on the calendar year assignment window and would also make available county-level data based on the assignable population identified using the offset assignment window. Additionally, we would update the public use files that reflect the distribution of each ACO's assigned beneficiary population by county to include a field indicating each ACO's assignment methodology selection for the applicable performance year.

We noted our belief that this additional data would facilitate modeling of the proposed changes to the calculation of county-level FFS expenditures used in Shared Savings Program benchmark calculations. Concurrent with the issuance of the proposed rule, we provided through the Shared Savings Program website at *www.cms.gov/sharedsavingsprogram/* data files containing risk-adjusted county-level FFS expenditures for 2018–2020 calculated based on an assignable beneficiary population identified using an offset assignment window.

We proposed new regulations at §§ 425.652, 425.654, and 425.656 to reflect this proposal. (Refer to section III.G.5.i. of the proposed rule for a discussion of the organization of the proposed provisions in 42 CFR part 425, subpart G.)

In the proposed rule, we noted that in order to finalize the proposed changes to the regional component of the update factor, we would need to use our statutory authority under section 1899(i)(3) of the Act. We referred readers to section III.G.5.c.(3) of the proposed rule and the Regulatory Impacts Analysis section for related discussions regarding the use of this authority with respect to the proposed modifications to the update factor.

We sought comment on these proposals.

The following is a summary of the public comments received on the proposed modifications to the methodology for calculating county FFS expenditures to reflect differences in prospective assignment and preliminary prospective assignment with retrospective reconciliation and our responses:

Comment: Several commenters supported the proposal to modify the calculation of risk-adjusted regional expenditures used in the regional adjustment and in the regional component of the blended factors used to trend and update the benchmark. Some of these commenters outlined specific reasons for their support. Two commenters supported the idea of removing the selection bias that currently favors ACOs under prospective assignment. One commenter agreed with CMS that COVID–19 has created significant variation and supported the idea that an ACO's assignment methodology should apply to all aspects of the benchmarking methodology. Another commenter supported using assignment windows in benchmark calculations that are consistent with an ACO's selected assignment methodology.

Response: We thank commenters for their support of the proposal to align the assignment windows used to calculate county FFS expenditures with an ACO's selected assignment methodology.

Comment: Multiple commenters requested that CMS mitigate any potential negative impacts that this proposal could have on ACOs under prospective assignment. Commenters listed their concerns, which included potentially lower benchmarks for ACOs under prospective assignment, a disproportionate impact on specific ACOs/ACO cohorts (the specific ACO cohorts were not identified by the commenters). A couple of these commenters provided specific recommendations for CMS on how to alter the proposal to limit its potential adverse impacts. Specifically, one commenter requested that CMS consider capping the adverse impacts of this policy for ACOs under prospective assignment. This commenter provided an example under which the impact on a given prospective ACO's benchmark would be limited to no more than a +/− 0.5 percent change as a result of this policy. Another commenter recommended that CMS mitigate the potential negative impacts of the policy by phasing it in over a period of years, making the change optional, or limiting its influence on historical benchmarks.

Response: We appreciate commenters' sharing their concerns about ACOs receiving lower benchmarks as a result of the proposed modifications to the methodology for calculating county FFS expenditures. However, given the observed historical bias favoring ACOs under prospective assignment and the fact that implementing the proposed policy change would align a component of benchmark calculations with an

[347] Refer to *Data.CMS.gov,* County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries, available at *https://data.cms.gov/medicare-shared-savings-program/county-level-aggregate-expenditure-and-risk-score-data-on-assignable-beneficiaries.*

[348] Refer to *Data.CMS.gov,* Number of Accountable Care Organization Assigned Beneficiaries by County, available at *https://data.cms.gov/medicare-shared-savings-program/number-of-accountable-care-organization-assigned-beneficiaries-by-county.*

ACO's selected assignment methodology, we believe that finalizing the proposed policy would bring greater consistency to the program, create a more neutral choice between assignment methodologies, and increase incentives for ACOs under the prospective assignment methodology to grow more efficient over time. Therefore, we disagree with the commenters' assertions that this policy could have unfair, adverse impacts for ACOs under prospective assignment or for other cohorts of ACOs.

Comment: One commenter requested more information on the underlying cause of higher historical benchmarks for ACOs under prospective assignment. This commenter also requested that, in the event this proposal is finalized, CMS consider revising its policy for annual wellness visits (AWVs) to transition to a calendar year basis (the commenter did not provide any rationale for the suggested AWV changes).

Response: We believe that the underlying cause of the more favorable historical benchmarks for ACOs under prospective assignment was clearly described in section III.G.5d.(1) of the proposed rule. Risk-adjusted expenditures for populations identified based on the offset assignment window are systematically lower than risk-adjusted expenditures for populations identified based on the calendar year assignment window, all else equal. CMS has conducted additional modeling of the impact of this bias since the proposed rule was issued. Based on this updated modeling using historical benchmarks for ACOs participating in PY 2020, we estimate that actual regionally adjusted historical benchmarks were 0.2 percent to 2.0 percent higher for ACOs under prospective assignment than they would have been if the regional adjustment had been calculated using risk-adjusted regional expenditures for assignable beneficiaries identified using the offset assignment window used under prospective assignment. The median estimated bias was 1.0 percent. Additionally, we decline to consider the commenter's suggestion that CMS consider revising its policy for annual wellness timelines because it is outside the scope of the proposal being considered.

Comment: Two commenters expressed concern that this proposal would grant a potential structural advantage to ACOs under the preliminary prospective assignment with retrospective reconciliation methodology. One commenter stated that although they agree in principle with the proposal to align the assignment windows used to calculate benchmarks with the assignment windows used to assign beneficiaries and calculate assigned beneficiary expenditures, their internal analysis suggests that implementing the proposal would generate a bias in favor of ACOs under retrospective assignment. This commenter claimed that their analysis using data from the largest TINs in the country suggests that ACOs may receive a more favorable regional adjustment under preliminary prospective assignment with retrospective reconciliation than under prospective assignment if this proposal was implemented. However, the commenter did not elaborate on the specific methodology used to reach this conclusion or the reasons that ACOs would receive more favorable regional adjustments under preliminary prospective assignment. The other commenter raised concern that the proposed policy ''could widen a structural advantage for retrospective assignment''. Both commenters suggested that ACOs may change assignment methodologies from prospective to preliminary prospective assignment with retrospective reconciliation due to this policy change, which could add operational burden and cost.

Both commenters requested that CMS take more time to understand the impact of the proposed policy before implementing it and provided additional recommendations for CMS' consideration, including establishing a pilot period before finalizing the proposal, offering transparency to ACOs by making final settlement results available that utilize both calendar year and offset assignment windows to calculate county FFS expenditures, and offering ACOs waiver flexibility with respect to this policy.

Response: We had some difficulty understanding the commenters' conclusions because some of the data analysis methodologies underlying their assertions were unclear and the sources of a potential bias favoring ACOs electing preliminary prospective assignment with retrospective reconciliation were not thoroughly described. Based on the observed historical trend that risk-adjusted expenditures for populations identified based on the offset assignment window are systematically lower than risk-adjusted expenditures for populations identified based on the calendar year assignment window, we believe that it is appropriate to align the methodology for determining the components of the benchmark calculation with an ACO's chosen assignment methodology. We believe that the proposed approach would also support a more neutral choice between assignment methodologies and minimize bias in benchmark calculations. However, we plan to continue monitoring for biases for or against any assignment methodology across the program as a whole in the future. With respect to the commenters' suggestion that CMS take more time to study the impact of the proposed policy, we note that CMS has studied and modeled this proposal using multiple years of historical data and made public files available for stakeholders to assess its likely impact. We believe that this level of analysis and transparency will help the commenters and others interested in further reviewing how this policy may relate to their ACO.

After consideration of these public comments, we are finalizing as proposed the modifications to our methodology for calculating county FFS expenditures to provide for the use of separate assignment windows for ACOs depending on their selected assignment methodology. We are finalizing our proposal to specify in the new regulation at § 425.654 the methodology for calculating county FFS expenditures with an offset assignment window for ACOs selecting prospective assignment and with a calendar year assignment window for ACOs selecting preliminary prospective assignment with retrospective reconciliation and for calculating regional expenditures using these county FFS expenditures. We are also finalizing our proposal to specify in the new regulations at §§ 425.652 and 425.656 the use of regional expenditures calculated under § 425.654 in certain benchmark calculations.

e. Improving the Risk Adjustment Methodology To Better Account for Medically Complex, High-Cost Beneficiaries and Guard Against Coding Initiatives

(1) Background

Currently, for ACOs in agreement periods beginning on or after July 1, 2019, we account for changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark for an agreement period and also in adjusting the benchmark for each performance year during the agreement period. In accordance with § 425.601(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using CMS Hierarchical Condition Category (CMS–HCC) prospective risk scores (herein referred to as prospective HCC risk scores).

Pursuant to § 425.601(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In making this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period (referred to herein as the ''3 percent cap''). This cap is the maximum increase in prospective HCC risk scores allowed for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent. That is, the prospective HCC risk ratios (ratio of performance year risk score to the BY3 risk score) applied to historical benchmark expenditures to capture changes in health status between BY3 and the performance year will never be higher than 1.030 for any performance year over the course of the agreement period. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.[349]

The 3 percent cap was finalized through the December 2018 final rule (83 FR 68013) to address concerns with the prior approach for risk adjustment, which used a methodology that differentiated between newly assigned and continuously assigned beneficiaries, as defined in § 425.20. The issues raised by interested parties included concerns that the risk adjustment methodology did not adequately adjust for changes in health status among continuously assigned beneficiaries between the benchmark and performance years and that performing risk adjustment separately for newly and continuously assigned beneficiaries created uncertainty around benchmarks and made it difficult for ACOs to anticipate how risk scores would affect their financial performance (refer to 76 FR 67916 through 67919, 80 FR 32777 through 32778, 81 FR 37962 through 37968, 83 FR 68008 through 68013). As a result, in the December 2018 final rule, we modified the risk adjustment methodology to provide for the use of prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period, for agreement periods beginning on July 1, 2019, and in subsequent years (83 FR 68013).

As we stated in the CY 2023 PFS proposed rule, we believe this current policy has several advantages relative to the original risk adjustment methodology distinguishing between newly and continuously assigned beneficiaries, including: allowing for some upward growth in prospective HCC risk scores between the benchmark period and the performance year for an ACO's entire assigned beneficiary population, providing better recognition for changes in beneficiary health status between the benchmark period and the performance year, and providing greater clarity for ACOs than the previous methodology, while still limiting the impact of ACO coding initiatives. However, interested parties remain concerned about the program's risk adjustment methodology, including the 3 percent cap. In the CY 2022 PFS proposed rule, we solicited comment on several issues related to the Shared Savings Program's risk adjustment methodology (86 FR 39294 and 39295).

- Approaches, generally, to improving the risk adjustment methodology for the Shared Savings Program, and specifically for ACOs with medically complex, high-cost beneficiaries.
- Approaches to risk adjustment that would balance the need for accurate and complete coding, while protecting against incentivizing coding intensity initiatives by ACO participants and ACO providers/suppliers (which may be even more problematic for ACOs with high penetration in their region) that increase risk score growth above the existing 3 percent cap.
- Alternate approaches that would increase the cap on an ACO's risk score growth in relation to risk score growth in the ACO's regional service area.
- The potential interactions between policies to remove assigned beneficiaries from the assignable beneficiary population used to calculate regional FFS expenditures and growth rates, and policies addressing regional risk score growth.

For a full summary of the comments submitted in response to our comment solicitation, we refer readers to the relevant discussion in the CY 2022 PFS final rule (86 FR 65302 through 65306). Among the comments received, many commenters expressed concern about the existing 3 percent cap on positive risk score growth, as well as the absence of a cap (or floor) on negative adjustments to account for risk score decreases. Several commenters indicated that the current 3 percent cap on risk score growth is unfair over a 5-year period, suggesting that the cap is too low over a period of this length. Additionally, several commenters suggested that the existing policy is driving inequity and may disadvantage ACOs that serve more vulnerable populations or beneficiaries with complex medical needs. Some commenters explained that beneficiaries who are in the disabled and the aged/dual eligible Medicare enrollment types are, in most combinations, more than twice as likely to have risk score growth above the cap as those who are in the aged/non-dual eligible category. These concerns are similar to certain comments made in response to the original proposal for the 3 percent cap and summarized in the December 2018 final rule (83 FR 68010 through 68012). Additionally, some commenters indicated that due to a variety of factors, such as sample size and volatility, the rates at which Medicare enrollment types are subject to the 3 percent cap on risk score growth are often significantly different. A commenter explained that there can also be significant risk score volatility when the high-risk patient population is small. This concern was also raised in response to the original proposal for the current policy (83 FR 68012). Several commenters on that proposal recommended that any cap be applied at the aggregate level rather than the enrollment type level, with one commenter suggesting that we cap the prospective HCC risk ratios in the aggregate across the four beneficiary enrollment types to account for smaller sample sizes and resulting higher volatility for certain enrollment types.

Many of the comments received in response to the comment solicitation in the CY 2022 PFS proposed rule also expressed concern that the current policy places a cap on the ACO's risk score growth but does not restrict regional risk score growth that is reflected in the regional component of the update factor, noting that this penalizes ACOs in markets where a region's risk score growth exceeds the 3 percent cap (86 FR 65304). Other

[349] Refer to the December 2018 final rule (83 FR 68007 through 68013), section on ''Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year''. See also, the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, January 2022), section 3.6, available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1.*

commenters, notably MedPAC, expressed support for CMS' considerable caution in the area of risk adjustment, noting that population-based models can be highly susceptible to coding incentives and that the Shared Savings Program does not include a retrospective coding adjustment to offset these incentives. MedPAC recommended that CMS should address the underlying incentives for coding intensity and the accuracy of risk adjustment before considering any policy that would increase the risk score growth cap (86 FR 65304).

(2) Revisions

In response to these concerns, we considered three options to modify the existing 3 percent cap on risk score growth: (1) Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and apply the cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible); (2) Apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year; and (3) Allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, where the percentage applied would be equal to 1 minus the ACO's regional market share (continuing our consideration of the approach described in the CY 2022 PFS proposed rule (86 FR 39294)).

In the CY 2023 PFS proposed rule, we stated our belief that the first two options for modifications to the risk adjustment methodology (applying the cap on risk score growth in aggregate across Medicare enrollment types, with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year) would address several of the concerns raised by interested parties by: accounting for higher volatility in prospective HCC risk scores for certain enrollment types due to smaller sample sizes; allowing for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are frequently subject to the cap on risk score growth currently); and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. We also explained our belief that the third option (to allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area) would address some of the commenters' concerns about the possible impacts of regional prospective HCC risk score growth, but would not address the multiple other concerns addressed by options 1 and 2. We also noted that the approach described in the second option includes a component of the first option (applying the cap on an ACO's risk score growth in aggregate across Medicare enrollment types). We also noted that we had considered the third option independently from the first and second options and did not consider using the third option in combination with either the first or second option. That is, we did not consider an approach under which we would account for the difference between the 3 percent cap and the risk score growth in the ACO's regional service area (third option) in combination with applying a cap on risk score growth in aggregate across Medicare enrollment types, with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year (the first and second options, respectively). We stated that we view these two approaches to be inconsistent with each other, as the third approach allows an ACO's risk score growth to rise above 3 percent based on risk score growth in the ACO's regional service area, whereas the first and second options would retain the 3 percent cap, but apply it at the aggregate level (with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year).

As discussed in the proposed rule, after careful consideration and modeling of the impacts of these three potential modifications to the existing 3 percent cap on positive prospective HCC risk score growth, we proposed to use the authority granted by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other such factors as the Secretary determines to be appropriate, to modify the existing 3 percent cap on risk score growth using the first option. We also sought comment on the second and third options as potential alternatives to the proposed approach. We noted that we would consider the comments received on these alternative options along with the comments on the proposal to adopt the first option in the development of our final policy and indicated that we might consider adopting one of these alternatives in place of the proposed approach if we conclude that it would better address the concerns with the current risk adjustment methodology.

Under the proposal of the first option, an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points. Specifically, we proposed that we would:

- Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores.
- Then apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

Demographic risk scores are based on certain demographic attributes that do not vary with the beneficiary's health condition, such as age, sex, Medicaid status, and original reason for Medicare entitlement.[350] Unlike prospective HCC risk scores, demographic risk scores are not subject to coding intensity because they do not use diagnosis information. In the proposed rule, we noted that accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive prospective HCC risk score growth could allow for higher benchmarks than the current methodology for ACOs that have experienced increases in health risk among their assigned beneficiary populations, while still safeguarding the Trust Funds by limiting returns due to coding initiatives. We also noted that the CMS Innovation Center's Global and Professional Direct Contracting (GPDC) Model, which will transition to the redesigned and renamed Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model on January 1, 2023, will

[350] Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #7, February 2019), section 3.4.2, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-V7.pdf*.

also take into account the underlying demographics of a model participant's aligned beneficiary population when determining whether risk score growth will be capped starting in PY 2024.[351]

As proposed, the positive 3 percent cap (after accounting for changes in demographic risk scores) would also apply in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible). In other words, we would calculate a single aggregate value for the cap equal to the dollar-weighted average growth in demographic risk scores across the four enrollment types plus 3 percentage points. We would only apply this cap to risk score growth for a particular enrollment type if the aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeds the value of the cap. We noted that we believed this would make it less likely that the prospective HCC risk scores for Medicare enrollment types with smaller populations, typically populations of ESRD, disabled, or aged/dual eligible beneficiaries, would be subject to the cap. We also explained that these smaller populations are more likely to experience random variation in risk score growth as a relatively small number of assigned beneficiaries with large changes in prospective HCC risk scores can have an outsized impact on the average score for the Medicare enrollment type.

To implement the new cap, we proposed to follow these steps:

- *Step 1:* Determine demographic risk score growth for each Medicare enrollment type. Demographic risk score growth is measured as the ratio of the ACO's performance year demographic risk score for an enrollment type to the ACO's BY3 demographic risk score for that enrollment type. Before calculating these demographic risk ratios, the demographic risk scores for each enrollment type for each year would be renormalized by dividing by the national mean demographic risk score for that enrollment type for that year.
- *Step 2:* Calculate the dollar-weighted average demographic risk ratio across the four enrollment types to obtain a single aggregate weighted average demographic risk ratio. The dollar weight for each enrollment type would be equal to historical benchmark expenditures for that enrollment type divided by the sum of historical benchmark expenditures across all enrollment types. Historical benchmark expenditures for each enrollment type would be calculated as per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type. The aggregate dollar-weighted average demographic risk ratio would be computed by multiplying the risk ratio for each enrollment type by its respective dollar weight and then summing across the four enrollment types. We noted that the approach of using an aggregate dollar-weighted average in this calculation would be similar to the approach used in the Shared Savings Program's original benchmarking methodology to determine whether demographic factors would be used to adjust risk scores for an ACO's continuously assigned beneficiaries.[352]
- *Step 3:* Calculate the sum of the aggregate dollar-weighted average demographic risk ratio from Step 2 and 0.030. This would represent the aggregate cap.
- Step 4: Determine prospective HCC risk score growth for each Medicare enrollment type. Prospective HCC risk score growth would be measured as the ratio of the ACO's performance year prospective HCC risk score for that enrollment type to the ACO's BY3 prospective HCC risk score for that enrollment type. Before calculating these prospective HCC risk ratios, the prospective HCC risk scores for each enrollment type for each year would be renormalized by dividing by the national mean prospective HCC risk score for that enrollment type for that year.
- *Step 5:* Calculate the aggregate growth in prospective HCC risk scores by calculating the dollar-weighted average prospective HCC risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average prospective HCC risk ratio, using the same dollar weights and the same approach described in Step 2.
- *Step 6:* Determine if the ACO will be subject to the cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is less than the aggregate cap determined in Step 3, no cap would apply to the prospective HCC risk ratio for any enrollment type, even if the prospective HCC risk ratio for a given enrollment type is higher than the aggregate cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is greater than or equal to the aggregate cap determined in Step 3, proceed to Step 7.
- *Step 7:* Compare the prospective HCC risk ratio for each enrollment type calculated in Step 4 to the aggregate cap determined in Step 3. If the prospective HCC risk ratio for a given enrollment type is greater than the aggregate cap, the prospective HCC risk ratio for that enrollment type would be set equal to the aggregate cap. If the prospective HCC risk ratio for a given enrollment type is less than or equal to the aggregate cap, no cap would apply to the prospective HCC risk ratio for that enrollment type.

The resulting prospective HCC risk ratios would then be multiplied by the ACO's historical benchmark expenditures for the relevant Medicare enrollment type at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year.

Table 76 provides a numeric example of the proposed methodology for a hypothetical ACO that is determined to be subject to the cap:

[351] CMS. Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model. February 24, 2022. Available at *https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model.*

[352] Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #7, February 2019), section 3.4.2, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-V7.pdf.*

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Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules; Final and Interim Final Rules

TABLE 76: Example of Risk Score Calculation for Hypothetical ACO Subject to Cap

Medicare Enrollment Type	Dollar Weights	Demographic Risk Ratio	Aggregate Cap	Prospective HCC Risk Ratio (Before Cap)	Is ACO Subject to Cap?	Prospective HCC Risk Ratio (After Cap, if Applicable)
ESRD	0.050	1.035		0.980		0.980
Disabled	0.075	1.020		1.050		1.050
Aged/dual	0.080	0.990		1.089		1.056
Aged/non-dual	0.795	1.030		1.076		1.056
Weighted Average		1.026	1.056	1.070	Yes	

For this hypothetical ACO, the dollar-weighted average demographic risk ratio is 1.026, meaning that demographic risk score growth averaged across the four enrollment types was 2.6 percent from BY3 to the performance year for the ACO's assigned beneficiaries, when measured against national mean risk score growth. To calculate the cap, we would add 0.03 to this value, arriving at an aggregate cap of 1.056. This ACO is determined to be subject to the cap because its dollar-weighted average prospective HCC risk ratio of 1.070 was higher than the aggregate cap. When comparing the aggregate cap to the prospective HCC risk ratio for each individual enrollment type, risk score growth for both the aged/dual eligible and aged/non-dual eligible enrollment types would be constrained by the cap. In this example, the aggregate cap that is ultimately applied is higher than the current 3 percent cap, meaning that this hypothetical ACO would benefit from the proposed policy relative to the current policy.

In the second numeric example described in Table 77, the ACO's aggregate demographic risk ratio is less than 1 and its aggregate cap of 1.028 is less than the current effective risk score cap of 1.030. In this case, the ACO's dollar-weighted average prospective HCC risk ratio of 1.013 is below the aggregate cap meaning that no cap would be applied to the prospective HCC risk score growth for any enrollment type, even though the ACO's ESRD, disabled, and aged/dual eligible populations all have prospective HCC risk ratios above the aggregate cap. This ACO would also benefit from the proposed policy relative to the current policy, with its benefit solely stemming from the use of an aggregate cap.

TABLE 77: Example of Calculation for a Hypothetical ACO Not Subject to Cap

Medicare Enrollment Type	Dollar Weights	Demographic Risk Ratio	Aggregate Cap	Prospective HCC Risk Ratio (Before Cap)	Is ACO Subject to Cap?	Prospective HCC Risk Ratio (After Cap, if Applicable)
ESRD	0.041	1.046		1.051		1.051
Disabled	0.098	1.027		1.032		1.032
Aged/dual	0.139	1.023		1.047		1.047
Aged/non-dual	0.722	0.986		1.002		1.002
Weighted Average		0.998	1.028	1.013	No	

While the examples above show ACOs that would benefit from the proposed risk adjustment policy relative to the current policy, we acknowledged in the proposed rule that there are ACOs that would receive a lower updated benchmark under the proposed policy, all else being equal. Namely, ACOs with a dollar-weighted average demographic risk ratio less than 1 found to be subject to the aggregate cap (which by default, will be less than 1.030) would have their upward risk score growth constrained more by the proposed aggregate cap than the existing 3 percent cap.

We simulated the impact of the proposed policy change using PY 2020 financial reconciliation data from ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 45 percent of ACOs would have had a higher updated benchmark with the proposed policy compared to the current policy, 5 percent would have had a lower updated benchmark with the proposed policy, and 50 percent would have been unaffected (that is, because they were not subject to any cap under either policy). Fifty-three ACOs had their prospective HCC risk ratio capped for at least one Medicare enrollment type under the proposed policy, compared to 177 ACOs under the current policy. Among ACOs that were capped under the current policy but not the proposed policy, many had prospective HCC risk score growth above 1.030 for one or more of the typically smaller enrollment types (that is, ESRD, disabled, aged/dual eligible) but not for their aged/non-dual eligible population. Table 78 illustrates that 47 percent of ACOs were subject to the current 3 percent cap imposed at the enrollment type level for one or more of the ESRD, disabled or aged/dual eligible enrollment types versus 17 percent for aged/non-dual eligible. Under the

proposed policy, the share would fall to 14 percent for both groups.

TABLE 78: Share of ACOs Subject to Risk Score Cap by Enrollment Type

	ESRD	Disabled	Aged/dual	ESRD, disabled and/or aged/dual	Aged/non-dual
Capped under Current Policy (Actual)	22%	22%	23%	47%	17%
Capped under Proposed Policy (Simulated)	5%	10%	10%	14%	14%

Based on this modeling, in the proposed rule we explained our belief that a significant share of ACOs would either be unaffected by or benefit from the proposed policy, especially those with increases in health risk as measured by demographic risk ratios, while a small share would do worse, likely reflecting decreases in health risk for their assigned beneficiary population as measured by demographic risk ratios. Additionally, we noted that the prospective HCC risk ratios for ESRD, disabled, and aged/dual eligible Medicare enrollment types would be much less likely to be capped under this proposed policy which would improve the incentives for ACOs to treat these medically complex, high-cost populations. At the same time, we noted that we believed the proposed policy would continue to be protective of the Trust Funds by continuing to limit incentives for coding intensity, as it would retain the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population.

Under the second option that we considered, we would continue to employ a fixed 3 percent cap on positive adjustments to prospective HCC risk scores, but we would apply the cap at the aggregate level. Specifically, the current 3 percent cap on risk score growth would apply in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible) instead of being applied separately for the population of beneficiaries in each Medicare enrollment type. We would only apply the current 3 percent cap on risk score growth for a particular enrollment type if the ACO's aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeded the value of the cap.

In the proposed rule, we explained that one advantage of this second, alternative option over the proposed approach, which allows aggregate prospective HCC risk score growth above 3 percent when aggregate demographic risk score growth is positive, is that no ACOs would receive a lower updated benchmark under this methodology compared to the current approach. However, according to our simulations using PY 2020 financial reconciliation data from ACOs in agreement periods beginning on or after July 1, 2019, while around 5 percent of ACOs would have had higher benchmarks under this second, alternative approach compared to the proposed approach, around 12 percent would have had lower benchmarks under this approach compared to the proposed approach. Thus, we noted that we believed that this second, alternative approach would, in aggregate, be less advantageous to ACOs than the proposed approach.

Under the third option that we considered, which we also described in the CY 2022 PFS proposed rule (86 FR 39294), we would allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area. The percentage applied would be equal to 1 minus the ACO's regional market share. For example, if regional risk score growth for a particular enrollment type was 5 percent and the ACO's regional market share was 20 percent, we would increase the cap on the ACO's risk score growth for that enrollment type by an amount equal to the difference between the regional risk score growth and the existing cap (2 percent) multiplied by one minus the ACO's regional market share (80 percent). Thus, the ACO would face a cap for this enrollment type equal to 4.6 percent instead of 3 percent (3 percent + (2 percent × 80 percent)). This approach would raise the existing cap while limiting the ability for ACOs with high penetration in their regional service areas to increase their cap by engaging in coding intensity initiatives that significantly raise their regions' prospective HCC risk scores. While this third, alternative option could potentially mitigate concerns raised by some commenters about the impacts of regional prospective HCC risk score growth, modeling suggested that relatively fewer ACOs would benefit under this alternative approach as compared to the proposed methodology incorporating demographic risk score growth. As we explained in the proposed rule, a key reason for this is that a relatively small share of ACOs affected by the existing 3 percent cap on risk score growth operate in regional service areas where regional risk score growth was greater than 3 percent.

In the CY 2023 PFS proposed rule, we noted that we still have concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those highly penetrated in their regional service areas, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. We also noted that we believed that our proposed methodology would avoid this undesired incentive while still accounting for changes in health risk for an ACO's assigned beneficiary population to a greater extent than the current policy and would also help to address cases where regional risk score growth stems from higher volatility due to small sample sizes or shifting demographics within a regional service area.

As discussed in the proposed rule, our modeling suggests that a majority of ACOs that operate in regions with risk score growth in excess of 3 percent for at least one Medicare enrollment type would have a higher updated benchmark under the proposed policy than the current policy. In addition, we explained our belief that our proposal to incorporate a prospective, external factor in the growth rates used to update the historical benchmark (see section III.G.5.c.(3) of the proposed rule) would further help to mitigate concerns raised by some commenters about the impacts of regional risk score growth, by

decreasing the weight placed on the two-way blend of national and regional growth rates when updating an ACO's historical benchmark for each performance year in the ACO's agreement period.

Although requested by some commenters in previous rulemaking, we declined to consider an approach that would limit the impact of prospective HCC risk score decreases. As we have described in past rulemaking (83 FR 68011), we remain concerned that such an approach would encourage favorable risk selection. If ACOs seek to attract low-cost beneficiaries or avoid high-cost beneficiaries, they could lower their performance year expenditures without any corresponding adjustment to their benchmark due to the cap on negative prospective HCC risk adjustments. We noted that we continued to believe that this effect would be detrimental to medically complex patients, who may miss the opportunity to receive better coordinated care through an ACO, as well as to the Medicare Trust Funds. We also declined to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area, as requested by some commenters as we were concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs that are highly penetrated in their regional service areas. Currently, ACOs that are highly penetrated in their regional service area have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. We noted that capping risk score growth in an ACO's regional service area could change these incentives and encourage ACOs to engage in coding initiatives.

We proposed to revise the regulations governing risk adjustment under the BASIC track and the ENHANCED track at § 425.605(a)(1) and § 425.610(a)(2), respectively, to reflect the proposed modifications to the risk adjustment methodology.

We sought comment on the proposed changes to the risk adjustment methodology for agreement periods beginning on or after January 1, 2024. While we noted that we believed that the proposed modifications to the program's risk adjustment methodology in conjunction with the other policies we were proposing would provide the best balance between addressing concerns raised by interested parties and limiting incentives for coding intensity and risk selection, we also sought comment on the two alternatives considered. We noted that we would consider the comments received on these alternative options along with the comments on our proposed changes to the risk adjustment methodology, and that we might consider adopting one of these alternatives in place of the proposed approach if we conclude that it would better address the concerns with the current risk adjustment methodology.

The following is a summary of the public comments received on the proposal to improve the risk adjustment methodology to better account for medically complex, high-cost beneficiaries and guard against coding initiatives and our responses:

Comment: Many commenters supported the proposal to account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and to apply the cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

Several commenters stated that they believe this proposed change to risk adjustment methodology would create a benchmark that is fairer and more representative of an ACO's assigned population. One commenter noted that effective risk adjustment discourages ACOs from taking steps to attract healthier beneficiaries or avoid sicker ones and makes program participation more attractive by reducing ACOs' exposure to financial risk stemming from fluctuations in patient mix. This commenter noted that ''relaxing'' the cap on risk score growth, as the proposed policy would do in some instances, would allow risk adjustment to do a better job of meeting these goals in cases where ACOs experience large increases in risk scores.

Several supportive commenters noted the proposed policy would continue to effectively guard against coding initiatives while balancing incentives for ACOs to care for high-risk beneficiaries. One commenter stated that the *current* 3 percent cap not only limits reward for coding initiatives but may also limit incentives for ACOs to care for high-risk beneficiaries. This commenter stated that the proposed policy would increase incentives for ACOs to care for underserved populations, while also protecting against coding initiatives and unwarranted spending increases since demographic risk score changes are less susceptible to coding initiatives than claims-based prospective HCC risk scores. Another commenter gave an example of how demographic risk scores are less susceptible to coding initiatives; one input to demographic risk scores is age, and a beneficiary is either 75 years old, or they are not, so age is not subject to coding intensity. That commenter stated that because they believe the only reason to have a cap on risk score growth is to address concerns around coding initiatives and demographic risk scores are not subject to coding initiatives, they support accounting for all changes in demographic risk scores. Another commenter explained their support for the proposal to apply the 3 percent cap in aggregate across the four Medicare enrollment types, as it would allow certain segments of the population to have ''appropriate coding documentation'' while also safeguarding against coding initiatives. Another commenter stated they supported the proposed changes because they would allow the risk adjustment methodology to better reflect changes to an ACO's assigned population without any unintended increase in coding intensity. One commenter explained that ACO coding initiatives represent a waste of real resources, since resources that ACOs invest in identifying and coding patient diagnoses will likely do ''little or nothing'' to improve patient care. Another commenter noted that they appreciate what CMS is doing to try to lessen the impact of coding initiatives, however, they also referenced concerns about the complexity of risk adjustment, and the potential for the current risk adjustment policy to drive inequity.

Many commenters stated that they support the proposed policy as it better incentivizes ACOs to care for certain populations, such as high-cost, medically complex, high-need, dually eligible, or underserved beneficiaries, with some saying this policy would create more equity than the current policy. Several commenters explained their belief the *current* policy is driving inequity. A few commenters stated that current policy may disadvantage ACOs that serve more vulnerable populations of beneficiaries with complex medical needs, and that the policy proposal offers an improvement over the current policy. A few commenters also noted that this proposal would better account for medically complex, higher cost beneficiaries, with one stating that that these beneficiaries would benefit from the proposal and another stating that the proposal would allow for more accurate benchmarks for ACOs that care for those populations. Another commenter added that the proposed policy would ensure

ACOs are not disincentivized from serving high-risk groups. A few commenters explained that the proposed policy would strengthen incentives for ACOs to care for underserved populations, with one explaining that enabling more ''accurate and appropriate'' payment for high-need beneficiaries will help facilitate increasing the number of ACOs participating in the Shared Savings Program who are focusing on enhancing equity by targeting underserved populations. Another commenter explained that the proposed policy is an improvement over current policy, as the current policy ''underemphasizes'' demographic risk factors and encourages ACOs to underserve beneficiaries with lower ''social determinant of health profiles,'' such as beneficiaries dually eligible for Medicare and Medicaid.

Many commenters indicated that one way the proposed policy would help to incentivize care for high-risk beneficiaries is through applying the 3 percent cap in aggregate across the four Medicare enrollment types, instead of capping by enrollment type. One commenter noted that applying the cap in aggregate will help to mitigate ACOs' avoiding providing care for certain underserved groups of beneficiaries. A few commenters noted that application of the current cap by enrollment type negatively impacts or disadvantages ACOs serving certain types of beneficiaries such as beneficiaries in the ESRD, disabled, and aged/dual enrollment types, with several commenters explaining that these enrollment types are more likely to be subject to the current 3 percent cap than the aged/non-dual enrollment type. One commenter stated that the current policy of capping by enrollment type creates a ''perverse'' incentive to avoid patients from high-risk enrollment types in favor of patients from enrollment types that are less likely to be subject to the 3 percent cap. Another commenter expressed their support for the aggregate cap because they believe that the current methodology does not do enough to adjust for changes in health status among beneficiaries that are assigned in one of the benchmark years and remain assigned in the performance year.

A few commenters noted that applying the cap at the aggregate level will help account for higher volatility in year-to-year changes in risk scores across the Medicare enrollment types, with one noting this would be especially true for the ESRD enrollment type. Another commenter explained that this change would make it less likely for the cap to apply when there are smaller sample sizes for high-risk enrollment types (that is, ESRD, disabled, and aged/dual). One commenter noted that among their own ACOs they see considerable variation in the risk ratios between the enrollment types, whereas they would expect that coding initiatives would increase all the risk ratios uniformly. Therefore, the commenter noted the variation is likely due to underlying changes in the beneficiary populations, not coding initiatives.

Response: We agree with commenters that the proposed policy would address several of the concerns previously raised by interested parties by allowing for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. The proposed policy also accounts for potentially significant changes in prospective HCC risk scores for certain enrollment types due to the smaller number of assigned beneficiaries in those enrollment types.

Comment: A few commenters who supported the proposed policy also offered caution about the policy. One commenter cautioned that it may introduce more complexity and less financial certainty. Several commenters cautioned that the proposed policy could hurt some ACOs if their demographic risk score drops.

Response: While we agree that incorporating changes in demographic risk scores and using an aggregate cap across all enrollment types would increase the complexity of the risk adjustment cap methodology, we believe the benefits of the proposed policy, as described in in section III.G.5.e.(2) of the proposed rule, outweigh the increased complexity. We disagree that our proposal would result in less financial certainty. We believe that the proposed policy would better account for changes in prospective HCC risk scores for certain enrollment types due to smaller numbers of assigned beneficiaries and reflect underlying changes in health risk for ACO's assigned beneficiary population as measured by demographic risk ratios.

Based on our modeling of the proposed policy as described in section III.G.5.e.(2) of the proposed rule, we believe that a significant share of ACOs, especially those with increases in health risk as measured by demographic risk ratios, would either be unaffected by or benefit from the proposed policies, while a small share of ACOs would have lower benchmarks, likely reflecting decreases in health risk for their assigned beneficiary population as measured by demographic risk ratios.

In addition to simulations discussed in section III.G.5.e.(2) of the proposed rule, which used PY 2020 financial reconciliation data, we have also simulated the impact of the proposed policy change using PY 2021 financial reconciliation data from ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 81 out of 332 ACOs had their prospective HCC risk ratio capped for at least one Medicare enrollment type under the proposed policy, compared to 185 ACOs under the current policy. Among ACOs that were capped under the current policy but not the proposed policy, many had prospective HCC risk score growth above 1.030 for one or more of the typically smaller enrollment types (that is, ESRD, disabled, aged/dual eligible) but not for their aged/non-dual eligible population. Table 79 illustrates that 50 percent of ACOs were subject to the current 3 percent cap imposed at the enrollment type level for one or more of the ESRD, disabled or aged/dual eligible enrollment types versus 30 percent for aged/non-dual eligible. Under the proposed policy, the share would fall to below 25 percent for both groups.

TABLE 79: Share of ACOs Subject to Risk Score Cap by Enrollment Type

	ESRD	Disabled	Aged/dual	ESRD, disabled and/or aged/dual	Aged/non-dual
Capped under Current Policy (Actual)	16%	25%	33%	50%	30%
Capped under Proposed Policy (Simulated)	6%	14%	17%	20%	24%

Based on both the PY 2020 and PY 2021 modeling, ACOs would be much less likely to have prospective HCC risk ratios for ESRD, disabled, and aged/dual eligible Medicare enrollment types capped under the proposed policies, which should improve the incentives for ACOs to treat these medically complex, high-cost populations. At the same time, we believe that the proposed policy would continue to protect the Trust Funds by continuing to limit incentives for coding intensity, as it would retain the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population.

Comment: One commenter was opposed to the proposal to account for changes in demographic risk scores before applying the 3 percent cap. This commenter did not indicate if they supported or opposed the proposal to apply the 3 percent cap in aggregate across the four Medicare enrollment types. The commenter stated that accounting for changes in demographic risk scores would hurt their ACO. They explained that the population of Medicare beneficiaries in their region is growing at more than double the national average, especially among those who have just ''aged-in'' to Medicare. They expressed concern that this increase in younger Medicare beneficiaries would lower demographic risk scores over time. The commenter stated that these demographic risk scores would be low compared to the ''reality of [the] population's true risk status''. They urged CMS to consider a possible unintended consequence to this policy proposal, which they believed could encourage ACOs to ''cherry-pick'' patients based on demographics like age, since younger patients may have lower demographic risk scores.

Response: As described earlier in this section, we believe that changes in demographic risk ratios reflect actual changes in health risk for ACO's assigned beneficiary population. We also believe that the proposal to account for changes in demographic risk ratios would create incentives for ACOs to care for older beneficiaries, as well as beneficiaries in the aged/dual, disabled and ESRD enrollment types as risk score growth for these enrollment types would be less likely to be capped, as discussed earlier in this section. We are unsure why the commenter believes that the demographic risk scores of their ACO's assigned beneficiaries do not reflect the population's actual risk status. However, we note that after accounting for changes in demographic risk ratios, the proposed policy would continue to allow for up to three percent growth in prospective HCC risk scores. At this time, we believe that accounting for changes in demographic risk ratios prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores is appropriate, but we will continue to monitor the impacts of the cap and may propose further refinements to our risk adjustment policies in future rulemaking.

Comment: MedPAC supported accounting for all changes in demographic risk scores prior to applying the cap but disagreed with our proposal to maintain the 3 percent cap after accounting for demographic risk scores, believing it should be reduced. More specifically, MedPAC noted its belief that there is insufficient justification for maintaining the current 3 percent cap after accounting for demographic risk score changes. They explained their belief that part of the impetus for the current policy of allowing risk scores to increase by 3 percent was that it would better account for demographic changes that are largely out of an ACO's control. MedPAC did not believe that further risk score growth above the current 3 percent cap was justified. MedPAC expects that changes in an ACO's population health status would be adequately accounted for by the CMS–HCC risk adjustment model, and the current 3 percent cap would likely cover anomalies when ACO populations have deteriorating health status.

MedPAC disagreed with CMS that continuing to allow for a 3 percent cap would incentivize ACOs to care for underrepresented beneficiaries. MedPAC explained that applying the 3 percent cap after accounting for demographic risk score changes would primarily benefit ACOs that serve disproportionately more white and aged/non-dual beneficiaries. MedPAC explained that allowing this increase in risk scores presumes that CMS expects ACOs' assigned populations to become sicker more rapidly than the national population of assignable beneficiaries within each of the four Medicare enrollment types and pointed to statements by CMS in the CY 2023 PFS proposed rule that indicate otherwise. MedPAC also stated that despite the fact that the non-ACO population is increasingly comprised of higher spending beneficiaries and medically complex patients, the growth in risk scores for this population has been slower than that of beneficiaries assigned to ACOs.

MedPAC explained its belief, based on its own analysis and other recent research,[353] that the majority of CMS–HCC risk score growth for beneficiaries assigned to ACOs comes from coding initiatives and not from changes in beneficiary demographics or deteriorating health status. Another commenter, who did not clearly state whether they supported or did not support the proposed policy, stated that there should be guardrails to deter ACOs from taking advantage of an increased cap with coding initiatives.

Response: When we finalized the 3 percent cap in the December 2018 final rule (83 FR 68007 through 68013), we acknowledged that the policy balanced competing concerns between the need to allow for some upward growth in prospective HCC risk scores between the benchmark period and the performance year and the concern that those risk scores, in general, are susceptible to coding initiatives. We believe that the proposed policy continues to balance these competing concerns. Specifically, we believe that the proposed policy would be protective of the Trust Funds by limiting incentives for coding intensity as it would retain the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population, while also allowing for more significant changes in prospective HCC risk scores for certain enrollment types with smaller numbers of assigned beneficiaries and for potentially higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of high risk beneficiaries in the aged/dual eligible, disabled and ESRD enrollment types.

While we recognize there is a risk of rewarding coding initiatives by maintaining the 3 percent cap on growth in prospective HCC scores, there are also reasons to allow some prospective HCC risk score growth beyond demographic risk score growth. For example, there may be natural variation over time in the health of an ACO's assigned population, an ACO may establish new services that provide care for medically complex populations in their regional service area, or an ACO may attract a sicker population over time in response to Shared Savings Program policies designed to encourage ACOs to care for these populations. In addition, some increased coding by ACO participants and ACO providers/

[353] Citing Chernew, M.E., J. Carichner, J. Impreso, et al. 2021. Coding-driven changes in measured risk in accountable care organizations. Health Affairs 40, no. 12 (December). *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.00361.*

suppliers may be appropriate when more complete clinical information at the point of care is required to help facilitate care coordination, quality improvement, and population management activities. We also recognize that certain acute events, such as a heart attack, which almost always requires a hospitalization, are likely to have an upward impact on prospective HCC risk scores that is not attributable to provider coding initiatives. Additionally, if an ACO begins to serve previously underserved beneficiaries during an agreement period, those beneficiaries may not have had complete diagnosis coding due to lack of access to care. As a result, capturing their healthcare needs may also have an upward impact on prospective HCC risk scores for the ACO's assigned beneficiary population that is not attributable to provider coding initiatives.

While we believe that there are reasons to allow for some upward growth in prospective HCC risk scores between the benchmark period and the performance year, the proposed policy would continue to guard against coding initiatives. As described earlier, the proposed policy retains the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population. Additionally, ACOs experiencing a decrease in health risk for their assigned beneficiary population as measured by demographic risk ratios would likely have an aggregate demographic risk ratio less than 1, meaning that their aggregate cap on prospective HCC risk score growth would be less than the current cap of 3 percent. We also note that the cap on positive growth of prospective HCC risk scores remains the same for the entirety of an ACO's 5-year agreement period. We believe it is reasonable to expect some increase in beneficiary health risk over a 5-year period even in the absence of coding initiatives. Although we believe that the proposed cap on positive risk adjustments is reasonable and appropriate, we will continue to monitor impacts of the cap and may propose further refinements to our risk adjustment policies in future rulemaking.

Comment: Several commenters that were supportive of the proposed policy asked that the cap applied at the aggregate level after accounting for all changes in demographic risk scores be raised above 3 percent. Several requested that the cap be raised to 5 percent. Another commenter requested that CMS remove the cap on increases in diagnosis risk scores, as well as demographic risk scores.

Many commenters explained their request for a higher cap. Several commenters stated their belief that a 3 percent cap is insufficient and/or arbitrary when applied over the course of a 5-year agreement period. Several stated that allowing risk scores to increase by only 3 percent after adjusting for demographic risk scores will not fully assist outlier ACOs that will still be capped under the proposed policy. A couple of commenters cited findings from NAACOS that 87 percent of ACOs would have had at least one enrollment type capped at either positive or negative 3 percent (even though the current and proposed policy do not include a cap on risk score decreases) within the first 3 years of their agreement period, with 88 percent of ACOs capped in the first performance year, 85 in the second performance year, and 92 percent in the third performance year. However, these commenters did not provide further details on how their modeling was developed.

Many commenters noted a higher cap would incentivize ACOs to care for certain populations, such as high-cost, medically complex, high-risk, underserved and/or beneficiaries with new or worsening illnesses. Several commenters stated their belief that under the current cap ACOs can be penalized for accurately coding and maintaining the same level of risk over their agreement period. A few commenters explained that raising the cap above 3 percent would reduce the negative impact of physicians accurately identifying patient needs, especially in underserved communities. Many commenters similarly stated that that a higher cap would decrease the penalty on ACOs for accurate coding of conditions that may have historically been underreported for underserved beneficiaries.

A couple of commenters explained that as ACO penetration increases in underserved areas, where patients have not had appropriate access to high quality care, physicians in ACOs will increasingly identify underreported healthcare needs and a static cap on risk score growth will penalize this appropriate effort to accurately document the health of the community. According to the commenters, the cap on risk score growth is a meaningful disincentive for treating underserved communities that CMS should address if it is to be successful in meeting the goal of increasing ACO participation in these areas. Another commenter explained that ACOs serving these underserved populations must devote and deploy significant resources to capturing and care planning around the needs of complex patients who have not had sufficient contact with the health care system to have a grasp on their health risks and disease burden or that need education around managing chronic illnesses. The commenter stated that, as a result, it is crucial that risk adjustment accounts for the actual risk burden of assigned beneficiaries so an ACO's benchmark reflects the full amount of resources needed to provide comprehensive care to this beneficiary population. That commenter concluded that a higher risk score growth cap will encourage providers and suppliers in underserved areas to join ACOs in larger numbers, knowing that their resource allocations will be sufficiently accounted for in benchmark adjustments that reflect the actual risk burden of their assigned beneficiary population.

Another commenter stated that maintaining the cap on risk scores does not allow ACOs to capture the significant turnover and changes in health status that their beneficiaries experience, and that this is particularly true as the burden of illness in the Medicare population increases over time. Another commenter similarly stated that even if the 3 percent cap on positive risk score increases applies only after accounting for changes in demographic risk scores, the increased costs of individuals who develop a medically complex, high-cost condition after they have been assigned to an ACO will not be adequately accounted for. That commenter explained that failing to adjust fully for changes in beneficiary health status ignores the fact that even when care is optimally managed, individuals become sicker, and therefore, more expensive to care for as disease progresses. The commenter gave as an example the case of a beneficiary who has been continuously attributed to an ACO and is diagnosed with cancer, stating that it is inappropriate for the ACO to be responsible for that additional cost without adjustments from Medicare for higher spending related to that beneficiary.

A few commenters stated that increasing the cap is important given the effects of the COVID–19 pandemic on healthcare utilization. One of those commenters explained that the COVID–19 PHE caused significant decreases in patient encounter volume, and as a result, ACOs were unable to capture ''large swaths'' of beneficiaries' HCCs. Thus, the commenter explained, most ACO risk scores for 2021 were ''extremely'' low but they will likely increase significantly in subsequent

years because patients have returned to the office. A couple of commenters noted another reason that risk scores may increase in subsequent years is that many patients delayed care during the COVID–19 pandemic and may now have a higher severity of illness. One of those commenters concluded that applying the existing cap artificially penalizes ACOs for patients that delayed or missed receiving care because they needed to stay in the safety of their homes during the pandemic. A few commenters noted that ACOs that started an agreement period in January of 2022, and for which 2021 is their third benchmark year, would be significantly impacted by the COVID–19 PHE because they are likely to have significant risk score growth between BY3 and the performance years of their agreement period. Specifically, these commenters noted that risk scores for 2021 would be based on diagnoses captured the year before, which is 2020. The reduction in services in 2020 due to the pandemic may have caused an artificial reduction in risk scores in 2021 that, in turn, will result in ACOs starting a new agreement period in 2022 being more likely to be subject to the 3 percent cap.

One commenter, who requested that CMS raise the cap on risk score changes by at least 10 percent, noted that in an assessment they conducted they saw a number of diagnoses that are documented in a medical record but that are not submitted in claims due to the structural limitation of the number of diagnoses that can be submitted on a CMS–1500 claim form. The commenter did not provide additional rationale for how raising the risk score cap to at least 10 percent would be applied relative to the existing or proposed risk adjustment methodology.

Response: At this time, we decline to lift the cap on positive adjustments resulting from changes in prospective HCC risk scores above 3 percent. We believe that the proposed policy, under which the cap would apply after accounting for changes in demographic risk scores, will allow for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual, disabled and ESRD enrollment types, while still protecting against increases in coding intensity. We believe that further increasing the cap would allow for excessive returns for coding initiatives. While we do not intend to hinder appropriate efforts to accurately document the health of the beneficiaries, we note, as discussed earlier in this section, that MedPAC has observed that the majority of the CMS–HCC risk score growth for ACOs comes from coding initiatives and not from changes in beneficiary demographics or deteriorating health status.

With regards to the concerns raised by commenters about the impact of the COVID–19 pandemic on risk scores, we believe that CMS' methodology of renormalizing risk scores by dividing by the national mean will mitigate the impacts of any changes in ACO risk scores that may have stemmed from the impact of COVID–19 such that the cap will not inappropriately limit risk score growth for ACOs that started a new agreement period in 2022. Although we believe that the proposed cap on positive risk adjustments is reasonable and appropriate, we will continue to monitor impacts of the cap and may propose further refinements to our risk adjustment policies in future rulemaking.

With regard to the commenter that requested that CMS remove the cap on diagnosis risk scores, as well as demographic risk scores, we clarify that the 3 percent cap is on diagnosis, or HCC, risk scores, not demographic risk scores. Regarding the comment raising concerns about structural limitations on reporting diagnosis codes on the CMS–1500 claim form, we note that the allowance of twelve diagnosis codes is the national format for CMS FFS claims as developed by the National Uniform Claim Committee and claims used to compute risk scores for both assigned and assignable FFS beneficiaries under the Shared Savings Program contain a maximum of twelve diagnosis codes ensuring comparability between the two populations.

Comment: Several commenters requested that a cap be placed on negative changes in risk scores, also referred to as a symmetrical cap. One commenter who opposed the proposed policy suggested that CMS apply a symmetrical 5 percent cap across all enrollment types. Some of the commenters that were generally supportive of the proposed policy but that requested the cap be increased to 5 percent also requested a symmetrical downward cap of negative 5 percent. Many of those commenters seemed to indicate that if the cap could not be raised to 5 percent, a downward 3 percent cap should be applied along with the positive 3 percent cap. There were several other commenters who also requested a negative cap be instituted in addition to a positive cap, but did not request the cap be increased, instead asking for a symmetrical 3 percent cap.

A few of the commenters requesting a downward cap stated that an ACO may experience a potential decrease in its risk score if others in their region increase their coding intensity, and that this could be made worse for ACOs with large numbers of specialists who have fewer opportunities to increase their risk score. Another commenter stated that a downward cap would protect ACOs with less sophisticated coding efforts from large adjustments in their benchmark resulting from increased national coding and provide more predictability. One commenter noted that the application of a symmetrical floor on an ACO's risk score would be similar to the risk adjustment model the Innovation Center uses in the GPDC Model (which will transition to the redesigned and renamed ACO REACH Model on January 1, 2023). One commenter stated that a higher, symmetrical cap is important given the effects of the COVID–19 pandemic. This commenter stated that patients appear to be sicker and more medically complex than before the pandemic, so a higher symmetrical cap amount would more appropriately account for risk adjustment changes over a 5-year agreement period.

Response: As described in section III.G.5.e.(2) of the proposed rule, we decline to consider an approach that would limit the impact of prospective HCC risk score decreases at this time. As we have described in past rulemaking (83 FR 68011), we remain concerned that such an approach would encourage favorable risk selection. If ACOs seek to attract low-cost beneficiaries or avoid high-cost beneficiaries, they could lower their performance year expenditures without a corresponding adjustment to their benchmark due to the cap on negative prospective HCC risk adjustments. We noted that we continue to believe that this effect would be detrimental to medically complex patients, who may miss the opportunity to receive better coordinated care through an ACO, as well as to the Medicare Trust Funds. We will continue to monitor the impacts of HCC risk score changes and may propose further refinements to our risk adjustment policies in future rulemaking.

Comment: A couple of commenters that requested raising the cap applied to ACO prospective HCC risk score growth to 5 percent additionally requested that the cap be allowed to further increase for ACOs in regions where risk score growth exceeds five percent, with one stating that a flat percentage cap will always disadvantage ACOs in regions where risk score growth exceeds the cap and another stating that this additional flexibility would ensure ACOs are not

disadvantaged by operating in underserved communities.

Many commenters wrote in support of capping regional risk ratios in addition to capping ACO risk ratios. Several commenters stated that it is critical that whatever policy CMS finalizes for capping ACOs' risk score growth the same policy must also apply to regional risk scores. Several commenters noted that CMS should not apply adjustments to only one side of the equation, referring to capping ACO risk ratios without capping regional risk ratios, with many of them saying this would lead to unintended consequences and another saying it would have inequitable results. One commenter stated that by not capping regional risk ratios, CMS would be sending a message that is not aligned with reducing inequity. Several commenters stated that not capping increases in regional risk scores will stifle growth in exactly the areas CMS wants growth the most. A few commenters explained that lack of regional risk score growth caps incentivizes ACOs not to grow in places with certain types of populations, such as those with increasing health burdens, higher needs, and/or higher numbers of aged/dual and disabled enrollees. Several commenters stated that they do not believe that it was CMS's intent to financially penalize ACOs for growing in counties where beneficiaries are getting sicker but that this is effectively what is done by applying the cap only to the ACO and not to the regional risk ratios.

One commenter stated that they agree with CMS' statements in the proposed rule and comments made by CMS officials that there is reason to be concerned about regional risk ratios being subject to coding intensity, but that they disagree with CMS that it is a small problem when the risk ratio for a region exceeds the cap. Several commenters cited analysis by Milliman [354] which found that 15 percent of Shared Savings Program beneficiaries already reside in counties that have risk ratios above the 3 percent cap. Many of these commenters noted that this means that every ACO in those counties will incur losses for every additional at-risk beneficiary they establish a relationship with. One commenter added that Milliman's analysis also found that in 2020 40 percent of ACOs served regions where at least one Medicare enrollment type exceeded the cap, and that by 2024 Milliman estimates that one in four ACOs will serve regions with risk ratios greater than three percent. This commenter stated that they knew of specific ACOs that have seen their savings rate cut in half due to their region exceeding the three percent cap. Another commenter stated that since the risk scores used to calculate the risk-adjusted regional benchmark trend are not capped, the regional risk score trend could reduce an ACO's benchmark by more than 3 percent.

Response: As described in section III.G.5.e.(2) of the proposed rule, in developing our proposed policy we declined to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area, as requested by some commenters, as we are concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs that are highly penetrated in their regional service areas. Currently, ACOs that are highly penetrated in their regional service area have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. Capping risk score growth in an ACO's regional service area could remove this disincentive and encourage ACOs to engage in coding initiatives.

We also noted in section III.G.5.e.(2) of the proposed rule that we did not consider an approach under which we would account for the difference between the 3 percent cap and risk score growth in the ACO's regional service area in combination with applying a cap on risk score growth in aggregate across Medicare enrollment types (with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year). As we explained in the proposed rule, we view these two approaches to be inconsistent with each other, as one approach allows an ACO's risk score growth to rise above 3 percent based on risk score growth in the ACO's regional service area, whereas the other would retain the 3 percent cap, but apply it at the aggregate level. We also noted that we still have concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those highly penetrated in their regional service areas, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. We also noted our belief that the proposed methodology would avoid this undesired incentive while still accounting for changes in health risk for an ACO's assigned beneficiary population to a greater extent than the current policy and would also help to address cases where regional risk score growth stems from volatility due to the small number of assignable beneficiaries in a particular enrollment type or shifting demographics within a regional service area.

In section III.G.5.e.(2) of the proposed rule, we stated that a relatively small share of ACOs affected by the existing 3 percent cap on risk score growth operated in regional service areas where regional risk score growth was greater than 3 percent. Since then, we have done additional analysis. Using PY 2020 data for ACOs in agreement periods beginning on or after July 1, 2019, we found that sixteen percent of ACOs were operating in a region where the regional risk ratio was above 1.03 for at least one enrollment type and 4 percent were operating in a region where the weighted average regional risk ratio was above 1.03.[355] Using PY 2021 data, 31 percent of ACOs were operating in a region where the regional risk ratio was above 1.03 for at least one enrollment type and 11 percent were operating in a region where the weighted average regional risk ratio was above 1.03. Reviewing this more recent data, we continue to believe a relatively small share of ACOs operate in regional service areas where regional risk score growth is greater than 3 percent, but we will continue to monitor the impacts of regional risk score growth and may propose further refinements to our risk adjustment policies in future rulemaking.

As noted previously in this section of this final rule, the modeling conducted during the development of the proposed policy suggests that a majority of ACOs that operate in regions with risk score growth in excess of 3 percent for at least one Medicare enrollment type would have had a higher updated benchmark under the proposed policy than the current policy. This continues to be true in our modeling using PY 2021 data. In addition, we believe that our decision to finalize the proposal to incorporate a prospective, external factor in the growth rates used to update the historical benchmark (see section

[354] Kildow, J., Gusland, C., Kramer, M.J., & Li, C. Evaluating the financial cost of the asymmetry in the MSSP risk score growth cap. May 10, 2022. available at *https://us.milliman.com/en/insight/evaluating-the-financial-cost-of-the-asymmetry-in-the-mssp-risk-score-growth-cap.*

[355] For purposes of this analysis, we estimated regional risk scores for the performance year and BY3 by dividing non-risk adjusted regional expenditures for each enrollment type by risk-adjusted regional expenditures for that enrollment type.

III.G.5.c.(3) of this final rule) will further help to mitigate concerns raised by some commenters about the impacts of regional risk score growth, by decreasing the weight placed on the two-way blend of national and regional growth rates when updating an ACO's historical benchmark for each performance year in the ACO's agreement period.

Comment: A few commenters urged CMS to allow ACOs that are in the middle of an agreement period on January 1, 2024, the flexibility to opt into this proposed policy without having to early renew. One commenter described the early renewal process as being onerous. Another asked that, where possible, this policy should apply to all currently participating ACOs with earlier agreement period start dates (such as, agreement periods beginning on January 1, 2023, and earlier).

Response: We decline the commenters' suggestion and are finalizing our proposal to apply the changes to the risk adjustment methodology on an agreement period basis. The revisions we are making in this final rule to the risk adjustment methodology will apply to ACOs entering a new agreement period beginning on or after January 1, 2024. Elsewhere in section III.G.5 of the final rule, we explain our concerns with an approach to applying benchmarking changes to ACOs within an agreement period in responding to similar suggestions. Among other reasons, such an approach would introduce considerable operational complexity into the program's benchmarking methodology, particularly as the revised risk adjustment methodology is one of a package of changes, we are finalizing to the benchmarking methodology to be applicable for agreement periods beginning on January 1, 2024, and in subsequent years.

We recognize that currently participating ACOs that entered an agreement period prior to January 1, 2024, may wish to pursue the option to early renew for a new agreement period beginning on January 1, 2024, by terminating their current agreement and immediately entering a new agreement period, so that they would have the opportunity to participate under the revised benchmarking methodology. (Refer to paragraph (2) of the definition of ''renewing ACO'' in § 425.20, and the application procedures set forth in § 425.224.) We note that early renewal, like renewing upon completion of an agreement period, will result in rebasing of the ACO's historical benchmark, and will affect the ACO's eligibility for certain participation options (refer to section III.G.2. of this final rule), as well as the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (refer to § 425.600(f)).

Comment: MedPAC recommended that CMS address the underlying incentives for coding initiatives and the accuracy of risk adjustment before considering any policy that would increase the risk score growth cap (such as the proposed policy), repeating their comment on the CY 2022 PFS proposed rule summarized in the CY 2022 PFS final rule (86 FR 65304). MedPAC also recommended that CMS use 2 years of diagnostic data for risk adjustment as permitted under the 21st Century Cures Act, which they believe would improve the accuracy of coefficients estimated with FFS data and reduce year-to-year variation in beneficiary risk scores, along with reducing the administrative burden for ACO participants related to HCC documentation. MedPAC further suggested that CMS should only consider changes to the 3 percent cap after making this suggested change and after observing the effect of the phase-in from 2020 to 2022 of the Alternative Payment Condition Count (APCC) CMS–HCC risk adjustment model, which they noted was designed to improve the accuracy of risk adjustment for high-spending beneficiaries. In addition, MedPAC also advocated for the approach outlined in the Commission's June 2022 report to the Congress that would limit the effect of outliers (that is, beneficiaries with the largest underpredictions and overpredictions in spending) on risk score coefficients. MedPAC relayed that the Commission's analysis showed that this change would improve the accuracy of predicted spending under the risk-adjustment model, especially for medically complex beneficiaries. MedPAC stated that until CMS is willing to consider underlying changes that directly affect coding incentives or provides an empirical justification for a 3 percent allowance for coding changes (after allowing demographic risk score changes), the agency should consider applying a uniform coding adjustment across all ACOs to offset the increases to benchmarks via coding increases. This adjustment would protect the Medicare program from subsidies given to ACOs for their coding efforts. MedPAC urged that to the extent that CMS considers any additional coding allowance in the future (including for regional changes in risk scores), CMS should apply an adjustment that ensures the average increase in risk scores across all ACOs is no greater than the average increase in risk scores for the assignable population. To mitigate coding initiatives, they suggested that CMS could group ACOs into categories of high, medium, and low coding intensity and then apply a coding intensity adjustment based on the average level of coding intensity for each group (similar to an option the Commission discussed in its March 2017 report to the Congress).

Response: We appreciate MedPAC's suggestions, and we believe our current risk adjustment methodology which renormalizes risk scores for each enrollment type based on a national assignable FFS population, and our proposed changes to apply the 3 percent cap after accounting for demographic risk score changes address many of the concerns raised by MedPAC. However, CMS will continue to monitor how the risk adjustment model is used in the Shared Savings Program and the impact of the policies finalized in this rule and may propose further changes or refinements in future rulemaking. We also note that many of these suggestions go beyond the scope of the modifications we proposed to the program's risk adjustment methodology.

Comment: A few commenters offered two recommendations for CMS: (1) removing dually eligible beneficiaries from the risk adjustment calculation and limiting it to non-dually eligible beneficiaries; and (2) adding ESRD patients to this calculation. These commenters explained that they wanted the dually eligible beneficiaries removed because the cost of care required for these beneficiaries is much greater and would not be addressed by the proposed modifications to risk adjustment methodology. These commenters also noted that adding ESRD patients would account for high-cost beneficiaries more accurately.

Response: We believe these comments could be interpreted in multiple ways and would require additional clarity before we could consider implementing the commenters' suggestions. However, we note that for the reasons discussed previously in this section, we believe the proposed modifications to the risk adjustment methodology, which we are adopting in this final rule, will make it less likely that the aged/dual eligible enrollment type is capped. Regarding the commenters' second request, we clarify that beneficiaries in the ESRD enrollment type are included in risk adjustment calculations using the separate CMS ESRD risk adjustment model.

Comment: One commenter indicated their support for the alternative option,

also referred to as the second option, to apply an aggregate cap without first accounting for changes to demographic risk scores. This commenter stated that they were ''very pleased'' with CMS' proposal to apply the 3 percent cap in aggregate across the four Medicare enrollment types, which they stated would allow ACOs that care for larger populations of beneficiaries in the ESRD, disabled, and aged/dual enrollment types to receive higher benchmarks than under the current risk adjustment methodology. However, this commenter urged CMS to reconsider its proposal to move forward with a methodology that would first account for demographic risk changes prior to applying the 3 percent cap on risk score, particularly for ACOs serving populations with a high rate of death. This commenter explained that they are an ACO that serves many high-risk beneficiaries at the end of life, as measured by a high death rate in their long-term institutionalized (LTI) population, and are concerned that churn in their assigned beneficiary population, which causes fluctuations in their annual demographic score, would result in unintended year-to-year changes in their aggregate risk score cap, creating significant annual instability for their ACO. This commenter asked that at a minimum, CMS use the higher of the proposed policy or this alternative option when calculating the risk score cap for each ACO to avoid unforeseen and negative consequences to ACOs with a large proportion of high-risk beneficiaries.

Response: We decline to finalize the alternative option of applying the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year. We also decline the commenter's suggestion that we use the higher of the proposed policy or this alternative option.

As noted earlier in this section and in section III.G.5.e.(2) of the proposed rule, based on our modeling of the proposed policy, we believe that a significant share of ACOs, especially those with increases in health risk as measured by demographic risk ratios, would either be unaffected by or benefit from the proposed policy, while a small share would do worse, likely reflecting decreases in health risk for their assigned beneficiary population as measured by reductions in demographic risk ratios.

Additionally, as noted in section III.G.5.e.(2) of the proposed rule, while one advantage of this alternative option of applying the cap on risk score growth in aggregate across Medicare enrollment types, without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year over the proposed approach is that no ACOs would receive a lower updated benchmark, according to our simulations using PY 2020 financial reconciliation data from ACOs this alternative approach would, in aggregate, be less advantageous to ACOs than the proposed approach. This remains true in our simulations using PY 2021 financial reconciliation data.

Comment: Several commenters urged CMS to standardize the risk adjustment methodology it uses, with some commenters asking for standardization across all Medicare programs and models and others focusing on standardization across the Shared Savings Program and MA. Some of these commenters asked CMS to limit MA risk score growth and others asked that we allow ACO risk scores to grow the same way they do in MA plans. Several of these commenters discussed differences in the limits on coding intensity between MA and the Shared Savings Program, with many commenters indicating that more risk score growth is allowed in the MA program than in the Shared Savings Program.

One commenter argued that CMS should take steps to limit MA risk score growth, and if that cannot be done, should pursue a policy of bringing the risk score methodology for the two programs into parity. The commenter noted that if this issue is not resolved, it is likely that providers and suppliers will continue their movement out of ACOs and into the ''much more lucrative'' MA program. Another commenter argued that eliminating the cap on ACO risk score growth and replacing it with the MA coding intensity adjustment would be the best way to bring parity between the two programs. Other commenters stated that, at a minimum, CMS should align the methodology used in the ENHANCED track of the Shared Savings Program with MA, since currently providers and suppliers have different incentives under the two programs which lead to inconsistent coding practices. One commenter stated that CMS should consider leveling the Medicare risk adjustment (MRA) playing field between MA plans and ACOs because it will increase ACO participation by providers and suppliers and propel participation in value-based care models by 2030. This commenter noted that most of their providers and suppliers participate in multiple MA plans that have established oversight and internal audits into MRA coding, and typically use the same care parameters for both FFS and MA plans. However, their participants are frustrated by the different methodologies for risk score normalization and determining risk adjustments and the different impacts on payments under MA and the Shared Savings Program. One commenter also urged CMS to reduce the opportunity for either ACOs or MA plans to increase their risk scores through coding initiatives in order to reduce the resources wasted in this area. However, this commenter noted that, contrary to CMS' assertion in the proposed rule, allowing for more aggressive coding initiatives by ACOs probably would not increase costs to the Federal government because it would reduce the difference in coding intensity between traditional Medicare and MA, which would potentially reduce payments to MA plans which would offset the cost of these more aggressive coding initiatives by ACOs. Several commenters that requested a cap on downward risk score growth noted that a cap on downward adjustments would help ACOs to compete with MA plans. Another commenter encouraged CMS to explore ways to implement the CMS Innovation Center HCC concurrent risk adjustment model in the Shared Savings Program. They explained that concurrent risk models are better able to predict costs for populations with high-disease burden or who are otherwise seriously ill, because the approach can better capture a rapid deterioration in health in the current year, such as through the occurrence of acute episodes that are difficult to predict or prevent (for example, heart attack). In contrast, they explained that the existing CMS–HCC prospective risk adjustment model predicts current-year costs using health status indicators (diagnoses) from the prior year.

Response: We appreciate the commenters' suggestions but note that these suggestions go beyond the scope of modifications we proposed to the program's risk adjustment methodology.

Comment: A couple of commenters requested that CMS change the risk adjustment methodology across all Medicare models by: updating the HCC Model to use ICD–10 codes; refining HCC diagnoses; and incorporating a social determinants of health (SDOH) component into the HCC severity calculations. In regard to the use of ICD–10 codes, one of the commenters explained that the current methodology

is based on ICD–9 codes, which have been largely phased out under the Medicare payment systems in favor of ICD–10 codes. The commenter stated that ICD–10 codes allow for multiple clinical concepts, offering more specificity than ICD–9 codes.

Another commenter stated that the current Shared Savings Program risk adjustment policy could be improved further by incorporating sociodemographic factors such as food insecurity, homelessness, and other factors. The commenter explained that SDOH are widely recognized as important predictors in clinical care, noting that the American Medical Association (AMA) has recognized the importance of SDOH in the medical decision-making component used in the assignment of evaluation and management code level. That commenter stated that incorporating SDOH disease interactions would provide a mechanism to encourage the collection of information on SDOH without incentivizing coding initiatives for financial improvement and should be used to appropriately capture the impact of SDOH on patient severity reporting.

Response: We appreciate the commenters' suggestions but note that these suggestions go beyond the scope of the proposed modifications to the Shared Savings Program's risk adjustment methodology. We will monitor the impacts of the combination of Shared Savings Program policies that we are finalizing in this rule, and as we gain experience with the updated risk adjustment methodology, we will continue to consider these recommendations to help inform future rulemaking.

After consideration of the public comments, we are finalizing the proposed modifications to the risk adjustment methodology to account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and to apply the cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible), with one modification to correct an error in the description of the methodology for calculating of the weighted average demographic and prospective HCC risk scores in the proposed rule.

As described earlier in this section of this final rule, in the CY 2023 PFS proposed rule we proposed to calculate the weighted average demographic risk ratio across the four Medicare enrollment types, where the weight applied to the demographic risk ratio for each enrollment type would be equal to historical benchmark expenditures for that enrollment type divided by the sum of historical benchmark expenditures across all enrollment types. We indicated that the historical benchmark expenditures for each enrollment type would be calculated as per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type. We also indicated that those same weights would be applied to the prospective HCC risk ratios for each of the four Medicare enrollment types in the calculation of the weighted average prospective HCC risk ratio. We need to correct the description of the weights applied to the risk ratios for each of the four Medicare enrollment types when calculating the weighted average demographic risk ratio and the prospective HCC risk ratio. The weights applied will be equal to the per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's performance year assigned beneficiary person years for that enrollment type (not multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type as previously erroneously stated). This error was typographical. The correct weights were used in determining the weighted average prospective HCC and demographic risk ratios in the simulations discussed earlier in this section of this final rule, whose results are shown in Tables 78 and 79. Additionally, we believe that weighting prospective HCC and demographic risk ratios for each enrollment type by both per capita historical benchmark expenditures and performance year person years for each enrollment type is warranted when calculating weighted average prospective HCC and demographic risk ratios because of the assumption that growth in expenditures is proportional to growth in risk scores. We also note that, while in the proposed rule and earlier in this section of the final rule we used the term ''dollar-weighted average'' when describing the weighted average prospective HCC and demographic risk scores, we have elected to no longer use this terminology as the weights used in the weighted averages are not just per capita historical benchmark expenditures (or ''dollars'') but also performance year person years.

We are finalizing the proposed revisions to the regulations at § 425.605(a)(1) and § 425.610(a)(2) with modifications to incorporate the aforementioned correction to the methodology for determining the aggregate weighted average growth in demographic risk scores and the aggregate weighted average growth in prospective HCC risk scores, and to no longer use the term ''dollar-weighted''. Accordingly, we have revised the language in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C). In addition, the proposed provisions at §§ 425.605(a)(1)(ii)(C)(*1*) and (*2),* and 425.610(a)(2)(ii)(C)(*1)* and (*2*) have been removed as they are no longer needed in light of the revisions to §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C). The resulting final regulation text accurately describes the weights used when calculating the weighted average growth in demographic risk scores or prospective HCC risk scores. Specifically, the final regulation text now states that when calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the historical benchmark expenditures for that enrollment type and the performance year person years for that enrollment type.

f. Increased Opportunities for Low Revenue ACOs to Share in Savings

(1) Background

In the November 2011 final rule (76 FR 67927 through 67929), we explained that a goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards. However, we also acknowledged that observed savings can also occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. Thus, even if an ACO engages in no activities to improve the quality and efficiency of the services it delivers, in certain cases, differences between the benchmark expenditures and assigned patients' expenditures would be observed during some performance

periods merely because of such normal variation. Consequently, section 1899(d)(1)(B)(i) of the Act requires us to specify an MSR to account for the normal variation in expenditures, based upon the number of Medicare FFS beneficiaries assigned to the ACO. As we stated in the November 2011 final rule, the MSR should be set in a way that gives us some assurance that the ACO's performance is a result of its interventions, not normal variation in expenditures. However, we also do not want an outcome where savings that have been earned are not recognized.

Establishing an MSR on the basis of standard inferential statistics that take into account the size of an ACO's beneficiary population provides confidence that, once the savings achieved by the ACO exceed the MSR, the change in expenditures represents actual performance improvements by the ACO as opposed to normal variations. There are several policy implications associated with the methodology used to set the MSR. A higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieving savings, a higher MSR could also discourage potentially successful ACOs, especially physician-organized ACOs and smaller ACOs in rural areas, from participating in the program. In contrast, a lower MSR would encourage more potential ACOs to participate in the program but would also provide less confidence that shared savings amounts are a result of improvements in quality and efficiency made by an ACO. In the original rulemaking establishing the Shared Savings Program, we stated that we believed that the most appropriate policy concerning determination of the ''appropriate percent'' for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds. In the November 2011 final rule, we finalized an approach wherein the MSR and MLR are calculated as a percentage of the ACO's updated historical benchmark (see §§ 425.604(b) (Track 1), 425.606(b) (Track 2)).

In the June 2015 final rule, we finalized an approach to offer Track 2 ACOs and ACOs in the new Track 3 (subsequently renamed the ENHANCED track) the opportunity to select the MSR/MLR that will apply for the duration of the ACO's 3-year agreement period from several symmetrical MSR/MLR options (80 FR 32769 through 32771, and 80 FR 32779 and 32780; §§ 425.606(b)(1)(ii) and 425.610(b)(1)). We explained our belief that offering ACOs a choice of MSR/MLR will encourage ACOs to move to two-sided risk, and that ACOs are best positioned to determine the level of risk they are prepared to accept. For instance, ACOs that are more hesitant to enter a performance-based risk arrangement may choose a higher MSR/MLR, to have the protection of a higher threshold before the ACO would become liable to repay shared losses, thus mitigating downside risk, although the ACO would in turn be required to meet a higher threshold before being eligible to receive shared savings. ACOs that are comfortable with a lower threshold of protection from risk of shared losses may select a lower MSR/MLR to benefit from a corresponding lower threshold for eligibility for shared savings. We also explained our belief that applying the same MSR/MLR methodology in both of the risk-based tracks reduces complexity for CMS' operations and establishes more equal footing between the risk models. ACOs participating in the Track 1+ Model were also allowed the same choice of MSR/MLR to be applied for the duration of the ACO's agreement period under the Track 1+ Model.[356]

ACOs applying to a two-sided model (Track 2, Track 3 or the Track 1+ Model) could select from the following options:

- Zero percent MSR/MLR.
- Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.
- Symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under § 425.604(b) for Track 1. The MSR is the same as the MSR that would apply in the one-sided model, and the MLR is equal to the negative MSR.

[356] Refer to the Medicare ACO Track 1+ Model Participation Agreement, section V, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

In the December 2018 final rule, we finalized policies governing the MSR/MLR for ACOs in the BASIC track at § 425.605(b). Under the final policies, ACOs in a one-sided model of the BASIC track's glide path have a variable MSR based on the number of beneficiaries assigned to the ACO (§ 425.605(b)(1)). The variable MSR (ranging from 3.9 percent for ACOs with 5,000 assigned beneficiaries to 2.0 percent for ACOs with 60,000 or more assigned beneficiaries) is determined using the same methodology that was used for Track 1. ACOs in a two-sided model of the BASIC track are able to choose among the MSR/MLR options that are available to ACOs in the ENHANCED track. ACOs participating under Level A or B of the BASIC track's glide path will choose an MSR/MLR, ranging from zero to 2 percent (in 0.5 percent increments), or that is variable based on number of beneficiaries assigned to the ACO, before the start of their first performance year in a two-sided model (§ 425.605(b)(2)(i)). This selection will occur before the ACO enters Level C, D or E of the BASIC track's glide path, depending on whether the ACO is automatically transitioned to a two-sided model (Level C or E) or elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E), and will be in effect for the duration of the agreement period that the ACO is under two-sided risk (§ 425.605(b)(2)(ii)).

In addition to the MSR/MLR, we also use an ACO's quality score as part of the determination of eligibility for and calculation of shared savings and shared losses. In the CY 2021 PFS final rule, we adopted a new regulation at § 425.512(a) to reflect the new quality performance requirements under the Shared Savings Program for PY 2021 and subsequent performance years. For performance years beginning on January 1, 2021, and subsequent performance years, if the ACO meets the quality performance standard established under § 425.512, the ACO will share in savings at the maximum sharing rate based on the ACO's track/level of participation (refer to Table 80). The final sharing rate is applied to an ACO's savings on a first dollar basis up to the applicable performance payment limit, expressed as a percentage of the ACO's updated benchmark.

TABLE 80: Maximum Sharing Rate by Track

	BASIC Track's Glide Path				ENHANCED Track (risk/reward)
	Level A & B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once MSR met or exceeded)*	1st dollar savings at a rate of 40% if quality performance standard is met; not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 75% if quality performance standard is met, not to exceed 20% of updated benchmark.

* For BASIC Track Levels A and B refer to § 425.605(d)(1)(i) and (d)(1)(ii), for Levels C, D, and E refer to § 425.605(d)(1)(iii)(A) and (B), (d)(1)(iv)(A) and (B), and (d)(1)(v)(A) and (B), and for the ENHANCED Track refer to § 425.610 (d) and (e).

As discussed in the November 2011 final rule and during subsequent rulemaking cycles, we have received comments from ACOs and other interested parties expressing concerns regarding the MSR/MLR methodology and proposing revisions. Commenters responding to the April 2011 proposed rule [357] expressed concern that the proposed (and later finalized) methodology for establishing the MSR on a sliding scale based on population size would disadvantage smaller ACOs, including ACOs likely to form in rural areas and those largely comprised of small- and medium-sized physician practices, and discourage their participation by setting too high a bar on shared savings (76 FR 67928 and 67929). Some commenters considered the potential long-term consequences of this dynamic, indicating it could ultimately result in diminished provider competition in some markets or stifle the development of innovative care coordination strategies. Further, as other commenters indicated, smaller ACOs are likely to be in greatest need of additional capital to support start-up and operational expenses. Some commenters suggested that the MSRs that apply to smaller ACOs based on their number of assigned beneficiaries may make it impossible for these ACOs to ever share in savings.

Additionally, a number of commenters offered that other proposed policies under the Shared Savings Program, including, for example, the rigorous quality performance standards and the requirement that all ACOs ultimately accept downside performance risk, are sufficient to ensure savings are a result of actions by ACOs and obviate the need for an MSR. One commenter suggested a blended approach such that if an ACO exceeds the 2 percent MSR, it would be eligible for a lower sharing rate, but would not receive the full sharing rate unless it exceeded its statistically adjusted MSR.

In the December 2018 final rule (83 FR 67924 through 67928), we summarized commenters' responses to the proposals described in August 2018 proposed rule related to the MSR and MLR. One commenter asked that CMS reconsider its proposals in order to ''lessen restrictions and remove barriers to participation in risk sharing arrangements,'' but did not specify which aspects of the MSR/MLR proposals they believed to be restrictive or to create barriers. A number of commenters supported a combination of a lower MSR and higher sharing rates for low revenue ACOs participating in the BASIC track and offered several different alternatives. Commenters explained that combining a lower MSR and higher final sharing rate was necessary to ensure there are sufficient and attainable incentives to support ACOs' efforts to improve quality and lower cost, to provide early returns on investments, as well as predictability of savings and the financial support ACOs need to ensure successful participation, and to incentivize low revenue and physician-led ACOs to participate in the redesigned participation options under the Shared Savings Program.

In the CY 2023 PFS proposed rule, we stated that while it remains important to ensure performance payments are not based on normal expenditure fluctuations, we believe modification to our MSR policy would provide payments to ACOs with the greatest need for shared savings, in particular smaller, rural ACOs which tend to be less capitalized, allowing for investments in care redesign and quality improvement activities. We indicated that this modification would also align with the other changes we were proposing to the participation options and financial methodologies under the Shared Savings Program to encourage participation by new ACOs and ACOs that focus on underserved populations, such as the proposal to offer AIPs to new low revenue ACOs joining the BASIC track as described in section III.G.2. of the proposed rule.

(2) Revisions

In the CY 2023 PFS proposed rule, we proposed to use our authority under section 1899(i)(3) of the Act, for the use of other payment models, to expand the eligibility criteria to qualify for shared savings to enable certain low revenue ACOs participating in the BASIC track to share in savings even if the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act. Specifically, as described in the CY 2023 PFS proposed rule (87 FR 46196 through 46198), we proposed to modify the relevant provisions of § 425.605 to specify that ACOs participating in the BASIC track that do not meet the MSR requirement, but that do meet the quality performance standard or the proposed alternative quality performance standard under § 425.512 and otherwise maintain eligibility to participate in the Shared Savings Program, would qualify for a shared savings payment if the following criteria are met:

- The ACO has average per capita Medicare Parts A and B FFS expenditures below the updated benchmark.
- The ACO is a low revenue ACO as defined in § 425.20 at the time of financial reconciliation for the relevant performance year.

[357] The proposed rule proposing the establishment of the Shared Savings Program entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' appeared in the April 7, 2011 **Federal Register** (76 FR 19528) (herein referred to as the ''April 2011 proposed rule'').

• The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard required to share in savings at the maximum sharing rate would receive half of the maximum sharing rate for their level of participation (20 percent instead of 40 percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate but meet the proposed alternative quality performance standard, the sharing rate would be further adjusted according to the proposal outlined in section III.G.4.b. of the proposed rule (87 FR 46129 and 46130), which would reinstate a sliding scale approach for determining shared savings. This calculation would use an ACO's quality performance score, which would reflect the inclusion of health equity adjustment bonus points as described in section III.G.4.b.(7) of the proposed rule. A numerical example of the proposed modification to BASIC Track sharing rates for eligible ACOs is provided in Table 81.

TABLE 81: Numerical Example of Proposed Modification to BASIC Track Sharing Rates for Eligible ACOs

Track	BASIC Track, Level E
Total Benchmark Expenditures	$150,000,000
Total Performance Year Expenditures	$149,850,000
Total Benchmark Expenditures minus Total Performance Year Expenditures (Savings)	$150,000
Savings as a Percent of Benchmark	0.1%
Minimum Savings Rate	2%
Maximum Sharing Rate	50%
Health Equity Adjusted Quality Performance Score	45%
Met Criteria in Quality Performance Standard for Maximum Sharing Rate?	No
Met Quality Performance Standard for Scaled Sharing Rate?	Yes
Earned Performance Payment (before sequestration and application of shared savings limit)	
Current Policy	$0
Proposed Policy	(½ * 50%) * 45% * $150,000 = $16,875

As proposed, this approach would apply to low revenue ACOs entering an agreement period in the BASIC track beginning on January 1, 2024, and in subsequent years. High revenue ACOs in the BASIC track, ACOs below 5,000 assigned beneficiaries at the time of financial reconciliation, and ACOs in the ENHANCED track would not be eligible for this option. We proposed that this policy would apply to all ACOs meeting the criteria, including new, renewing, and re-entering ACOs, in order to provide incentives both for new ACOs to join the Shared Savings Program and for existing ACOs to remain in the program. We noted that this differed from the proposed eligibility criteria for AIPs outlined in section III.G.2.a.(2) of the proposed rule (87 FR 46099 and 46100), which we proposed to limit to ACOs that are new to the Shared Savings Program with the intent of lowering barriers to entry. Although as described in section III.G.2.b.(2) of the proposed rule (87 FR 46114 through 46119) we proposed to revise our regulations to permit all otherwise eligible ACOs that are inexperienced with performance-based risk Medicare ACO initiatives to elect to participate in one, 5-year agreement period under a one-sided model of the BASIC track's glide path regardless of revenue status, we explained our belief that it would be appropriate to limit this proposed policy change to the low revenue ACOs in the BASIC track in order to direct the payments to ACOs with the greatest need for capital, in particular smaller, rural ACOs which tend to be less capitalized, allowing for investments in care redesign and quality improvement activities. As discussed in the proposed rule, we did not believe it would be necessary or appropriate to extend this opportunity to high revenue ACOs as these ACOs, which tend to include institutional providers and are typically larger and better capitalized, have the potential to exert more influence, direction, and coordination over the full continuum of care, and thus have a greater potential to achieve the level of savings necessary to meet the MSR. Rather, we stated our belief that by retaining the requirement that high revenue ACOs meet or exceed their MSR, we would drive more meaningful systematic change by the ACOs that have the greatest potential to achieve significant change in spending. Furthermore, we noted that our proposal to exclude ACOs with fewer than 5,000 assigned beneficiaries at the time of financial reconciliation would align with the requirement under section 1899(b)(2)(D) of the Act and § 425.110 that an ACO have at least 5,000 assigned beneficiaries and guard against the heightened risk—absent an MSR—that any savings are the result of random variation.

We simulated the impact of the proposal using financial reconciliation data from PYs 2020, 2019, and 2019A.[358] There were 80, 109, and 60 positive within corridor ACOs (that is, ACOs that had performance year expenditures below benchmark expenditures but did not meet the MSR and did not receive shared savings

[358] PY 2019 refers to both the 12-month performance year from January 1, 2019 through December 31, 2019 and the 6-month performance year from January 1, 2019 through June 30, 2019. PY 2019A refers to the 6-month performance year from July 2, 2019 through December 31, 2019.

payments) in each year, respectively. Of these positive within corridor ACOs, 35 ACOs in 2020 and 2019, and 18 ACOs in 2019A would have met the criteria described in this section and received a shared savings payment under our proposed policy change. On average, the positive within corridor ACOs that would benefit from the proposed policy change were smaller (had fewer assigned beneficiaries) in all 3 performance years and a larger share of these ACOs were classified as rural in PYs 2020 and 2019.[359] In the proposed rule, we stated our belief that by offering additional opportunities for low revenue ACOs to share in savings, the proposed approach could increase participation in the Shared Savings Program by providing an incentive for new ACOs to join the program and for existing ACOs to remain in the program. In addition, the proposal would enable low revenue ACOs, which are most in need of additional capital, to make investments in care redesign and quality improvement activities and would also recognize incremental improvements in care by ACOs that receive AIPs.

Additional analysis completed after the publication of the CY 2023 PFS proposed rule upon the availability of PY 2021 financial reconciliation data yielded consistent results. Of the 111 positive within corridor ACOs in PY 2021, 33 would have been eligible for partial shared savings under this policy. Unlike in previous PYs, none of the positive within corridor ACOs in PY 2021 that would have been eligible for partial shared savings under this policy were classified as rural, but they did, on average, have fewer assigned beneficiaries than ineligible ACOs.

In the CY 2023 PFS proposed rule, we acknowledged that to exercise our authority under section 1899(i) of the Act, we must determine that a payment model under which certain low revenue ACOs participating in the BASIC track may qualify for shared savings payments even when the MSR as required under section 1899(d)(1)(B)(i) of the Act is not met, will improve the quality and efficiency of items and services furnished under the Medicare program, and that program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. By supporting expanded and sustained participation by ACOs in the Shared Savings Program, we noted our belief that the proposed approach would allow for lower growth in Medicare FFS expenditures. We also believed the proposed approach would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs would have an incentive to perform well on quality measures in order to maximize the shared savings they may receive. Further, the proposed approach would provide additional capital to enable low revenue ACOs to make investments in care redesign and quality improvement activities, potentially leading to improvements in the quality and efficiency of items and services furnished to Medicare FFS beneficiaries. We also stated our belief that the proposal, along with many of the other proposals in the proposed rule, would expand participation among ACOs serving higher cost beneficiaries for whom the savings potential is greater (relative to ACOs serving lower cost beneficiaries that may already find the current regional adjustment methodology an adequate incentive to participate in the program), and among low revenue ACOs, which have historically performed well in the program. For example, in PY 2018, about 49 percent of low revenue Shared Savings Program ACOs shared in savings compared to 28 percent of high revenue ACOs. These proportions were 63 percent and 40 percent in PY 2019, 69 percent and 40 percent in PY 2019–A, and 75 percent and 59 percent in PY 2020.[360] [361] Lastly, we noted that as discussed in the Regulatory Impact Analysis of the proposed rule (87 FR 46381)), the proposed change was not expected to result in a situation in which all policies adopted under the authority of section 1899(i) of the Act, when taken together, result in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

We proposed to amend the regulation at § 425.605, which governs calculation of shared savings and shared losses under the BASIC track, to specify an exception to the MSR requirement for eligible ACOs participating in an agreement period beginning on January 1, 2024, and in subsequent years, in a new provision at § 425.605(h). We also proposed modifications to the provisions in § 425.605(d)(1) specifying the calculation of the final sharing rate for the different levels of the BASIC track. Further, we proposed conforming changes to §§ 425.100(b)(1), 425.605(a), 425.605(b)(3), and 425.605(c)(2) to reflect this exception to the MSR requirement.

We sought comment on the proposal to expand the criteria ACOs can meet to qualify for shared savings under the BASIC track. The following is a summary of the public comments received on this proposal and our responses:

Comment: We received several comments in support of this proposal, citing the potential for ACOs to invest the savings earned under this policy in care redesign and quality improvement activities.

Many commenters provided additional reasons for their support of the proposed policy. Two commenters described how this policy could impact new ACOs, citing the time it takes for new ACOs to generate savings with one explaining how increased beneficiary engagement and uptake of preventive services may increase short-term spending. A few commenters noted the policy's potential to increase participation, with two explaining that savings earned under this policy could be used by ACOs to cover infrastructure costs, allowing them to continue participating in the program. Another commenter stated the benefits of this policy for physician-led ACOs, explaining that it would help them improve care and remain in the ACO program. A few commenters noted the proposed policy's potential to support ACOs with the largest need for shared savings, including small rural ACOs, independent primary care practices, and those serving underserved patient populations.

One commenter argued that the existing MSR is harmful to low revenue ACOs and agreed that this policy could encourage participation in the program, but they urged CMS to ensure that the low revenue standard is not gamed in such a manner that some ACOs qualify only through technicalities and are able to take undue advantage of any final policy.

A few commenters noted the value of the policy beyond the financial benefits. One commenter supported this proposal citing personal experience with missing the MSR requirement by a marginal amount. They understand the actuarial benefits of an MSR, but do not believe a strict cutoff makes for a good policy. They stated that the shared savings

[359] For this analysis, ACOs were classified as rural if the plurality of their assigned beneficiaries resided in either micropolitan or noncore counties as defined by The United States Census Bureau and the Office of Management and Budget (OMB).

[360] Refer to *Data.CMS.gov,* Performance Year Financial and Quality Results, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results/data.*

[361] For PY 2021, 69 percent of low revenue Shared Savings Program ACOs shared in savings compared to 46 percent of high revenue ACOs, based on analysis of PY 2021 financial reconciliation data completed after the publication of the CY 2023 PFS proposed rule.

earned under this policy may have little impact on an ACO's operating costs but would provide valuable motivation for program participants. Another commenter had a similar sentiment, stating that ACOs could miss out on shared savings by just a fraction of a percent, which is discouraging and could affect participation. Another commenter endorsed the proposal, noting that the amount of shared savings may not be sufficient to sustain ACO participation, but that it would help continuous investment in care management strategies and personnel, particularly if an ACO's eligibility to receive AIP payments has expired.

Response: We thank commenters for their support of the proposal to increase opportunities for eligible low revenue ACOs to share in savings by. We agree that this policy under which eligible low revenue ACOs may receive up to half of the maximum sharing rate for their level of participation will help bolster participation among both new and reentering ACOs, particularly those with the greatest need for shared savings, by allowing for investment in care improvement, covering infrastructure costs, and providing motivation for ACOs that generate savings but have not met the MSR requirement. However, we also believe it remains important to ensure shared savings payments are not based on normal expenditure fluctuations, and we believe that meeting the MSR should remain a necessary requirement for an ACO to receive shared savings based on the maximum sharing rate under their track.

Comment: We received one comment opposed to this proposal. The commenter expressed their belief that ACOs should meet the MSR to share in savings, stating that the MSR is necessary to protect the Trust Fund from making payments based solely on random variation, and that the performance of smaller ACOs may be driven by random variation even under the current MSR requirements. They also noted that this proposed policy is focused on low revenue ACOs, but 56 percent of Shared Savings Program ACOs are currently classified as low revenue. Moreover, they believe that the ACOs that would benefit from this policy would be those that already benefit from selection against high spending, medically complex, and underserved populations through positive regional adjustments to their benchmarks. The commenter supported more direct methods for increasing program participation and noted that there were several other proposals for the Shared Savings Program in the CY 2023 PFS proposed rule that could accomplish this.

Response: By supporting expanded and sustained participation by low revenue ACOs in the Shared Savings Program, we believe this proposed approach will allow for lower growth in Medicare FFS expenditures because low revenue ACOs have historically produced higher net per capita savings. As described in the Regulatory Impact Analysis in section VII. for this final rule, a key to generating net savings for the Shared Savings Program is attracting more ACOs into the BASIC track that serve higher spending populations, particularly low revenue physician-led ACOs. Making partial shared savings payments to certain ACOs in the BASIC track with savings below their MSR will only marginally increase payments to ACOs under the Shared Savings Program but is expected to increase the share of new ACOs that are low revenue participating in the Shared Savings Program. Because low revenue ACOs have historically performed well in the program, we expect this to increase overall program savings.

Comment: We received several comments that were generally supportive of the proposal but recommended alternative eligibility criteria.

Several commenters supported the proposed policy but recommended extending the opportunity to share in savings at a reduced rate to all ACOs. Some commenters cited the significant number of ACOs that generate some savings, but not enough to earn shared savings payments, and stated their belief that extending this proposal to all ACOs would help incentivize ACOs to remain in the program. One commenter stated that failing to extend this opportunity to all ACOs would limit the program's attractiveness to healthcare providers given the financial pressures they are currently facing. A couple of commenters argued that high revenue, hospital-led ACOs (like low revenue, physician-led ACOs) often include independent physicians and that they would be more likely to participate in the Shared Savings Program and engage in meaningful transformation if the likelihood of savings increased. One of these commenters noted limiting this opportunity to low revenue ACOs unfairly penalizes physicians for participating in an ACO that includes a hospital system.

One commenter recommended extending the proposed policy to all new ACOs in their first agreement period of the BASIC Track, including ACOs currently participating in their first agreement period in the Shared Savings Program. They argued that the policy as proposed limits the ability of under-resourced ACOs currently participating in their first agreement period to share in partial shared savings until entering a new agreement period, and therefore, limits the expansion of accountable care to patients primarily served by such providers. They stated expanding the eligibility criteria would provide a greater incentive for new providers and suppliers to join ACOs and provide them an onboarding opportunity to invest in the care transformation necessary to generate savings greater than the MSR.

Another commenter urged CMS to expand eligibility for the proposed policy to ACOs in the ENHANCED track. This commenter stated that the policy as proposed could create disincentives for ACOs to enter the ENHANCED track and that the opportunity to share in savings below the MSR may encourage ACOs to take on more risk through the ENHANCED track, leading to ACOs staying in the program longer and generating more savings for the ACO and the Trust Funds.

Response: While we acknowledge that ACOs that do not meet the proposed eligibility criteria could also benefit from increased opportunities to share in savings, we continue to believe it is appropriate to limit this policy to low revenue ACOs participating in the BASIC track, as proposed, in order to attract ACOs that serve higher spending populations into the BASIC track, particularly low revenue, physician-led ACOs that have historically performed well in the program. As described in the Regulatory Impact Analysis in section VII. of this final rule, increasing participation among these ACOs is key to generating net savings for the Shared Savings Program. By supporting ACOs with the greatest need for capital, in particular smaller, rural ACOs, which tend to be less capitalized, this policy is expected to increase participation among these ACOs and provide additional support for investments in care redesign and quality improvement activities. With respect to the requests that we expand this policy to ACOs participating in the ENHANCED track, we note that the ENHANCED track was designed for more advanced ACOs prepared for the higher levels of risk and reward. In addition, the higher maximum sharing rate of 75 percent that exists in the ENHANCED track already provides a strong incentive for these ACOs to participate.

Comment: Several commenters who supported the proposal and recommended expanding the eligibility

criteria also recommended eliminating the high/low revenue distinction from the Shared Savings Program.

Of the commenters who recommended extending this policy to all ACOs, some expressed belief that the high/low revenue distinction for ACOs is flawed and should be eliminated. One disagreed with the premise that hospital-led (high revenue) ACOs are less efficient than physician-led (low revenue) ACOs and that low revenue ACOs have less ability to control expenditures for beneficiaries. Many commenters noted that the high/low revenue distinction has discouraged partnership with certain types of healthcare providers. Another commenter took issue with the assumption that high revenue ACOs are likely to include hospitals, health systems, and/or other institutional providers and does not believe that whether an ACO treats underserved populations can be determined by the high/low revenue distinction. A couple of commenters suggested that many safety net providers that would most benefit from this opportunity—including RHCs, CAHs, and FQHCs—would likely be designated as high-revenue if they formed an ACO. Another commenter questioned the relevance of the high/low revenue designation to a redesign effort whose stated primary goal is to grow the Shared Savings Program and ensure its sustainability. They argued that the policy would sharply increase support for new, inexperienced, and low revenue participants but would offer few incentives to existing ACOs, especially those that are categorized as renewing, experienced with risk-bearing, or high revenue. They instead suggested that distinctions based on revenue and experience should be replaced with health equity criteria accounting for the needs of an ACO's assigned population and/or its community.

Some commenters who recommended removing the high/low revenue designation only had concerns with the low revenue criterion for this policy and did not comment on other eligibility requirements. One commenter who supported removing the high/low revenue designation argued that high revenue ACOs also contend with multiple financial and operational challenges and would benefit from this proposal. Another commenter suggested that, if CMS does not update the eligibility criteria to include high revenue ACOs, CMS should consider additional incentives to encourage participation of high revenue ACOs.

Response: We disagree with commenters that CMS should remove the revenue distinction from the Shared Savings Program, and therefore, the criteria ACOs must meet to qualify to receive shared savings under the proposed policy. We continue to believe high revenue ACOs have sufficient resources to support continued participation given they are generally composed of hospitals and health systems that have greater access to capital for investing in care redesign, better care coordination, and quality improvement. Furthermore, regarding the concern that safety net providers would be excluded from this opportunity, ACOs that include safety net providers without also including a hospital are overwhelmingly designated as low revenue.

Comment: One commenter supported this proposal but was concerned that the policy would only go into effect for ACOs entering a new agreement period in 2024 or a subsequent year, recommending it be applied to all ACOs, regardless of start year.

Response: We decline the commenter's recommendation that we extend this policy to ACOs in a current agreement period. As described in section III.G.5.a of this final rule, limiting this policy to ACOs entering a new agreement period beginning on or after January 1, 2024, will allow current and new ACOs to decide whether to renew for a new agreement period or join the Shared Savings Program, respectively, and provide sufficient time for CMS to implement these changes.

Comment: Some commenters who supported the proposed policy had additional recommendations related to this proposal. A few commenters recommended that CMS allow ACOs to change their MSR/MLR selection on an annual basis prior to the start of each performance year. These commenters believe that ACOs may be more comfortable with a lower MSR/MLR as they gain experience in the program and should not have to wait until entering a new agreement period to update their selection. They supported the increased flexibility and opportunity this would provide for ACOs in the program. Another commenter suggested implementing a sliding scale policy with an upper and lower MSR threshold where ACOs would share in a portion of shared savings as long as the lower threshold was met. They recommended this for all ACOs but particularly for ACOs in their first agreement period regardless of revenue status, arguing that it can take multiple years for an ACO to meet the current MSR requirement.

Response: At this time, we decline these commenters' suggestions as they go beyond the scope of the modifications we proposed to the program's eligibility criteria to qualify for shared savings. Additionally, for the reasons discussed in the August 2018 proposed rule (83 FR 41837) and the December 2018 final rule (83 FR 67923), we continue to believe it is appropriate to decline requests to allow ACOs to change their MSR/MLR selection on an annual basis. Allowing for an annual selection of the MSR/MLR by ACOs in a two-sided level of the BASIC Track or the ENHANCED track could lead to gaming as ACOs gain more experience in the program and would not be sufficiently protective of the Trust Funds.

After consideration of the comments, we are finalizing the proposal to increase opportunities for eligible low revenue ACOs to share in savings as proposed. We will use an ACO's health equity adjusted quality performance score, which, as discussed in section III.G.4.b.(7) of this final rule, will incorporate LIS status in addition to dually eligible beneficiary status and ADI in the calculation of the underserved multiplier, to determine the ACO's eligibility to share in savings and the amount of shared savings for ACOs that meet the alternative quality performance standard. We are also finalizing the proposed revisions to § 425.605 to incorporate this policy without modification.

g. Ongoing Consideration of Concerns About the Impact of the PHE for COVID–19 on ACOs' Expenditures

On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19 (hereafter referred to as the PHE for COVID–19). On March 11, 2020, the World Health Organization (WHO) publicly characterized COVID–19 as a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 outbreak a national emergency. The term ''Public Health Emergency,'' as defined in the regulation at § 400.200, identifies the PHE determined to exist nationwide as of January 27, 2020, by the Secretary under Section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals. This determination was, as of this publication, subsequently renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, and October 13, 2022. In the March 31st

COVID–19 IFC (85 FR 19267 and 19268) and the May 8th COVID–19 IFC (85 FR 27573 through 27587) we adopted several modifications to policies under the Shared Savings Program in response to the PHE.

In the March 31st COVID–19 IFC (85 FR 19267 and 19268), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances (EUC) policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may have been unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19.

In the May 8th COVID–19 IFC (85 FR 27573 through 27587), we modified certain Shared Savings Program policies to: (1) allow ACOs whose current agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1 year; (2) allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (3) adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication.

As discussed in the May 8th COVID–19 IFC (85 FR 27578 through 27582) and in accordance with § 425.611, all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19 are excluded from the following Shared Savings Program calculations:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures.
- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

As part of the March 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Medicare sequestration adjustments were temporarily suspended. This suspension was further extended through March 31, 2022, in subsequent legislation. From April 1, 2022, to June 30, 2022, sequestration was set at 1 percent. Starting July 1, 2022, sequestration increased to 2 percent. When full Medicare sequestration is in effect, a 2 percent reduction to shared savings payments is applied before applying an ACO's shared savings limit. As a result of the suspension of sequestration, shared savings payments made in CY 2020 and CY 2021 (for PYs 2019 and 2020) were roughly 2 percent higher than they would have been otherwise for ACOs that did not earn shared savings in excess of their shared savings limit.

In December 2017, we issued an interim final rule with comment period entitled ''Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the ''December 2017 IFC''), which appeared in the December 26, 2017 **Federal Register** (82 FR 60912 through 60919). In the December 2017 IFC, we established a policy for mitigating shared losses for Shared Savings Program ACOs participating in a performance-based risk track, when the ACO's assigned beneficiaries were located in geographic areas that were impacted by extreme and uncontrollable circumstances, such as hurricanes, wildfires, or other triggering events, during PY 2017. In the CY 2019 PFS final rule (83 FR 59707), we extended the extreme and uncontrollable circumstances policy finalized for PY 2017 to PY 2018 and subsequent performance years. We apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected areas. Further, we have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

The Secretary's declaration of the PHE for COVID–19 in January 2020 triggered the Medicare Shared Savings Program's Extreme and Uncontrollable Circumstances Policy. The extreme and uncontrollable circumstances of the PHE for COVID–19 began in January 2020 and will apply nationwide for the duration of the PHE for COVID–19. As set forth in §§ 25.605(f) (applicable to ACOs in two-sided models of the BASIC track) and 425.610(i) (applicable to ACOs in the ENHANCED track), we reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. The PHE for COVID–19 was considered an extreme and uncontrollable circumstance that applied to all counties in the United States for the entirety of PY 2020 and PY 2021, and no ACOs were liable for shared losses for those performance years as any such losses were fully mitigated by the adjustment for extreme and uncontrollable circumstances.

As a result of forgoing the 2021 application cycle for new applications, agreement periods starting in 2022 are the first agreement periods for which 2020 and 2021 serve as benchmark years for ACOs in the Shared Savings Program. Interested parties have expressed concern that the policy adjustments made in response to the PHE for COVID–19 may not fully address the potential for relatively lower expenditures resulting from lower utilization by non-COVID–19 patients. For example, in 2020, Parts A and B FFS expenditures decreased by 7 percent nationally compared to 2019. This decrease in utilization and expenditures could result in relatively lower benchmark year expenditures for ACOs in agreement periods beginning in 2022, 2023 or 2024 for which 2020 and/or 2021 are benchmark years. Several interested parties have suggested alternative approaches to establishing benchmarks for ACOs for which 2020 and 2021 are benchmark years, including using alternative years (such as 2017, 2018, and 2019), or differently weighting COVID–19 affected years in the calculation of financial benchmarks. In the CY 2023 PFS proposed rule, we noted that the impact of COVID–19 was not uniform for all areas of the country as surges occurred in different geographic areas at different times.

Removing specific years from benchmark calculations would have varied effects on different geographic areas depending on when COVID–19 had the largest impact in those areas. Thus, as we explained in the proposed rule, such approaches could produce mixed results; one analysis performed by the Institute for Accountable Care [362] estimated that 55 percent of ACOs would have lower benchmarks if 2020 were dropped from the benchmark period.

In the CY 2023 PFS proposed rule, we described OACT's analysis of current data, which indicated that ACOs exhibiting sharp declines in spending in 2020 tended to show rebounds in spending in 2021 such that historical benchmarks averaged across a base period including both 2020 and 2021 would appear to represent a reasonable basis from which to update ACO spending targets going forward. Due to the rebound in 2021 national expenditures, which increased by roughly 8.4 percent between 2021 Q1 (lowest observed expenditures since the PHE for COVID–19 began) and 2021 Q4, we stated our belief that the current blended national-regional trend and update factors would be sufficient to address and mitigate the impact of the start of the PHE for COVID–19 on benchmark year expenditures. ACOs that did not experience such an increase in spending between 2021 Q1 and 2021 Q4 would still be subject to a regional adjustment that could beneficially impact their benchmark determination. We also explained that the proposal described in section III.G.5.c.(3) of the proposed rule to utilize a three-way blend of the ACPT/national-regional growth rates to update benchmarks would further mitigate any potential adverse effects of the PHE for COVID–19 on historical benchmarks while also protecting against unanticipated variation in performance year expenditures and utilization resulting from a future PHE. We sought comment on the analysis regarding the impact of the PHE for COVID–19 on Shared Savings Program ACOs' expenditures. In addition, we noted that we would continue to monitor the impact of the PHE for COVID–19 to determine whether any further changes may be necessary to account for the effects of this PHE or future PHEs.

The following is a summary of the public comments received on the impact of the PHE for COVID–19 on ACOs' expenditures and our responses:

Comment: Several commenters supported the current policies in place to address the impact of the PHE for COVID–19 on ACO expenditures and agreed that no further direct interventions are necessary at this time. One commenter noted that PY 2022 final historical benchmarks, which include both 2020 and 2021, were stable relative to previous benchmarks that did not include years impacted by the PHE for COVID–19. This commenter also asked for clarification regarding when COVID–19 hospitalizations will be added back into expenditure calculations.

Response: We thank these commenters for their support of the existing policies. To clarify, as finalized in the CY 2021 PFS final rule (85 FR 84780), all Part A and Part B claims that occur during an inpatient episode of treatment for COVID–19 will be removed from program calculations when the date of discharge occurs within the PHE as defined in 42 CFR 400.200. Furthermore, adjustments for episodes of care for the treatment of COVID–19, will continue to be reflected in any program calculations that include the time period covered by the PHE for COVID–19. Thus, any qualifying claims that were excluded from program calculations for a performance year that in the future becomes a benchmark year, will continue to be excluded when that performance year is included in program calculations. In particular, 2020 serves as a benchmark year for currently participating ACOs that entered an agreement period on January 1, 2022 and will also be a benchmark year for ACOs that enter an agreement period on January 1, 2023. In light of the shift to 5-year agreement periods, adjustments made to expenditures during benchmark year 2020 will continue to be reflected in benchmark calculations until the end of PY 2027 (the final performance year for 2023 starters), under the program's existing policies.

Comment: Several commenters expressed concern about including 2020 and 2021 as benchmark years due to the impact of COVID–19 on expenditures and utilization rates. These commenters noted that other Medicare programs have not used years affected by COVID–19 when determining financial or quality benchmarks and requested that CMS extend this policy to the Shared Savings Program. The commenters requested that ACOs be allowed to select years prior to the PHE for COVID–19 to be used as benchmark years in place of 2020 or 2021 because in regions that have been slower to recover from the impact of the pandemic the use of both 2020 and 2021 in combination as benchmark years still will not be enough to mitigate potential negative effects on their benchmarks. One commenter expressed concern about the low utilization rates observed during the PHE for COVID–19 and recommended that CMS consider additional adjustments to account for this.

Response: Our analysis of the 3-year weighted average expenditures used to calculate PY 2022 final historical benchmarks, show that historical benchmarks averaged across a base period including both 2020 and 2021, appear to represent a reasonable basis from which to establish ACO spending targets. Additionally, as spending continues to rebound from the low levels observed in 2020, the national-regional trend factors used to calculate updated historical benchmarks at the time of financial reconciliation will further mitigate any adverse effects that 2020 and 2021 may have on an ACO's financial performance. We also believe that regional trend factors used to update the historical benchmark at the time of financial reconciliation will be sufficient to offset any regional behavior that diverges significantly from national trends.

We did not propose any changes in the CY 2023 PFS proposed rule to address the impact of the PHE for COVID–19 on ACOs' expenditures. However, we will continue to monitor the impact of the PHE for COVID–19 on the Shared Savings Program.

h. Supplemental Payment for Indian Health Service and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in the December 2018 final rule (83 FR 67856 and 67857), we exclude Indirect Medical Education (IME), Disproportionate Share Hospital (DSH) and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations because we do not wish to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking (76 FR 67919 through 67922, and 80 FR 32796 through 32799). In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. As explained in the FY 2023 IPPS/LTCH PPS final rule, this supplemental payment is necessary to avoid causing undue long-term financial disruption to IHS/Tribal hospitals and hospitals located in

[362] Institute for Accountable Care. Analysis of Policy Options to Reduce the Impact of COVID–19 on ACO Benchmarks. October 13, 2021. Available at *https://www.institute4ac.org/covid-19-aco-benchmarks-analysis/*.

Puerto Rico as a result of a change in the data used to determine uncompensated care payments for these hospitals beginning in FY 2023.

In order to align Shared Savings Program policies with updates made to Medicare FFS payment policies, we proposed to exclude this supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program. Further, for consistency with our current approach of using total revenue, including IME, DSH and uncompensated care payments, in Shared Savings Program calculations of ACO participant revenue,[363] we proposed to similarly include the supplemental payment to IHS/Tribal hospitals and hospitals located in Puerto Rico in such calculations for the performance year beginning January 1, 2023, and subsequent performance years. More specifically, ACO participant revenue is used in determining whether an ACO is a low revenue ACO or high revenue ACO as defined in § 425.20, and in determining the revenue-based loss sharing limits under two-sided models of the BASIC track's glide path in accordance with § 425.605. Because the new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico is intended to prevent disruptions due to a change in the uncompensated care payment methodology for these hospitals and uses these hospitals' FY 2022 uncompensated care payments as the starting point for this calculation, in the CY 2023 PFS proposed rule, we stated our belief that it should be treated consistently with how we currently treat uncompensated care payments in Shared Savings Program calculations. We sought comment on the proposed change to the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, including the determination of benchmark and performance year expenditures, as well as the calculation of ACO participant revenue.

In the November 2011 final rule (76 FR 67919), we explained that section 1899(d) of the Act provides flexibility to adjust the benchmark for IME and DSH payments, and certain other adjustments to Parts A and B payments. Section 1899(d)(1)(B)(ii) of the Act states, among other things, that the benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate. However, when it comes to performance year expenditures, section 1899(d)(1)(B)(i) of the Act provides authority to adjust expenditures in the performance period for beneficiary characteristics, but does not provide authority to adjust for ''other factors.'' Thus, we noted that while we could make some adjustments to the benchmark pursuant to section 1899(d)(1)(B)(ii) of the Act, to exclude certain payments, we could not make similar adjustments in our calculation of performance year expenditures. In the November 2011 final rule (76 FR 67921 and 67922), we adopted an alternate payment methodology that excluded IME and DSH payments from ACO benchmark and performance year expenditures, as authorized by section 1899(i) of the Act. We have maintained this approach to excluding IME and DSH payments across all Shared Savings Program calculations of benchmark and performance year expenditures, as specified in 42 CFR part 425, subpart G.

Consistent with our longstanding policy with respect to excluding IME and DSH payments from benchmarking and performance year expenditures, we proposed to use our authority under section 1899(i)(3) of the Act to use other payment models to remove the supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures. To exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model would improve the quality and efficiency of items and services furnished under the Medicare program and that program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. Because we proposed to exclude the supplemental payment from benchmark year expenditures using our authority under section 1899(d)(1)(B)(ii) of the Act, we explained that removing this payment from performance year expenditures would ensure greater parity between benchmark and performance year expenditure calculations. Further, we noted that by removing the supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures, we can reward more accurately actual decreases in unnecessary utilization of health care services. Excluding supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditure calculations ensures these payments do not make it more challenging for an ACO to generate shared savings as compared to its updated historical benchmark. We also noted that, for ACOs participating under two-sided models of the BASIC track's glide path, excluding the supplemental payment from performance year expenditures may help to mitigate the amount of losses generated by an ACO, although including the supplemental payment in the calculation of ACO participant revenue used to determine the revenue-based loss sharing limit may result in a relatively higher loss sharing limit used in determining an ACO's shared losses.

As discussed in the proposed rule, considering the balance of these factors, we believed that the approach, as proposed, could help ensure participation of IHS/Tribal hospitals and hospitals located in Puerto Rico in ACOs, and their engagement in the accountable care model. In turn, this could result in Medicare beneficiaries receiving higher quality, better coordinated and more cost-efficient care in these settings. We also noted that we did not expect that excluding the new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures would result in greater payments to ACOs than would otherwise have been made if the new supplemental payment were included. We indicated that we would continue to reexamine this policy in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. We also noted that in the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We proposed to modify the provisions of the existing regulations describing calculations of benchmark year and performance year expenditures to incorporate a reference to the exclusion of the new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, for the performance year beginning January 1, 2023, and subsequent performance

[363] In the December 2018 final rule, see for example the discussion of the calculation of ACO participant revenue as used in the determining the revenue-based loss sharing limits under the BASIC track (83 FR 67856) and the determination of whether an ACO qualifies as a low revenue ACO or a high revenue ACO (83 FR 67875).

years, and to include this exclusion in proposed new sections of the regulations as follows:

- Within § 425.601(a)(1)(i) and proposed § 425.652(a)(1)(i), specifying the calculation of payment amounts included in Parts A and B FFS claims using a 3-month claims run out with a completion factor, for computing per capita Medicare Parts A and B benchmark expenditures for beneficiaries that would have been assigned to ACO in any of the 3 most recent years prior to the start of the agreement period.
- Within § 425.601(c)(2)(i) and proposed § 425.654(a)(2)(i), specifying the calculation of county-level assignable beneficiary expenditures using payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor.
- Within § 425.605(a)(5)(i), describing the calculation of performance year expenditures under the BASIC track using payment amounts included in Medicare Parts A and B FFS claims for the ACO's assigned beneficiary population for the performance year.
- Within § 425.610(a)(6)(i), describing the calculation of performance year expenditures under the ENHANCED track using payment amounts included in Medicare Parts A and B FFS claims for the ACO's assigned beneficiaries for the performance year.
- Within proposed § 425.660(b)(1)(i), describing the calculation of the ACPT.

The following is a summary of the public comments received on our proposals regarding the treatment of the supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico for purposes of calculations under the Shared Savings Program and our responses:

Comment: We received one comment supporting our proposal to modify the provisions of the existing regulations describing calculations of benchmark year and performance year expenditures to incorporate a reference to the exclusion of the new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, for the performance year beginning January 1, 2023, and subsequent performance years. This commenter offered support without rationale.

Response: We appreciate the commenter's support of this proposal. We are finalizing our proposal to exclude the new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from the calculation of benchmark year and performance year expenditures for the performance year beginning January 1, 2023, and subsequent performance years. We are also finalizing the modifications to the existing regulations describing calculations of benchmark and performance year expenditures to incorporate a reference to the exclusion of the new supplemental payment, as proposed. Further, as discussed in the proposed rule, we will include the supplemental payment to IHS/Tribal hospitals and hospitals located in Puerto Rico in Shared Savings Program calculations of ACO participant revenue for the performance year beginning January 1, 2023, and subsequent performance years.

i. Organization and Structure of the Regulations Text Within 42 CFR Part 425 Subpart G; Technical and Conforming Changes

In section III.G.5.i of the proposed rule (87 FR 46201 and 46202), we explained that since the Shared Savings Program was established in 2012, the benchmarking methodology has been specified in several sections of the Shared Savings Program regulations within 42 CFR part 425, subpart G. Section 425.601 specifies the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years. Sections 425.602 and 425.603 specify the benchmarking methodology applicable to earlier agreement periods for new and renewing ACOs, respectively. We noted that we have tended to include the entirety of the benchmarking methodology applicable to ACOs, based on their agreement period start date, within a single section of the regulations. We also explained that there is a limited number of unused sections within the range between §§ 425.600 and 425.613, and no remaining sections in sequential order immediately following the existing benchmarking sections within this range.

A variety of other provisions are contained within subpart G. Specifically, § 425.600 specifies selection of risk models. The methodology for calculation of shared savings or losses (as applicable) under each of the Shared Savings Program's financial models is specified within §§ 425.604 (Track 1), 425.605 (BASIC track), 425.606 (Track 2), and 425.610 (ENHANCED track). Several sections specify particular requirements or exceptions relating to determining performance for ACOs in earlier performance years: § 425.608 applied to determine first year performance for ACOs beginning their participation in the program on April 1 or July 1, 2012; and § 425.609 applied to determine performance for a 6-month performance year (or performance period) during CY 2019. Section 425.611 specifies adjustments to Shared Savings Program calculations to address the COVID–19 pandemic. Section 425.612 specifies waivers of payment rules and other Medicare requirements, including the SNF 3-day rule waiver, and § 425.613 addresses expanded use of telehealth services furnished by physicians or other practitioners participating in applicable Shared Savings Program ACOs.

As discussed in the CY 2023 PFS proposed rule, we considered how to restructure the regulations to incorporate the proposed modifications to the benchmarking methodology in the proposed rule. One consideration discussed was that the existing provisions of the regulations under subpart G are referred to within programmatic material, including guidance and technical specifications documents. For continuity and clarity, we noted that it would be important to maintain the organization of the existing provisions, as opposed to renumbering these existing sections. We also considered the need for a regulations text structure that would organize the details for the multiple aspects of the benchmarking calculations, each of which is detailed and complex. Lastly, as discussed in section III.G.2. of the proposed rule, we proposed to specify the policies governing the proposed AIPs in a new section of the regulations at § 425.630. For these reasons, we proposed to specify the proposed modifications to the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years in a series of new regulations at §§ 425.650 through 425.660. We proposed the following organization and structure for subpart G of the regulations:

- Reserve sections §§ 425.614 through 425.629, prior to the proposed new section of the regulations at § 425.630 on the option to receive AIPs.
- Reserve sections §§ 425.631 through 425.649.
- Establish a new section of the regulations at § 425.650, generally describing the organization of the sections on the benchmarking methodology within 42 CFR part 425, subpart G.
- Establish a new section of the regulations at § 425.652 which specifies the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on

January 1, 2024, and in subsequent years.

• Establish a new section of the regulations at § 425.654, which specifies the methodology for calculating county expenditures and regional expenditures for agreement periods beginning on January 1, 2024, and in subsequent years.

• Establish a new section of the regulations at § 425.656, which specifies the methodology for calculating the regional adjustment to the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

• Establish a new section of the regulations at § 425.658, which specifies the methodology for calculating the prior savings adjustment to the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

• Establish a new section of the regulations at § 425.660, which specifies the methodology for calculating the ACPT used in updating the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

We also proposed to make certain technical and conforming changes to the following provisions to reflect the proposal to add new regulations at §§ 425.652 through 425.660 to establish the benchmarking methodology applicable to all agreement periods starting on January 1, 2024, and in subsequent years.

• Under subpart C, which governs application procedures, add a reference to § 425.652 in § 425.204(g).

• Under subpart G, which governs shared savings and losses calculations, do the following—

++ In § 425.600(f)(4), add a reference to § 425.656(d) in § 425.600(f)(4)(ii) and a reference to § 425.652(c) in § 425.600(f)(4)(iii);

++ Revise § 425.601 to specify that it applies to agreement periods beginning on or after July 1, 2019, and before January 1, 2024;

++ Add references to § 425.652 in §§ 425.605(a), 425.605(a)(2), 425.605(d)(1)(iii)(D)(*2*), 425.605(d)(1)(iv)(D)(*2*), 425.605(d)(1)(v)(D)(*2*), 425.610(a), and 425.610(g);

++ Add a reference to § 425.652(a)(10) in § 425.610(a)(3);

++ Add a reference to § 425.654(a) in § 425.611(c)(2)(i);

++ Add a reference to § 425.652(a)(4) in § 425.611(c)(2)(ii)(A);

++ Add a reference to § 425.654(a)(3) in § 425.611(c)(2)(ii)(B);

++ Within § 425.611(c)(2)(iii), remove the specific reference to 5 percent of national per capita FFS expenditures for assignable beneficiaries, to account for the proposed modifications to the cap on the regional adjustment as specified in section III.G.5.c.(5) of the proposed rule, and to add a reference to § 425.656(c)(3), which refers to the cap of 5 percent of the national per capita expenditure amount applied to positive regional adjustments, and the cap of 1.5 percent of the national per capita expenditure amount applied to negative regional adjustments for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years; and add a reference to § 425.652(a)(8)(iv) which refers to the cap equal to 5 percent of the national per capita expenditure amount that is applied in calculating the prior savings adjustment; and

++ Add references to § 425.652(a)(5)(ii) (referring to the national component of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3) and § 425.652(b)(2)(i) (referring to the national component of the blended growth rate used to update the benchmark) in § 425.611(c)(2)(v).

• Under subpart I, which governs the reconsideration review process, add a reference to § 425.652 in § 425.800(a)(4).

We also proposed to correct the following inadvertent errors in cross-references:

• In § 425.601(f)(5)(ii), remove the reference ''paragraph (f)(4)(i) of this section'', and add in its place the reference ''paragraph (f)(5)(i) of this section''.

• In § 425.601(f)(5)(iv), remove the reference ''paragraphs (f)(1) and (2) of this section'', and add in its place the reference ''paragraphs (f)(1) through (3) of this section''.

Additionally, we explained our belief that it would be appropriate to specify in the proposed new regulation at § 425.656(e) a narrower set of special rules for determining the weights used in calculating the regional adjustment for certain ACOs that previously participated in the Shared Savings Program. In the December 2018 final rule (83 FR 68024), we established § 425.601(e)(2)(ii) which specifies that for renewing or re-entering ACOs whose prior agreement period benchmark was calculated according to § 425.603(c), we consider the agreement period the ACO is entering upon renewal or re-entry in combination with either of the following in determining the weight used in the regional adjustment calculation in the ACO's new agreement period: (A) The weight previously applied to calculate the regional adjustment to the ACO's benchmark in the ACO's most recent prior agreement period; or (B) For new ACOs that are identified as re-entering ACOs, we consider the weight previously applied to calculate the regional adjustment to the benchmark for the ACO in which the majority of the new ACO's participants were participating previously. With the agreement period beginning on January 1, 2022, all ACOs continuing their participation in the Shared Savings Program that were previously under the benchmarking rebasing methodology specified in § 425.603 are now participating under the benchmarking methodology specified in § 425.601. However, it is possible that an ACO that participated in a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019, and whose rebased benchmark was established in accordance with § 425.603(c), and whose participation agreement expired without having been renewed, or whose participation agreement was terminated under § 425.218 or § 425.220, may seek to re-enter the Shared Savings Program. Therefore, we explained our belief that it would be necessary to maintain special rules for determining the weights used in the regional adjustment calculation for re-entering ACOs. Accordingly, we proposed to incorporate the policies that currently apply to re-entering ACOs under § 425.601(e)(2)(ii) in the new regulation at § 425.656(e).

Lastly, we proposed to remove from the existing regulations on calculating county expenditures and regional expenditures an extraneous step in the calculation specified under § 425.601(d)(3). This provision specifies that CMS weights aggregate expenditure values determined for each population of beneficiaries according to Medicare enrollment type to reflect the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year. However, as we noted in the proposed rule, at no point in the calculation do we actually combine the risk-adjusted regional expenditures across the four Medicare enrollment types to determine a single risk-adjusted regional expenditure value. Risk-adjusted regional expenditures are incorporated in all relevant calculations at the Medicare enrollment type level. Similarly, as part of our proposal to establish a new regulation at § 425.654 to govern the calculation of county expenditures and regional expenditures for agreement periods beginning on January 1, 2024, and in subsequent

years, we would also omit this extraneous step in the calculation.

We did not receive any comments specifically addressing the organization and structure of the regulations text within 42 CFR part 425 subpart G, or the technical and conforming changes proposed in section III.G.5.i of the CY 2023 PFS proposed rule, and we are finalizing these changes as proposed with the exception of minor technical corrections to the structure and formatting of § 425.601(d). We note that to the extent that comments addressed proposed provisions within the new regulations at § 425.630 and §§ 425.650 through 425.660, these comments are summarized and responded to elsewhere within section III.G.5. of this final rule.

6. Administrative Burden and Other Policy Refinements

a. Overview

We are dedicated to reducing unnecessary ACO and CMS administrative burden where possible. In response to requests from interested parties from prior rules, we proposed 2 burden reduction proposals and 2 policy refinements in the CY 2023 PFS proposed rule. We noted that if finalized in the CY 2023 PFS final rule, the policy proposals and refinements would be implemented January 1, 2023. Specifically, we proposed the following, which are discussed in more detail in sections (b) through (e) below:

- Modify § 425.310 to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating notifications to beneficiaries and participants.
- Amend the beneficiary notification requirements at § 425.312 to reduce the frequency of certain beneficiary notifications from once annually to once in an agreement period, and to further clarify the settings in which ACO participants are expected to make required beneficiary notifications by displaying signs in their facilities.
- Streamline the SNF 3-Day Rule Waiver application review process by amending requirements at § 425.612(a)(1)(i)(A) to include an ACO attestation that plan narratives are in place and available to CMS upon request.
- Amend the regulations at §§ 425.702(c)(2) and 425.704(b) to recognize ACOs structured as OHCAs for data sharing purposes.

We noted that we anticipate that, collectively, these proposals would significantly reduce administrative burden in the Shared Savings Program.

b. Modify Marketing Material Review Requirements

(1) Background

The Shared Savings Program regulations define ''marketing materials and activities'' at § 425.20 to include, without limitation, ''general audience materials'' and activities used or conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers about the Shared Savings Program. General audience materials include brochures, advertisements, outreach events, letters to beneficiaries, web pages, data-sharing opt-out letters, mailings, and social media. The following beneficiary communications are not marketing materials and activities: certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health-related issues; educational information on specific medical conditions; written referrals for health care items and services; and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

In addition, the Shared Savings Program regulations impose certain marketing requirements at § 425.310 regarding the content and approval of marketing materials and activities. Specifically, under § 425.310(c), all marketing materials and activities must: (1) use template language developed by CMS, if available; (2) not be used in a discriminatory manner or for discriminatory purposes; (3) comply with § 425.304 regarding beneficiary incentives; and (4) not be materially inaccurate or misleading. Under § 425.310(a), marketing materials may be used 5 business days following their submission to CMS if: (1) The ACO certifies compliance with all the marketing requirements under this section; and (2) CMS does not disapprove the marketing materials or activities. Under § 425.310(b), marketing materials and activities are deemed approved after the initial 5-day review period. In other words, if CMS has not disapproved of the marketing submission within 5 days, the ACO may use the submitted marketing materials. CMS may subsequently issue a written notice of disapproval at any time, including after the expiration of the initial 5-day review period, at which point the ACO must discontinue use of the disapproved marketing materials. Per § 425.310(d), failure of an ACO to comply with the marketing requirements will subject the ACO to pre-termination actions sets forth in § 425.216, termination from the program under § 425.218, or both.

As indicated in the November 2011 final rule (74 FR 67948), we finalized these marketing policies as an aspect of patient-centeredness, indicating that we believed it would be appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of ACO-related marketing activities and materials to ensure that such communications and marketing are used only for appropriate purposes, such as notification that a beneficiary's healthcare provider is participating in the ACO, issuance of any CMS-required notices, or notification of provider or ACO terminations.

Historically, the majority of marketing submissions for the Shared Savings Program are approved upon review or are found not to constitute marketing materials and activities, as defined at § 425.20. For example, in 2021, of 241 Shared Savings Program marketing material submissions reviewed by CMS, 163 (~68 percent) of those submissions were approved, while only 1 submission (0.4 percent) was denied. For the remaining 77 submissions (~32 percent), 58 submissions did not to meet the definition of marketing materials and activities; 9 were approved after the ACO responded with additional information or resubmitted revised materials; 9 were withdrawn for unspecified reasons, and 1 was neither approved nor denied and remained in non-compliant status.

We believe that marketing materials and activities are important communications between an ACO and its patients and participants, and we remain committed to patient-centered care, patient engagement, and program transparency in the Shared Savings Program. However, given the breakdown of marketing material review dispositions, the time and resources CMS currently expends to review all submitted marketing materials, and the additional effort involved in ACOs submitting these materials prior to use, we believe the current submission requirements create an unnecessary administrative burden for both CMS and ACOs that is not outweighed by the benefits of the current policy.

(2) Modify Regulations on Review of ACO Marketing Materials

To reduce unnecessary administrative burden, we proposed to remove the

requirement at § 425.310(a) that ACOs submit marketing materials and activities to CMS before use, but to maintain the requirement that ACOs must provide marketing materials upon request. Additionally, we proposed to remove the provisions in § 425.310(b) regarding deemed approval of marketing materials and activities after a 5-day review period. We noted that ACOs must continue to comply with all Shared Savings Program regulations, including the marketing material content requirements that currently appear at § 425.310(c). As proposed, the policy does not affect an ACO's obligation to comply with marketing content requirements, and we proposed to retain the authority to request the submission of marketing materials and activities at any time. We proposed that if we determine an ACO's marketing materials and activities to be non-compliant, we will issue a written notice of disapproval under proposed § 425.310(b)(1). In addition, we proposed that ACOs must discontinue (and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue) use of any disapproved materials or activities. Under our proposal, we would retain language stating that the failure to comply with the requirements of § 425.310 will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

We believe that the existing marketing material content requirements and the proposed policy to review marketing materials and activities upon request would provide sufficient safeguards and appropriate patient protections. Additionally, beneficiaries may express concerns regarding ACO marketing materials by utilizing the 1–800–MEDICARE hotline, contacting their healthcare provider, or submitting a complaint to the Medicare Ombudsman's office, while ACOs and other interested parties may use any of these avenues, as well as express concerns via the Shared Savings Program mailbox or via their ACO coordinators.

We noted that we would codify the proposal by revising § 425.310 to remove existing references to CMS' collection, review, and approval of marketing materials. Specifically, we proposed to remove the marketing material file and use requirement at § 425.310(a) so that they may be used without prior approval. We proposed that § 425.310(a) would set forth without change the marketing material content requirements that currently appear in paragraph (c) (for example, the requirement to use template language and not be materially inaccurate or misleading). We proposed to revise paragraph (b) to remove language at § 425.310 (b)(1) regarding deemed approval after expiration of a 5-day review period and to retitle the section ''Monitoring.'' Under proposed paragraph (b)(1), CMS may request the submission of marketing materials and activities at any time, and if CMS determines that the marketing materials and activities do not comply with the content requirements of paragraph (a), CMS will issue written notice of disapproval to the ACO. Proposed paragraph (b)(2) sets forth without change language that currently appears § 425.310(b)(2)(ii) regarding the duty to cease use of disapproved marketing materials and activities. Finally, proposed paragraph (c) would set forth, without change, the sanctions provision that currently appears at § 425.310(d).

We noted that if finalized, our proposed modifications to § 425.310 would become effective on January 1, 2023. We believe that, if finalized, this proposal would reduce administrative burden for both CMS and for ACOs, while maintaining program integrity and beneficiary protections. We believe the revised regulation would provide sufficient safeguards and appropriate patient protections.

The following is a summary of the public comments received on the proposal to modify regulations on the review of ACO marketing materials and our responses:

Comment: Many commenters supported the proposal to eliminate the requirement that ACOs submit marketing materials to CMS for review and approval prior to dissemination among ACO participants and Medicare beneficiaries. Many commenters encouraged CMS to finalize this policy as proposed and agreed that marketing notices include important program information for ACO participants and beneficiaries and that materials can be retained and provided to CMS upon request with minimal burden.

Response: We appreciate commenters' support of our proposal to modify the program requirements for submitting marketing materials prior to use. We remind commenters that CMS is maintaining the current requirement for ACOs to make any marketing materials available to CMS upon request. As we stated in the CY 2023 PFS proposed rule (87 FR 46203), we have found that most marketing materials are compliant, and that because the majority of materials are compliant, the submission of marketing materials prior to use is an unnecessary program burden. We appreciate commenters' support of the proposal to eliminate the requirement that ACOs submit marketing materials to CMS for review and approval prior to dissemination among ACO participants and Medicare beneficiaries.

Comment: A few commenters disagreed with CMS's proposal to remove the requirement that ACOs submit marketing materials for review and approval before disseminating them. The commenters contended that marketing materials and activities are important communications between an ACO and its beneficiaries and ACO participants. Therefore, they stressed that continued review by CMS of marketing materials before use is essential.

Response: We appreciate commenters' support of important patient protections in providing program communications to patients that empower them to make informed choices about where and how they receive care. We disagree that the current file and use requirements are essential. ACOs have an understanding of marketing requirements and have systems in place to adhere to all marketing material requirements, as demonstrated by the generally compliant materials ACOs have submitted to CMS for review and approval. As we noted in the CY 2023 PFS proposed rule, CMS conducted an analysis on all marketing materials reviewed in PY 2021 and found that less than 1 percent of submitted materials were not approved. Therefore, we believe that the submission of marketing materials prior to use is an unnecessary administrative burden for ACOs. Our proposed policy maintains the requirement that ACOs must make materials available upon CMS request and CMS reserves to right to review all, or a subset, of an ACO's marketing material at any point during the agreement period. Based on our prior experience, we believe that this requirement is sufficient to ensure continued adherence to Shared Savings Program policies and will uphold and safeguard important beneficiary protections.

Comment: We received a few comments suggesting that CMS make template language publicly available to promote transparency and solicit feedback from ACOs, patient advocacy groups, and other interested parties. Commenters also requested flexibility from CMS in the template language to be site-specific with regards to the type of practice or facility, in an effort to ensure that the language enhances beneficiary understanding of the benefits of receiving care in an ACO and

advising them of important program requirements such as data sharing with CMS and among the different providers who coordinate a beneficiary's care. Additionally, we received one comment requesting that CMS eliminate the posted notice requirement completely.

Response: We appreciate commenters' suggestions on how to improve program marketing materials and templates and are committed to working with CMS' Office of Communications to revise our communication templates with the goal of decreasing beneficiary confusion and ensuring the provided information is clearly communicated and understood by a wide audience. However, we disagree that CMS should eliminate the posted notice requirement or grant flexibility allowing ACOs to make changes to the template to communicate the type of facility being represented and contend that templates are different from other types of marketing materials because of the standardization of the content across ACOs. We also note that templates are intended to balance program benefits (improved care quality and coordination) and inform providers and suppliers of incentives (the potential to earn shared savings) when participating in value-based healthcare and that this information be transparent for all involved and reiterate that CMS will make efforts to ensure that future template versions are versatile and convey the appropriate information, regardless of facility type.

For the reasons provided above, we are finalizing our proposal without change effective January 1, 2023. Specifically, we are reorganizing and revising § 425.310 to remove the provision at § 425.310(a) regarding the obligation to submit marketing materials to CMS prior to use. Revised § 425.310(a) sets forth without change the marketing material content requirements that currently appear in paragraph (c) (for example, the requirement to use template language and not be materially inaccurate or misleading). Under revised § 425.310(b)(1), CMS may request the submission of marketing materials and activities at any time, and if CMS determines that the marketing materials and activities do not comply with the content requirements of § 425.310(a), CMS will issue written notice of disapproval to the ACO. Under § 425.310(b)(2), the ACO must discontinue, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue, use of any marketing materials or activities disapproved by CMS. Additionally, under § 425.310(c), failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

We again appreciate commenters' overwhelming support and suggestions for improving Shared Savings Program policies and in reducing unnecessary program burden. We will continue to work with the CMS Office of Communications to improve required templates and posters to ease beneficiary confusion, while ensuring that content features plain language, and is clear and concise.

c. Modify Beneficiary Notification Requirements

(1) Background

Under § 425.312(a), an ACO is required to ensure that Medicare FFS beneficiaries are notified of the following: (1) that each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program; (2) the beneficiary's opportunity to decline claims data sharing; and (3) the ability to, and process by which, the beneficiary may identify or change identification of a primary care provider for purposes of voluntary alignment.

Section 425.312(a)(2) sets forth the manner in which ACOs or ACO participants are required to notify beneficiaries of this information. ACO participants must post signs in their facilities and, in settings in which beneficiaries receive primary care services, make standardized written notices available upon request. In addition, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(ii)). Finally, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii)).

We periodically receive inquiries from ACOs seeking clarification as to the types of facilities in which signs are required to be posted. In addition, ACOs have continued to express concern regarding the obligation to provide an annual standardized notification prior to or at a beneficiary's first primary care service visit of the performance year. Specifically, ACOs state that such notices may confuse beneficiaries, who misinterpret the notice and believe that it signifies a change to their Medicare benefits or otherwise represents an undesirable or disadvantageous change regarding their health care services. ACOs assert that this confusion may cause a beneficiary to opt out of data sharing, which could result in less cohesive care, duplicative or unnecessary medical tests, or contraindicated prescription drug therapy. ACOs have reported that the information in the beneficiary information notice is unclear and that the frequency of notifications containing identical information is redundant. According to ACOs, the beneficiary notices also cause unnecessary administrative burden to ACOs because ACOs retain documentation that the notices were sent, and ACOs may be required to perform additional follow-up for patients contacting ACOs with questions regarding the notice.

CMS remains committed to program transparency. Beneficiary notices are important communication tools, and we believe that ACOs are in the best position to communicate with beneficiaries regarding their care and the purposes for Medicare claims data sharing. We want to ensure that beneficiaries understand the advantages of their participation in ACOs, that their data is secure, that only the minimum necessary data is collected, and how this data is used for purposes of improving the quality of care for beneficiaries in the Shared Savings Program. We are working to improve the beneficiary notice to ensure that the content of the notice utilizes plain language and is beneficiary-friendly, as well as affirming patient choice and clarifying the beneficiary's opportunity to decline claims data sharing.

(2) Clarify Location of Beneficiary Notification Signage

ACOs and ACO participants frequently ask whether CMS requires signage to be posted in all facilities or only those where primary care services are provided. Although we believe the existing regulation text is clear on this point, we wish to provide clarification that ACO participants are required to post beneficiary notification signs in all of their facilities, whether or not primary care services are provided in every facility. Accordingly, we proposed to modify § 425.312(a)(2)(i) to move the requirement for standardized written notices available to the newly proposed, redesignated § 425.312(a)(2)(ii). With this modification, CMS clarifies that an ACO participant must post signs in ''all'' of its facilities and make standardized written notices available

upon request in ''all'' settings in which beneficiaries receive primary care services. Signage notifies the entirety of a patient population that the facility participates in an ACO, and therefore, is qualitatively different from standardized written notices provided directly to individual patients in conjunction with primary care service visits. We noted that the requirement to furnish standardized written notices upon the request of a beneficiary applies only in settings or facilities in which beneficiaries receive primary care services. We did not propose to expand the care settings in which standardized written notices must be furnished to beneficiaries upon request.

(3) Reduce the Frequency of Annual Standardized Written Notices

In addition to providing standardized written notices to beneficiaries upon request, ACOs and ACO participants are currently required to furnish standardized written notices prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii), (iv)). We continue to believe that requiring periodic beneficiary notifications affords ACOs and ACO participants an opportunity for direct engagement with the beneficiary, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. The requirement promotes program transparency and empowers patients with the knowledge of the ACO's mission, data sharing requirements, and ACO operations, thereby allowing patients to make informed decisions about where they receive care. Therefore, we intend to retain the beneficiary notification policies, but in the interest of an overall reduction in administrative burden, we proposed to modify § 425.312(a) to reduce the frequency with which an ACO or ACO participant must furnish standardized written notifications to beneficiaries from up to 5 times per agreement period to once per agreement period. We also proposed to implement a new follow-up beneficiary communication that we expect will reduce beneficiary confusion and improve beneficiary comprehension. The proposed changes would become effective January 1, 2023.

First, we proposed to revise the requirements regarding annual beneficiary notifications, which currently appear at § 425.312(a)(2)(ii) and (iii). Specifically, at proposed § 425.312(a)(2)(iii), we proposed to provide that, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary with a standardized written notice at least once during an agreement period. Similarly, at proposed § 425.312(a)(2)(iv), we proposed to provide that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period. In either case, the standardized written notice must be furnished prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant, and the notice must be in the form and manner specified by CMS.

Second, in the interest of ensuring program transparency, maintaining beneficiary protections, reducing beneficiary confusion, and improving beneficiary comprehension, we proposed at § 425.312(a)(2)(v) to require the ACO or ACO participant to follow up with each beneficiary to whom it furnished the standardized written notice pursuant to proposed § 425.312(a)(2)(iii) or (iv). We proposed that the follow-up communication may be verbal or written and must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the first standardized written notice was provided. The follow-up communication must afford the beneficiary an opportunity to ask any outstanding questions they may have, thereby reducing any potential beneficiary confusion and improving their understanding of the advantages of value-based care. The follow-up communication may be provided in any manner, so long as the form of the follow-up communication includes a meaningful opportunity for beneficiaries to ask questions and engage with a representative of the ACO or ACO participant with regard to the beneficiary notice. Because of the flexibility granted to ACOs in communicating key features of the beneficiary notification, we proposed that ACOs track and document how this beneficiary communication is implemented and make this documentation available to CMS upon request.

ACOs should administer the communication in the way that best suits their beneficiary population. We believe that while the follow-up communication would be most effective when occurring during a primary care service visit, it may be delivered in another manner. We noted that while it is permissible to provide the standardized written notice again during the course of the follow-up communication, simply providing the same standardized written notice as the full extent of the follow-up communication is not sufficient to satisfy the proposed requirements at § 425.312(a)(v), since doing so would not allow for an opportunity to engage the beneficiary and ensure they have the chance to ask any questions they may have as a result of receiving the standardized written notice. The implementation of the follow-up communication does not create a new benefit or billable service, and therefore, no additional payment will be made for the follow-up communication.

We are actively engaged in efforts to improve beneficiary notification materials, which include gathering feedback from beneficiaries and beneficiary representatives to make improvements as to how we disseminate information to beneficiaries. Further, we noted that we would work expeditiously to provide any updated and new materials as they become available. Although the proposal would reduce the frequency with which beneficiaries would receive the information that appears in standardized written notices, we noted that this information remains readily available via signage in ACO facilities, as well as appearing in the Medicare & You Handbook. Additionally, we indicated that we would maintain the requirement for ACO participants to make the notice available upon request in all settings in which beneficiaries receive primary care services. We noted that ACOs and ACO participants may choose to provide the standardized written notice or follow-up beneficiary engagement communications more frequently than once per agreement period, and we would support their efforts to do so.

We sought comment on the proposed frequency of the notification and whether our proposal will reduce net burden and mitigate any potential beneficiary confusion.

The following is a summary of the public comments received on the proposed modifications to the beneficiary notification requirements and our responses:

Comment: Many commenters supported providing beneficiary notification requirements once per agreement period rather than once per performance year and agreed that such a change would reduce administrative burden and ensure program transparency for beneficiaries.

Response: We appreciate commenters' support of our proposal to reduce unnecessary administrative burden by

amending our regulation to require the provision of beneficiary notices once during an agreement period. As discussed in the CY 2023 PFS proposed rule, we agree that reducing the frequency of these notifications would reduce confusion for beneficiaries.

Comment: One commenter specifically supported the follow-up communication, particularly in light of our proposal to reduce the frequency of beneficiary notifications that are currently furnished annually. The commenter encouraged CMS to finalize the follow-up communication proposal as proposed because it would increase beneficiary protections.

Response: We appreciate this commenter's support for our proposal for a follow-up communication. We agree that a follow-up communication is important to ensure that beneficiaries understand the notification and have an opportunity to ask questions about the Shared Savings Program and the benefits of value-based care. We also find that while there may be some burden in providing the follow-up communication, there is an overall reduction in burden for ACOs, as the proposed policy reduces the number of times that the beneficiary notice will be provided during an agreement period.

Comment: Many commenters requested flexibility in the beneficiary information notice template and requested that CMS allow ACOs to tailor the language of the written notice and modify template language to best meet the needs of their beneficiaries within set standards. Other commenters requested flexibility in how an ACO provides the follow-up communication, suggesting that it should be via email or secure patient portal.

Response: We appreciate commenters' request for flexibility in the beneficiary notification language and the manner in which ACOs must conduct the follow-up communication. CMS conducted focus groups with beneficiaries and interested parties to improve the notification template. We believe strongly that our efforts to revise the notification templates, based on feedback from the focus groups, will reduce beneficiary confusion, improve clarity and clearly communicate the benefits of value-based care and do not believe that allowing modifications to the template language would further these goals or best serve the interests of Medicare beneficiaries. The revised notification and poster templates will be made available to ACOs this fall for use at the start of the January 1, 2023 performance year and will continue to allow for the inclusion of ACO-specific information in fillable fields. Furthermore, as we noted in the CY 2023 PFS proposed rule, we expect ACOs to conduct follow-up communications in the manner that best suits their patient population. We agree with commenters that this flexibility is necessary and expect that some follow-up communications will take place face to face, while others may be conducted via email or telephone outreach, or in a follow-up mailing, as long as there is a meaningful opportunity for engagement, and depending on the frequency of primary care visits and the health status of the patient.

Comment: Most commenters did not support the follow-up communication and contend that follow-up communication creates significant operational burden without meaningful benefit, as it requires significant administrative cost to coordinate, train, and document and it is unclear whether beneficiaries wish to have such an opportunity. Other commenters expressed that multiple notices, even a follow-up notice, will confuse beneficiaries. These commenters believe that one clear and concise notice is sufficient, and suggested that CMS explore alternate strategies and work with ACOs to promote beneficiary education and engagement.

Response: We appreciate commenters' thoughts on the practical effects of implementing a follow up beneficiary communication but disagree that a follow-up notice will increase confusion. We note that while the implementation of this policy may create some level of administrative burden, there is still an overall net reduction in the total amount of communications ACOs are required to convey under this final rule. Further, there are multiple acceptable options that ACOs may use when operationalizing this requirement. As we stated in the CY 2023 PFS proposed rule, the most desirable form of follow-up would occur face to face (for instance, at a primary care office visit), where the beneficiary and provider can discuss potential concerns. However, we understand that depending upon a patient's health status or other circumstances, the patient may not have another primary care visit within the 180-day window. In those cases, we believe that alternate forms of outreach to the beneficiary as described in the CY 2023 PFS proposed rule would be sufficient to provide the beneficiary with a meaningful opportunity to ask any outstanding questions they might have, and as such, serve as a tool to reduce beneficiary confusion and increase comprehension of the required beneficiary notifications. Examples of appropriate modes of conducting this follow-up communication include disseminating it via secure patient portal, postal mail, or email, or outreach conducted via telephone or video visit. However, we reiterate that the follow-up communication may be provided in any manner, so long as the form of the follow-up communication includes a meaningful opportunity for beneficiaries to ask questions and engage with a representative of the ACO or ACO participant with regard to the beneficiary notice. We believe this provides a balance between educating beneficiaries and extending the flexibility to ACOs to implement the requirement in a manner that works well for their ACO.

Comment: We received one comment advocating that notifications for all assigned beneficiaries be made at the start of each agreement period and each new assigned beneficiary on a biannual basis by means of a letter through the electronic medical record (EMR) or patient portal and also have a hard copy available for each beneficiary to view at the practice on request.

Response: We appreciate the commenter's suggestion. However, we recognize that different ACOs have different IT infrastructures and that not all ACOs may be able to communicate with their assigned beneficiaries in the manner suggested (for example, beneficiaries may not choose to access their EMRs or patient portals). Accordingly, CMS is allowing ACOs flexibility in how to conduct these follow-up communications, including, but not limited to, communicating via EMR or patient portal.

Comment: A few commenters supported CMS' proposal to clarify that ACO participants are currently required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services.

Response: We appreciate commenters' support of our proposal to clarify our signage requirement and to ensure that all beneficiaries who receive care in the facilities understand that the facility participates in an ACO.

Comment: One commenter contended that the ACO poster found in the ACO–MS Knowledge Library states, ''for more details about our ACO, ask the front desk for a copy of the ACO beneficiary notice.'' The commenter asked that CMS acknowledge that separate posters will be required. There would be one poster serving as notification in primary care locations to accommodate the ''standardized written notices available upon request in all settings in which

beneficiaries receive primary care services,'' and a second poster for all other ACO participant facilities that do not provide primary care services and would be excluded from providing standardized written notices upon request.

Response: We appreciate the commenter's suggestions regarding providing setting-specific posters. We are working with our colleagues in the Office of Communications to improve the poster which includes removing references to the standardized written notice.

Comment: A few commenters did not agree with our proposals to reduce communication between ACOs and assigned beneficiaries and contended that such communication is critical to informed healthcare decision making by beneficiaries.

Response: Again, we appreciate commenters highlighting the importance of timely communications and beneficiary protections. We share the same goal to improve beneficiary awareness and comprehension of value based care and believe that our notification requirement with a follow-up communication will achieve this goal while reducing the potential for beneficiaries to misinterpret the notice as communicating a change regarding their health care services and coverage. We believe that reducing the frequency of beneficiary notifications will help to mitigate any potential concerns that their FFS benefits are changing. Further, we continue to require poster notifications be placed in all ACO participant facilities.

Comment: We received one comment explaining that some ACOs partner with specialist practices, which may include sites where no assigned beneficiaries are seen. This commenter relayed that requiring ACO-related signage at such sites would create confusion for beneficiaries and thereby impose burden on the specialist providers who must take time to explain the irrelevant signage. The commenter encouraged CMS to modify the policy and clarify that signage is required only in facilities where ACO-aligned beneficiaries receive care.

Response: We appreciate the commenter's suggestion. We disagree that a non-assigned beneficiary does not benefit from the knowledge that their provider is participating in an ACO. We believe all providers and suppliers participating in an ACO play important roles in coordinating care for beneficiaries. We believe it is appropriate for beneficiaries, including those not assigned to an ACO, to understand that their health care provider works with other health care providers and an ACO to improve the quality and experience of care practices, since those improved care practices may ultimately benefit all patients. While we understand that this may cause some confusion, we remain committed to working with the CMS Office of Communications to improve all communications, including signage, to use plainer language and ensure beneficiary comprehension.

Comment: We received one comment with a mixed opinion about the proposals, urging CMS to work with stakeholders to find a comprehensive workable solution to the ongoing burden, redundancy, and beneficiary confusion that arises in these instances.

Response: We appreciate the commenter's support and collaboration, and we commit to working to refine the required communications and signage to ensure that beneficiary protections are in place and that the content is clear and concise for all readers.

We appreciate the commenters' support and suggestions to modify the beneficiary notice requirements. For the reasons discussed above, we are finalizing our policies as proposed at § 425.312. Specifically, we are revising § 425.312(a)(2) to provide that the notifications required under § 425.312(a)(1) must be carried out through the following methods: (i) by an ACO participant posting signs in all of its facilities; (ii) by an ACO participant making standardized written notices available upon request in all settings in which beneficiaries receive primary care services; (iii) in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each FFS beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS and prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant; and (iv) in the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS and during the performance year for which the beneficiary is prospectively assigned to the ACO; and (v) following the provision of the standardized written notice to a beneficiary, as specified in § 425.312(a)(2)(iii) and (iv) of this section, the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary.

Additionally, under § 425.312(2)(v)(A), the follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided. Under § 425.312(2)(v)(B), The ACO must retain a record of all beneficiaries receiving the follow-up communication and the form and manner in which the communication was made available to the beneficiary; the ACO must make these records available to CMS upon request.

d. Streamline SNF 3-Day Rule Waiver Application Review Process

Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient skilled nursing facility (SNF) care (the SNF 3-day rule). Section 1819(a) of the Act defines a SNF, in part, as an institution (or a distinct part of an institution) that is not primarily for the care and treatment of mental diseases but is primarily engaged in providing the following to residents: skilled nursing care and related services for residents who require medical or nursing care; or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The Medicare SNF benefit applies to beneficiaries who require a short-term intensive stay in a skilled nursing facility or rehabilitation facility, or both.

In the CY 2015 Shared Savings Program final rule (80 FR 32692), CMS used its authority under section 1899(f) to waive the SNF 3-day rule under section 1861(i) of the Act in order to carry out the provisions of section 1899 of the Act by offering ACOs that have accepted two-sided risk under the Shared Savings Program more flexibility under FFS Medicare to provide appropriate care for beneficiaries in the most appropriate care setting. We noted that we believe this is an opportunity to provide experienced, risk-bearing ACOs with additional flexibilities to increase quality and decrease costs.

The waiver is codified in the Shared Savings Program regulations at § 425.612(a)(1). Specifically, for PY 2017 and subsequent performance years, we waive the SNF 3-day rule for eligible beneficiaries that are assigned to an ACO participating in a two-sided model (or as provided in § 425.612(a)(1)(iv) during a grace period for beneficiaries excluded from prospective assignment to such an ACO) and who receive

covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO (a ''SNF Affiliate''). An ACO is eligible to use the SNF 3-Day Rule Waiver if the ACO participates in performance-based risk (for example, Levels C, D, or E of the BASIC track or the ENHANCED track) and has a SNF affiliate list. All other statutory and regulatory provisions regarding Medicare Part A post-hospital extended care services continue to apply.

An eligible ACO may apply for a programmatic waiver of the SNF 3-day rule to allow its assigned beneficiaries to receive coverage for inpatient SNF care without a prior 3-day inpatient hospital stay when admitted to a SNF affiliate. A SNF affiliate is a SNF that has executed a written agreement with an eligible ACO that meets the requirements of § 425.612(a)(1)(iii)(B) and is included on the ACO's SNF affiliate list. If the SNF affiliate is eligible to be included in the CMS 5-star Quality Rating System, it must have and maintain an overall rating of 3 or higher (§ 425.612(a)(1)(iii)(A)).

It is important to note that the Shared Savings Program SNF 3-Day Rule Waiver does not create a new benefit or extend Medicare SNF coverage to patients who could be treated in outpatient settings or who require long-term custodial care. Also, the SNF 3-Day Rule Waiver does not restrict a beneficiary's choice of provider or supplier. A beneficiary will continue to have the option to seek care from any Medicare FFS provider or supplier, including from a SNF or other facility that is not an affiliate of an ACO participating in the Shared Savings Program. If a beneficiary that is assigned to an ACO chooses to receive care from a SNF or other facility that is not an affiliate of the ACO, normal Medicare requirements apply, including the requirement for a 3-day inpatient hospitalization. The SNF 3-Day Rule Waiver is intended to provide ACOs that are participating in certain performance-based risk tracks with additional flexibility to increase quality and decrease costs.

(1) SNF 3-Day Rule Waiver Application Process

An ACO participating or applying to participate in performance-based risk within the BASIC track under § 425.605 or the ENHANCED track under § 425.610 may request to use the SNF 3-Day Rule Waiver at the time of application to participate in the program or during its agreement period. The waiver request must be submitted in a form and manner and by a deadline specified by CMS, which typically occurs once each year. Any ACO, including those applying for the waiver during the term of an existing participation agreement, must apply during the annual application process. Current regulations require that an ACO submit an application demonstrating that it has the capacity to identify and manage beneficiaries who would either be directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. Under § 425.612(a)(1)(i), to be eligible to use the SNF 3-Day Rule Waiver, an ACO must submit supplemental application materials that include, but are not limited to, a list of SNFs with whom the ACO will partner (that is, a SNF affiliate list), along with executed written SNF affiliate agreements between the ACO and each listed SNF, in addition to 3 narratives describing how the ACO plans to implement the waiver. The narratives must include: the communication plan between the ACO and its SNF affiliates, a care management plan for beneficiaries admitted to a SNF affiliate, and a beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes.

Historically, the SNF 3-Day Rule Waiver originated from the CMS Innovation Center's Pioneer ACO and Next Generation ACO Models. These models included application questions (answered by the ACO in a narrative format) which, while not codified in regulation, were transformed into plan narrative requirements in the Shared Savings Program SNF 3-Day Rule Waiver application. In the CY 2015 Shared Savings Program final rule (80 FR at 32805), we discussed a variety of issues that could be addressed in these narratives, such as the protocol that will be followed by ACOs for evaluating and approving admissions to a SNF under the waiver and consistent with the beneficiary eligibility requirements and the education and training for eligible SNFs regarding waiver requirements. We have not set forth specific ways that ACOs must address issues in their plan narratives because we believe the ACO is in the best position to establish its protocols, develop SNF training, and otherwise determine how to best coordinate care for patients transferred to their SNF affiliates.

After successfully implementing the Shared Savings Program SNF 3-Day Rule Waiver for several performance years, we determined in 2017 that some application requirements were burdensome for both CMS and ACOs, did not add value to the application review, or were not permitted by regulation. For example, the SNF 3-Day Rule Waiver application originally included a narrative describing any financial relationships between an ACO, SNF affiliate and acute care hospital. Because the Shared Savings Program regulations do not prohibit ACOs or SNFs from having financial arrangements with acute care hospitals, nor do they require such arrangements, we discontinued the submission of this narrative. Previously, ACOs also submitted documentation for each proposed SNF affiliate demonstrating they met minimum star rating requirements. Because CMS could obtain the required star rating information directly from the CMS Care Compare website, this application submission requirement was discontinued. We removed the requirement for these two application elements in the CY 2018 PFS final rule (82 FR 52976).

At the time of these modifications, CMS chose to retain the three narratives related to an ACO's communication plan, care management plan, and beneficiary evaluation and admission plan without establishing specific criteria for an ACO's process for implementing the SNF 3-Day Rule Waiver. We have since found that these plan narratives have not aided in our ability to evaluate an ACO's capacity to identify and manage beneficiaries who may be admitted to a SNF affiliate beyond what is otherwise established within the application. These narratives describe the plans that exist and that the ACO will adhere to requirements for beneficiary eligibility set forth in the waiver, but the program continues to provide operational flexibility to ACOs to develop their own internal processes and protocols.

(2) Modify the CMS Review Process for ACOs Applying for a Shared Savings Program SNF 3-Day Rule Waiver

We remain committed to reducing unnecessary application and/or program burden where possible and consider application attestations as a way of streamlining processes when appropriate. The submission of the three remaining narratives has largely functioned as a mechanism for ACOs to confirm that they have established operations for communicating between the ACO and its SNF affiliates, establishing a care management plan, and beneficiary evaluation and admission plan. The existence of the three narrative plans provides some assurance of an ACO's capacity to

identify and manage beneficiaries who may be admitted to a SNF affiliate. However, as a payer, we do not have the experience that would be required to evaluate the appropriateness of the contents of these plans. Therefore, to reduce CMS and ACO burden, we proposed to remove the requirement to submit the plan narratives and instead proposed to require ACOs to certify that they have a communication plan, care management plan, and beneficiary evaluation and admission plan in place prior to SNF 3-Day Rule Waiver approval. Such plans should continue to address the issues we previously discussed in the CY 2015 Shared Savings Program final rule at 80 FR 32805. ACOs must continue to develop robust processes to implement the 3-Day Rule Waiver and to successfully transition care for their identified FFS beneficiaries and must be able to provide upon request a narrative describing their communication plan, care management plan, and beneficiary evaluation and admission plan. We noted in the CY 2023 PFS proposed rule that if our proposed policy is finalized, an ACO would be subject to compliance action if it fails to submit, upon CMS request, the narratives about its capacity to manage patients under the waiver. The proposed attestation requirement retains oversight for ensuring that an ACO has the capacity to identify and manage beneficiaries while reducing burden during the application process.

Furthermore, we have determined that other provisions of our regulations provide sufficient safeguards to ensure that CMS can assess an ACO's capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient stay of less than 3 days. We also noted that we have found that these experienced, risk-bearing ACOs focus on care coordination and clinically-integrated, patient-centered care. Such investments in care coordination not only improve patient outcomes, but also serve to reduce the cost of care. In addition, our ongoing oversight and program compliance monitoring of the use of the waiver by ACOs helps us to ensure that ACOs have the capacity to identify and manage beneficiaries who are admitted to a SNF under the SNF 3-Day Rule Waiver.

In summary, we proposed to amend § 425.612(a)(1)(i)(A) to require that an ACO applying to use the SNF 3-Day Rule Waiver must submit an attestation that it has established plan narratives (communication plan, care management plan, and beneficiary evaluation and admission plan) and will make them available to CMS upon request. We proposed minor revisions to the narrative language by replacing ''the communication plan'' with ''a communication plan'' in § 425.612(a)(1)(i)(A)(*1*). We noted that we expected that, when implemented, the proposal will reduce the application review burden on CMS, as well as the burden on ACOs to submit this information.

The following is a summary of the public comments received on the proposals to streamline the SNF 3-day rule waiver application review process and our responses:

Comment: In general, the majority of commenters supported efforts to reduce administrative burden on ACOs, including the proposed modifications to the SNF 3-day rule waiver application. One commenter indicated that this would enable ACOs to redirect these resources toward patient care. Another stated this would substantially reduce the amount of upfront documentation required for submission with ACO's application.

Response: We appreciate commenters' support of our proposal to remove the requirements for ACOs to submit plan narratives (communication plan, care management plan, and beneficiary evaluation and admission plan) with the SNF 3-day rule waiver application for CMS approval, and instead to attest that the plans are in place and can be made available to CMS upon request. We agree with commenters that this will reduce unnecessary administrative burden when ACOs apply for the waiver and will increase usability of this important ACO benefit for patients.

Comment: One commenter recognized that CMS intends to decrease administrative burden, and requested that CMS ensure that the final rule protects program integrity and beneficiary access to care.

Response: We appreciate the commenter sharing their concern for program integrity and beneficiary access to care. With respect to access to care, we note that we did not propose and are not finalizing any change to the SNF 3-day waiver provisions that affects beneficiary access to care. We believe this final rule adequately protects the integrity of the program by maintaining the requirement to have communication, care management, and beneficiary evaluation and admission plans and maintaining all other programmatic requirements regarding the SNF 3-day waiver, including the eligibility criteria for SNF Affiliates and the requirement that an ACO provider/supplier who is a physician must evaluate and approve a beneficiary's admission to a SNF Affiliate.

Comment: We received one comment urging CMS to eliminate the requirement at § 425.612(a)(1)(ii)(H), which requires an ACO provider/supplier who is a physician to have evaluated and approved the beneficiary for admission to a SNF affiliate within three days prior to the SNF admission.

Response: We appreciate the commenter's suggestion, but note that it is beyond the scope of our proposal. We continue to believe that the requirement set forth at § 425.612(a)(1)(ii)(H) is an important protection for beneficiaries and aids ACOs in coordinating care for their assigned beneficiaries. We believe that the ACO is in the best position to oversee the transfer of beneficiaries to SNFs or LTC settings.

Comment: One commenter urged CMS to not finalize the proposal. The commenter appreciated the intent to make it easier for ACOs to obtain a waiver but stated that beneficiaries are not provided sufficient information about how to use and benefit from the waiver and that the proposed changes will make it more, not less, difficult for those attributed to an ACO to access the SNF 3-day rule waiver. The commenter urged CMS to take additional measures to ensure that eligible beneficiaries are aware they can receive services covered by a waiver and stated their concern that there are instances where beneficiaries who go to a SNF without a prior three-day inpatient hospital stay do not have their SNF stay covered by Medicare and instead are required to pay out-of-pocket so the expenses are not attributable to the ACO.

Response: Nothing in our proposal or this final rule alters the beneficiary eligibility requirements for receiving SNF care under the waiver. It is important to note that not every beneficiary will be determined to meet the criteria to be admitted under the waiver, for example, a beneficiary must be medically stable and not require inpatient or further inpatient hospital evaluation or treatment, and this final rule does not make changes to those established criteria. Our final policy is limited to allowing ACOs to attest that they have developed a communication plan with its SNF Affiliates, care management plan, and beneficiary evaluation and admission plan when transferring eligible beneficiaries to a SNF, and that they can be made available to CMS upon request.

Comment: One commenter requested that we make additional SNF 3-day rule waiver utilization data publicly available in order to allow a fuller understanding of the potential impact of increasing access to the SNF 3-day rule waiver. The commenter also expressed

interest in data which shows what, if any, impacts have been observed from waiving the three-day inpatient hospital stay requirement during the COVID–19 PHE.

Response: We appreciate this suggestion and are constantly reviewing Shared Savings Program data and frequently make updates to our publicly available reports. We will take this suggestion under advisement the next time we make updates.

Comment: Other commenters requested additional flexibility in the SNF 3-day rule waiver, and that waiver eligibility should be extended to ACOs in nonperformance-based risk tracks (BASIC track Level A and B) so that all ACOs have access to this a tool to manage costs and provide the right care at the most appropriate location. Another commenter requested CMS go further and eliminate the SNF 3-day qualifying inpatient stay requirement for long-term care nursing facility residents in an ACO.

Response: We appreciate the commenters' suggestions; however, we note that our policy modifications in this final rule were only intended to reduce the burden for ACOs when applying for SNF 3-day rule waivers and to promote the use of such waivers when and where they are authorized in our current policies. The commenters' suggestions are outside the scope of this rulemaking.

As a result of the discussion above and the support of commenters, we are finalizing without change our proposed policy to remove the requirement for ACOs to submit communication plan, care management plan, and beneficiary evaluation and admission plan narratives with a SNF 3-day rule waiver application. Specifically, we are revising § 425.612(a)(1)(i)(A) to require an ACO applying for the waiver to submit an attestation that it has established and will make available to CMS upon request communication, care management, and beneficiary evaluation and admission plan narratives describing how the ACO plans to implement the waiver.

e. Updating Shared Savings Program Data Sharing Regulations To Recognize ACOs Structured as Organized Health Care Arrangements (OHCAs) for Data Sharing Purposes

In the CY 2022 PFS final rule (86 FR 65261), we stated that we were considering whether it would be appropriate to revise the regulations at §§ 425.702(c) and 425.704(b) to allow data sharing with a Shared Savings Program ACO that has structured its relationship with its ACO participants as an OHCA, as that term is defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 CFR 160.103. This was in response to commenters who shared concerns about collecting patient-level all-payer data (eCQMs/MIPS CQM) from patients who were not assigned to the ACO. These commenters cited HIPAA and patient consent concerns related to sharing non-Medicare patient information with the ACO and with CMS for a population that is not assigned to the ACO and indicated that obtaining this consent would be an additional burden.

We explained in the CY 2022 PFS final rule (86 FR 65261) that we believed the disclosure of this all-payer data to CMS as required by § 414.1340(a) is permitted by the HIPAA Privacy rule under the provision that permits disclosures of protected health information (PHI) as ''required by law.'' [364] We also encouraged ACOs and their ACO participants to consult with their legal counsel as necessary to ensure that their business associate agreements (BAAs) address the need to share data for patients covered by all payers with the ACO to permit the ACO to comply with its legal obligation to completely and accurately report this data to CMS. Nevertheless, these comments prompted us to consider whether the current Shared Savings Program regulations provide sufficient flexibility regarding different arrangements permitted under HIPAA. In the CY 2022 PFS final rule, we stated that we were specifically considering potential revisions to the regulations at §§ 425.702(c) and 425.704(b) to permit data sharing with an ACO structured as an OHCA. We then proposed these changes in the CY 2023 PFS proposed rule (87 FR 46207 through 46208).

As described in the CY 2023 PFS proposed rule, in the April 2011 proposed rule (76 FR 19528, 19556), we discussed the importance of data sharing and beneficiary protections in light of existing HIPAA requirements. We noted that ACO participants and ACO providers/suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. We also stated that an ACO may itself be a HIPAA covered entity if it is a health care provider that conducts such transactions or may qualify as the business associate of its covered entity ACO participants and ACO providers/suppliers based on the quality assessment and improvement activities that the ACO is conducting on behalf of those ACO participants and ACO providers/suppliers (76 FR 19556). In the November 2011 final rule (76 FR 67846 through 67851), we established requirements for data sharing with ACOs that are designed around the HIPAA provisions for ''health care operations'' disclosures. These provisions permit CMS to disclose PHI without obtaining individual authorization for the health care operations activities of the recipient of the data (that is, the ACO).[365] As we explained in the CY 2015 PFS final rule (80 FR 32692), ACOs work with their ACO participants and ACO providers/suppliers to evaluate their performance, conduct quality assessment and improvement activities, perform care coordination activities, and conduct population-based activities relating to improved health for their assigned beneficiary population. When done by or on behalf of a covered entity, these are activities that would qualify as health care operations under the first and second paragraphs of the definition of ''health care operations'' at 45 CFR 164.501 (76 FR 19558). Therefore, in the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b), we have focused on ACOs that are themselves HIPAA-covered entities, or that are acting as business associates on behalf of their ACO participants and ACO providers/suppliers who are HIPAA-covered entities.

We stated in the CY 2023 PFS proposed rule that we believed that most ACOs are acting as business associates of their covered entity ACO participants (the providers and suppliers that are part of the ACO). However, we noted that we believed it is possible that some ACOs may choose to operate as an OHCA.

An OHCA is another type of entity that is recognized under the HIPAA regulations. An OHCA is a distinct entity from a covered entity or a business associate under HIPAA, although it is made up of covered entities. As most relevant to Shared Savings Program ACOs, under 45 CFR 160.103, an OHCA is defined to include an organized system of health care in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participate in specified joint activities such as quality assessment and

[364] 45 CFR 164.512(a).

[365] 45 CFR 164.506(c)(4).

improvement activities and payment activities.[366] In addition, the purpose of the OHCA is that participants in such clinically integrated settings are able to share health information freely not only for purposes of care, but also to improve their joint operations (65 FR 82494). The HIPAA Privacy Rule has specific provisions relevant to OHCAs. For example, under 45 CFR 164.506(c)(5), a covered entity that participates in an OHCA may disclose PHI about an individual to other participants in the OHCA for any health care operations activities of the OHCA.

We noted that the Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology (ONC) have recognized in joint guidance that ACOs may operate as OHCAs.[367] An ACO that operates as an OHCA would be able to share PHI among the covered entities in the OHCA without getting authorization from individuals for the health care operations of the OHCA and would be permitted to share PHI for the health care activities of the OHCA without entering into BAAs with each other.[368]

We proposed to modify the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b) to specify that for PY 2023 and subsequent performance years, ACOs acting as OHCAs may request aggregate reports and beneficiary-identifiable claims data from CMS, respectively. We stated that these proposed changes would recognize an OHCA as an additional organizational structure under which an ACO can request data from CMS. We explained that our intention was to update the data sharing regulations to reflect how ACOs may be structured and provide flexibility with respect to the different arrangements permitted under HIPAA for purposes of data sharing.

Separately, we stated our belief that an OHCA structure potentially could address some of the concerns that commenters have raised about ACOs collecting and reporting all-payer data to CMS as required under the APP. However, we noted that the proposal was limited to the Shared Savings Program regulations governing CMS' data sharing with ACOs and was not intended to affect or modify any existing obligations under the HIPAA Privacy Rule. We also noted that it is the ACOs' responsibility to consult with their legal counsel and others as necessary to determine how to structure their arrangements with their ACO participants and ACO providers/suppliers to comply with HIPAA requirements.

We received public comments on the proposal to update the Shared Savings Program data sharing regulations to recognize ACOs structured as OHCAs. The following is a summary of the comments we received and our responses.

Comment: A majority of commenters supported our proposal to modify the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b) to specify that ACOs acting as OHCAs may request aggregate reports and beneficiary-identifiable claims data from CMS, respectively. Several commenters stated that they supported this change because it would allow ACOs that operate as OHCAs to share the data needed to connect patients from across their delivery systems (urgent care, emergency department (ED), specialists) with primary care providers. One commenter supported the proposal and emphasized an interest in receiving as much data from CMS and in promoting as much transparency, as possible. Other commenters appreciated CMS' efforts generally to reduce administrative requirements for ACOs. One commenter explained that reporting, patient notification, and other administrative requirements cost ACOs staff time and financial resources and that the proposed modifications would minimize these requirements and enable ACOs to redirect resources toward patient care and reduce disincentives to participation in an ACO.

Response: We appreciate commenters' support for our proposed modifications to amend the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b) to specify that ACOs acting as OHCAs may request both aggregate reports and beneficiary-identifiable claims data. As we discussed in the proposed rule, these modifications will help ensure our data sharing regulations reflect how ACOs may be structured and provide flexibility with respect to different arrangements permitted under HIPAA for purposes of data sharing. We agree with the commenters that these changes may help ACOs improve operations, reduce administrative burden, increase opportunities for data sharing among ACO participants, and support transparency in Shared Savings Program data across the continuum of care.

Comment: Several commenters stated that while they supported the proposal, they disagreed that an OHCA structure would support all-payer quality reporting because, regardless of the structure used to comply with HIPAA (that is, business associate agreements versus OHCA), combining data across numerous EHR systems is an onerous process and EHR vendors are not yet equipped to support ACOs in this endeavor. These commenters asserted that they do not believe it is appropriate for CMS to assess ACOs' quality performance for patient populations outside of the ACO.

Response: We acknowledge the concerns raised by commenters about the challenges ACOs encounter when working across the multiple EHR systems used by their ACO participants. However, our proposed policy change was designed to ease the data sharing burden of ACOs that organize as OHCAs by ensuring that our regulations reflect how ACOs may be structured and provide flexibility with respect to the different arrangements permitted under HIPAA for purposes of data sharing. The proposed policy change was not intended to affect or modify any existing obligations under the HIPAA Privacy Rule. We recognize the commenters' concerns about reporting all-payer data, but we note that our proposed modification in section III.G.6 of the CY 2023 PFS proposed rule was limited to the way in which ACOs may be structured for purposes of the Shared Savings Program data sharing regulations, and we did not propose any modifications to previously finalized policies with respect to quality reporting in that section of the CY 2023 PFS proposed rule. Please see section III.G.4 of this final rule for a discussion of our proposed and final policies with respect to the quality performance standard and quality reporting requirements under the Shared Savings Program.

Comment: Another commenter supported the proposal and mentioned that it had ACOs that were organized as OHCAs in some States. This commenter stated that, while rare, there are instances in which State law conflicts with Federal laws governing data sharing and the lack of Federal guidance when those conflicts arise increases the costs of running an ACO because specialized legal counsel is needed, and this expense diverts investments into administration and away from population health.

Response: We understand that there may be conflicts that arise between State

[366] For the complete definition of an OHCA, see 45 CFR 160.103.

[367] Permitted Uses and Disclosures: Exchange for Health Care Operations (*https://www.healthit.gov/sites/default/files/exchange_health_care_ops.pdf*).

[368] Please see HIPAA For Professionals FAQ 242 (Are covered entities that engage in joint activities under an organized health care arrangement (OHCA) required to have business associate contracts with each other?) (*https://www.hhs.gov/hipaa/for-professionals/faq/242/may-i-share-protected-health-information-directly-with-another/index.html*).

and Federal laws governing data sharing, but we note that the proposed modifications were limited to the Shared Savings Program regulations governing CMS' data sharing with ACOs and were not intended to affect or modify any existing obligations under the HIPAA Privacy Rule or other laws. We encourage ACOs to consult with legal counsel as necessary to determine how to comply with applicable Federal and State laws. While we acknowledge that ACOs may incur costs when consulting with legal counsel, we believe that these costs are worthwhile investments for ACOs to ensure compliance with Federal and State laws.

After considering the comments, we are finalizing, as proposed, our revisions to the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b) to specify that ACOs acting as OHCAs may request aggregate reports and beneficiary-identifiable claims data. Under this policy change, CMS will recognize an OHCA as an additional organizational structure under which an ACO can request data from CMS and the updated data sharing regulations will better reflect how ACOs may be structured and provide flexibility with respect to the different arrangements permitted under HIPAA for purposes of data sharing.

7. Responses to the Comment Solicitation on Incorporating an Administrative Benchmarking Approach Into the Shared Savings Program

a. Background on Longer Term Approach to Benchmarking Under the Shared Savings Program

We have set a goal that 100 percent of Original Medicare beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.[369] Achieving this goal will require significant growth in the number of ACOs participating in the Shared Savings Program, or the number of beneficiaries served by existing ACOs, or both. Benchmarks are a core policy instrument for providing sufficient incentives for ACOs to enter and remain in the Shared Savings Program, with significant implications on impacts to the Medicare Trust Funds.

The benchmark is a cost target used to determine savings or losses for an ACO compared to performance year expenditures for its assigned beneficiary population and, importantly, to create incentives for ACOs to reduce spending and generate savings, which will be shared by the ACO and CMS; by extension, these savings opportunities also create incentives for providers and suppliers to participate in ACOs. Many factors need to be considered in establishing benchmarks including the variability in the composition of ACOs, the beneficiary populations they serve, and their experience with accountable care models, as well as the need to protect the Trust Funds and minimize unintended consequences such as market consolidation and patient risk selection. In the CY 2023 PFS proposed rule (87 FR 46208 through 46217), we described and solicited comment on a modified benchmarking methodology that may boost participation, increase savings to the Medicare Trust Funds, and make long-term participation in the Shared Savings Program possible for more ACOs.

As explained in the proposed rule, we currently establish, adjust, update and reset the historical benchmark under the Shared Savings Program in accordance with § 425.601. An ACO's benchmark is established based on historical expenditures for a population of beneficiaries that would have been assigned to that ACO in the 3 years prior to the start of its agreement period. In establishing the benchmark, we adjust the benchmark based on the ACO's spending relative to its service area (referred to as the regional adjustment). For each performance year of the ACO's 5-year agreement period, we risk adjust the benchmark for changes in severity and case mix of the ACO's assigned beneficiaries, and we update the benchmark using growth rates that are a blend of observed national and regional FFS spending trends. We reset (or rebase) the ACO's benchmark at the start of the ACO's second and each subsequent agreement period. Refer to section III.G.5. of the proposed rule for a more detailed description of the statutory and regulatory background of the Shared Savings Program's current benchmarking methodology and certain benchmark calculations, as well as proposed modifications to the current benchmarking methodology for agreement periods starting on January 1, 2024, and in subsequent years.

ACOs and other interested parties have expressed concerns about the effects of current benchmarking methods on ACOs' incentives to generate savings, the extent to which they are able to share in those savings, and thus the incentives for ACOs to enter and remain in the program over the long-term. Specifically, there are two ways in which the use of factors based on realized FFS spending (which reflects any ACO spending reductions) can lead to lower benchmarks, which we will refer to as ''ratchet'' effects: (1) downward pressure on an individual ACO's benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs.

The first type of ratchet effect occurs at the individual ACO level, when an ACO's own savings reduce its benchmark, which can occur when we reset the historical benchmark at the start of the ACO's second or subsequent agreement period. When the benchmark years correspond to performance years from the ACO's preceding agreement period, the benchmark reflects a portion of any spending reductions achieved by the ACO. A ratchet effect can also occur through the use of factors based on the regional FFS expenditures to adjust the benchmark and update an ACO's benchmark; specifically, when an ACO reduces spending, it also reduces average spending in its region, thereby lowering the regional adjustment to its benchmark. This effect becomes more prominent as an ACO has increasing market share in its region. Critically, ACOs must be able to retain the ability to achieve savings over the long-term to have an incentive to take the steps necessary to generate them, as there are costs associated with delivering care outside of the FFS construct and in running an ACO to lower (and maintain) reduced spending levels.

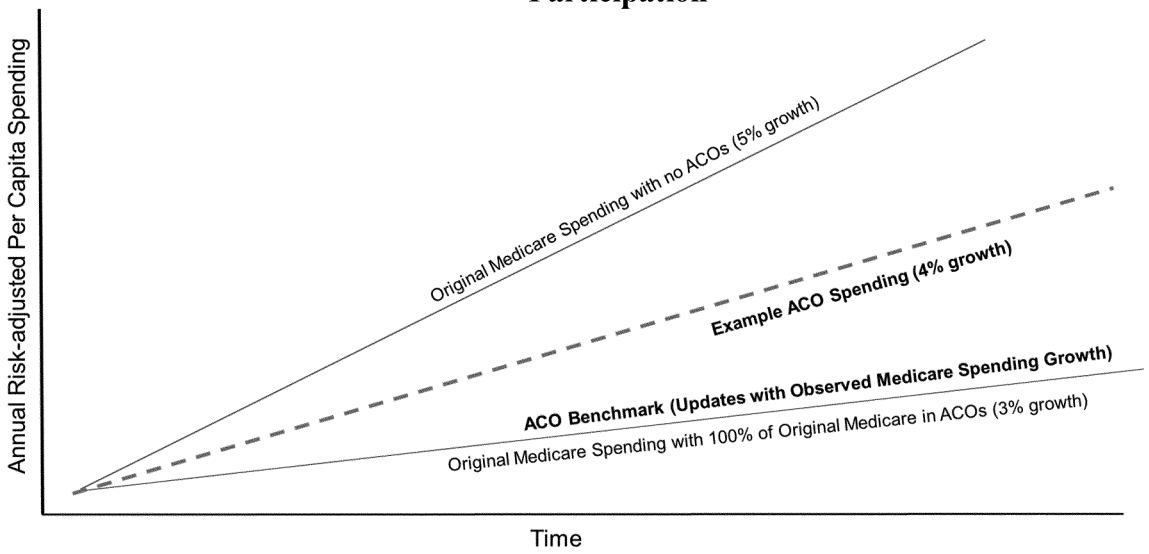
The second type of ratchet effect occurs at the program level, where overall program success can apply downward pressure on ACOs' benchmarks through the method for updating benchmarks each performance year for changes in expenditures between Base Year 3 (BY3) and the performance year. We explained in the proposed rule that we currently determine the update factor retrospectively using a blend of realized national and regional FFS expenditure growth rates, which incorporates the collective impact of ACOs on spending across Original Medicare. As a greater portion of Medicare FFS beneficiaries are assigned to ACOs, this program level ratcheting effect increasingly diminishes incentives to participate in the Shared Savings Program. If all beneficiaries enrolled in the Original Medicare FFS program under Parts A and B were assigned to an ACO, calculating the update factor based on realized

[369] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. *Health Affairs.* January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*.

spending growth rates would necessitate that some ACOs would experience expenditure growth in excess of the update factor (and forgo shared savings), even if all ACOs reduced spending growth. That is, an ACO would have to reduce spending more than the average ACO in order to earn savings, all else equal (absent regional adjustments to historical benchmarks). Similarly, program-wide savings lower the average per capita amounts of expenditures for an ACO's regional service area which are used in computing the regional adjustment to the historical benchmark. As ACOs' benchmarks converge toward average realized FFS spending, approximately half of ACOs will necessarily be given benchmarks below their spending at the start of their current agreement period, even if all ACOs have generated spending reductions relative to the counterfactual (that is, what spending would have been without the ACO). This downward pressure of program success on benchmark updates means that ACOs collectively keep less of the savings they generate. In the context of CMS' strategic objective to increase the number of Medicare beneficiaries in a care relationship with quality and total cost of care accountability, we anticipate that this program level ratcheting effect will become more pronounced with the growth in the number of beneficiaries assigned to ACOs, further weakening incentives to participate in the Shared Savings Program with the potential for impeding progress towards the fulfillment of this same goal.

For illustrative purposes, consider a scenario in which all Original Medicare beneficiaries are receiving the plurality of their primary care from an ACO provider/supplier, and thus are assigned to an ACO. Assume that FFS expenditure growth in the absence of ACOs would be 5 percent each year, but that ACOs, on average, slow expenditure growth to 3 percent each year. Under the current benchmarking approach, the update factor applied to an ACO's benchmark would be 3 percent, matching the average overall FFS expenditure growth rate under 100 percent ACO penetration. However, because 3 percent is the average growth rate, there will be ACOs with both higher and lower growth rates than 3 percent, meaning that some ACOs' growth in expenditures will outpace their benchmarks, even if they reduced spending relative to the counterfactual. In this example, an ACO that limited expenditure growth to 4 percent would (ignoring regional adjustments to the benchmark) show losses, despite reducing spending relative to the 5 percent growth rate expected without ACOs. Figure 2 provides a visual example of this scenario.

FIGURE 2: Illustrative Example of ACO Benchmarking and Spending Compared to Medicare Spending Growth With 100% ACO Participation and Without ACO Participation



MedPAC and researchers are also examining the Shared Savings Program benchmarking methodology and have noted many of the above concerns. MedPAC has discussed ratchet effects in ACO benchmarks in its November 2021 public meeting [370] and January 2022 public meeting,[371] with the general consensus that eliminating ratcheting effects is essential for the long-term sustainability of the Shared Savings Program. Many of the commissioners discussed a longer-term approach under which CMS would update ACOs' benchmarks annually using ''exogenous'' factors, meaning factors not impacted by the individual or collective performance of ACOs. Under this approach, which has also been referred to as administratively set benchmarks, benchmarks may be set prospectively based on projected growth in volume and intensity of FFS services, with guardrails in place to account for actual changes in FFS prices, demographics, and large projection errors. McWilliams, Chen, and Chernew have also raised concerns about ACO benchmark ratchet effects in outlining a blueprint for ACO benchmark changes in a recent white paper.[372]

Addressing these ratchet effects may also improve the experience of beneficiaries assigned to ACOs. ACOs are incentivized through sharing savings

[370] *https://www.medpac.gov/wp-content/uploads/2021/09/aco-benchmarks-medpac-nov-2021.pdf*; *https://www.medpac.gov/wp-content/uploads/2021/11/november21_medpac_transcript_sec.pdf*.

[371] *https://www.medpac.gov/wp-content/uploads/2021/10/APM-MedPAC-Jan22.pdf*; *https://www.medpac.gov/wp-content/uploads/2021/10/Jan22_MedPAC_Meeting_Transcript_SEC.pdf*.

[372] *https://www.brookings.edu/research/from-vision-to-design-in-advancing-medicare-payment-reform-a-blueprint-for-population-based-payments/*.

to provide services to beneficiaries that may not have been traditionally reimbursed under Medicare FFS. However, because any costs incurred in providing such services are not reflected in observed FFS spending but may help to reduce that spending and thus result in the ratcheting down of future benchmarks, incentives to provide such services are diminished. As we stated in the proposed rule, we anticipate that addressing these ratchet effects under the current benchmarking methodology will allow ACOs and their ACO participants to provide additional services, and therefore, improve the beneficiary experience in ACOs.

We have used a variety of approaches to mitigate the effect of ACO performance on their historical benchmarks, as described in earlier rulemaking and as summarized in section III.G.5. of the proposed rule, including: adjusting the ACO's rebased benchmark to account for savings generated by the ACO in its prior agreement period (§ 425.603(b)(2), June 2015 final rule, 80 FR 32788 through 32791); subsequently replacing the prior savings adjustment with an approach that incorporated factors based on regional FFS expenditures in resetting the ACO's benchmark through a regional adjustment (§ 425.603(c) through (f), June 2016 final rule, 81 FR 37953 through 37991); in addition, more recent modifications to use blended national-regional growth factors to trend and update the ACO's historical benchmark help ameliorate the ACO-specific ratchet effect caused by the use of regional trends to update benchmarks in areas where ACOs contribute substantially to regional trends (§ 425.601(a)(5), (b), December 2018 final rule, 83 FR 68005 through 68030).

In particular, the regional adjustment has reduced the impact of rebasing by partially decoupling an ACO's benchmark from its prior savings performance. Importantly, this adjustment also begins to converge benchmarks toward a consistent basis within a region, which we believe is an important objective for creating equitable payment within a market that rewards ACOs for relative efficiency. However, recent experience suggests that the regional adjustment may have led to selective participation, with 80–87 percent of ACOs subject to a regional adjustment having spending below their region for PYs 2017 through 2020, as shown in Table 82.[373]

TABLE 82: Regional Adjustments to Benchmarks, All ACOs Subject to Regional Adjustment

All ACOs Subject to Regional Adjustment				
PY	Number of ACOs Subject to Regional Adjustment	Number of ACOs with Positive Regional Adjustment	Number of ACOs with Negative Regional Adjustment	Percent of ACOs with Positive Regional Adjustment
2017	73	59	14	80.8%
2018	136	113	23	83.1%
2019	133	107	26	80.5%
2019A*	205	178	27	86.8%
2020	412	357	55	86.7%

* PY2019A refers to the 6-month performance year from July 1, 2019, to December 31, 2019.

Furthermore, as shown in Table 83, selective participation effects are stronger for ACOs subject to downside risk, with 92–100 percent of ACOs having positive regional adjustments. This suggests that as ACOs are required to participate under performance-based risk and higher levels of downside risk, these selective participation effects may continue to grow. Setting aside the net costs to the Trust Funds from subsidizing participation by ACOs with spending already below their region, the chief concern with this pattern of participation under the current methodology is that the providers/suppliers with the greatest savings potential (those with high spending relative to their region) have fewer incentives to participate.

TABLE 83: Regional Adjustments to Benchmarks, ACOs in Two-sided Risk with Regional Adjustment

Two-sided Risk ACOs & Regional Adjustment				
PY	Number of ACOs Subject to Regional Adjustment	Number of ACOs with Positive Regional Adjustment	Number of ACOs with Negative Regional Adjustment	Percent of ACOs with Positive Regional Adjustment
2017	6	6	0	100.0%
2018	25	24	1	96.0%
2019	26	24	2	92.3%
2019A	97	93	4	95.9%
2020	176	168	8	95.5%

[373] *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.*

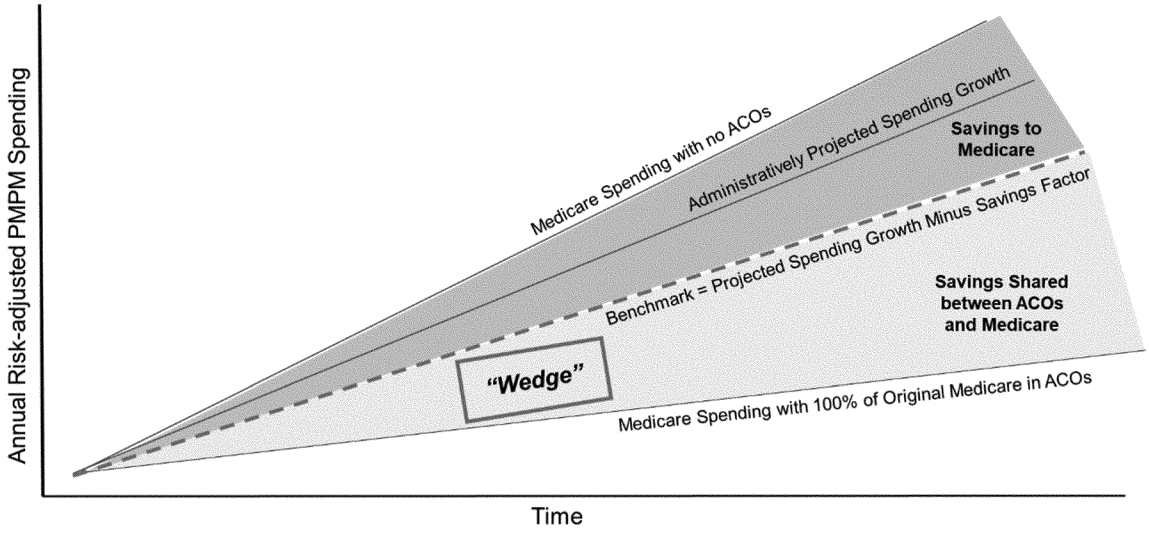
In the CY 2023 PFS proposed rule, we explained that through the proposed benchmarking changes discussed in section III.G.5. of the proposed rule, we were seeking to more immediately address certain ratchet effects and features within the existing benchmarking methodology that result in selective participation. Specifically, we noted that the proposals to incorporate a prior savings adjustment, mitigate the impact of the negative regional adjustment, and to modify the benchmark update to incorporate a prospective, external factor (ACPT) were intended to address these dynamics. In section III.G.7 of the proposed rule, we sought comment on broader changes to the benchmarking methodology that may be needed to further strengthen incentives for providers and suppliers to participate in the Shared Savings Program and generate savings while preserving a mechanism for convergence to a consistent regional benchmarking approach that does not elicit selective participation.

b. Administratively-Established Benchmarks as a Potential Solution To Address Benchmarking Concerns

In section III.G.7.b. of the CY 2023 PFS proposed rule, we sought comment on a direction for future benchmarking that is designed to create a sustainable pathway for long term program savings for both ACOs and CMS and to address interested parties' concerns around ratcheting. We included an overview of and discussed details of key components of this potential approach.

This approach involves separating benchmarking update factors from realized FFS expenditure growth through the implementation of a prospective, administratively set annual growth rate to update benchmarks. Under this approach, benchmarks would be allowed to rise above realized FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to participate and achieve savings. Over time, use of this administratively set growth rate would allow for a wedge to accrue between average benchmarks and realized spending reductions, offering greater and more sustainable savings opportunities over the long-term for both Medicare and ACOs. Importantly, average benchmark growth would only exceed realized FFS spending growth to the extent that ACOs reduce spending, such that benchmarks remain at or below FFS spending levels projected in the absence of ACO participation. A graphic depiction of administratively-established benchmarking is provided in Figure 3.

FIGURE 3: Illustrative Example of Administratively-Established Benchmarking Approach



We explained that in concert with shifting from a benchmark update based on observed, or realized, FFS expenditure growth to a prospectively set trend that does not ratchet benchmarks downward as ACOs slow observed FFS expenditure growth, we are considering approaches that would minimize rebasing effects between agreement periods.

An administratively set benchmarking approach also offers a path for converging benchmarks gradually towards a common risk-adjusted rate in each region, which we anticipate would mitigate selective participation and improve the savings potential of the program. Allowing benchmarks to remain above observed FFS spending as ACOs lower spending also allows convergence of benchmarks to a regional rate that is above average regional FFS spending. Accordingly, convergence would not require ACOs operating in the same region to outcompete each other to accrue savings and should not discourage participation by ACOs with above average observed spending to the same extent that they are discouraged under the present methodology. As long as ACOs are generating savings collectively, this approach would allow all ACOs a chance to earn shared savings while reducing overall spending relative to projections and protecting the Trust Funds. In addition, benchmarks that exceed FFS spending would give ACOs flexibility to meet beneficiary needs through alternative modes of care such as virtual care or care management programs that have not traditionally been reimbursed under FFS.

We further explained our belief that through the design of this approach, CMS could address the selective participation effects that currently discourage participation by ACOs with higher spending compared to their

regional services area. For example, we noted that we are considering an approach that would remove the negative regional adjustment to ACO historical benchmarks. This approach would mean that an ACO with spending above its regional average would receive a historical benchmark set at the ACO's average historical FFS expenditures, rather than below its historical spending levels due to the negative regional adjustment.

We also stated that we envision such an approach would ultimately generate sufficient spending reductions for higher spending providers and suppliers such that CMS could consider a further modified benchmarking methodology under which ACOs' benchmarks would be calculated using a regionally consistent baseline. This longer-term option was discussed in section III.G.7.d. of the proposed rule. To maintain the divergence between benchmarks and realized FFS expenditures, regional baselines would be set to incorporate accrued FFS expenditure reductions relative to projected growth, rather than setting regional baselines at average FFS spending, which would effectively claw back the accrued savings. We noted that we consider regionally consistent benchmarks to be an important objective for the longer-term sustainability of the Shared Savings Program in that they would create equitable payment within a market by rewarding ACOs for their relative efficiency. Such an approach could also reduce complexity relative to both the current methodology (including the proposed changes described in section III.G.5. of the proposed rule) and the administratively established benchmark methodology used to generate convergence.

We invited comments on these concepts and on the design of an administratively established benchmarking methodology. We welcomed comments on the stages for implementing such an approach within the Shared Savings Program, particularly on an initial convergence phase and a post-convergence phase, and any other considerations related to this approach that we had not addressed in the proposed rule. We noted that any such modifications to the benchmarking methodology would need to be adopted through notice and comment rulemaking.

As we explained in the comment solicitation in the proposed rule, we are continuing to consider the financial impact of this modified approach and are also considering other modifications to the design of the Shared Savings Program that may be needed along with an administratively established benchmarking methodology, including potential changes to the program's participation options and financial models (level of risk and potential reward). We sought comment on any additional modifications to the design of the Shared Savings Program that should be considered in conjunction with administratively set benchmarks.

Lastly, we noted that a number of the features of an administratively established benchmarking methodology diverge from the benchmarking requirements under section 1899(d)(1)(B)(ii) of the Act and would require the use of our authority under section 1899(i)(3) of the Act. Under section 1899(i)(3) of the Act, in order to use a payment model other than the payment model described in section 1899(d) of the Act, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. Accordingly, we also sought comment on the extent to which the use of administratively set benchmarks might have the potential to improve the quality and efficiency of care furnished to Medicare beneficiaries and any anticipated impact on Medicare expenditures. We noted that we would consider the information submitted as part of any determination of whether to propose in future rulemaking to implement aspects of an administratively-established benchmarking methodology in the Shared Savings Program.

c. Establishing an Administrative Benchmark Update Factor

(1) Overview

As we explained in the comment solicitation in the proposed rule, under the administratively-established benchmarking concept, we would continue to utilize an ACO's historical FFS expenditures to establish the ACO's historical benchmark. However, we would modify the existing methodology to fully remove negative regional adjustments to the benchmark. We noted that we would otherwise retain much of the existing methodology for calculating the historical benchmark, including, if finalized, the proposed changes detailed in section III.G.5. of the proposed rule.

When setting the historical benchmark, we would continue to calculate the annualized and truncated per capita expenditures for beneficiaries who would have been assigned to the ACO using the 3 most recent years prior to the start of the agreement period for each of the four Medicare enrollment types. We would then trend the BY1 and BY2 expenditures forward to BY3, using the existing blend of national and regional FFS expenditure growth rates, adjust for health risk using the CMS–HCC model, and apply benchmark year weights to the trended, risk-adjusted expenditures for each Medicare enrollment type. The benchmark year weights would remain as follows: for new ACOs, BY1 (10 percent), BY2 (30 percent), BY3 (60 percent), and for ACOs in their second or subsequent agreement period, each benchmark year is weighted equally.

As described in the comment solicitation, we would apply an alternative approach to annually updating the ACO's historical benchmark, using an OACT-projected ACPT factor, and applying a discount to the benchmark update to support savings to the Medicare program; the discount factor would vary based on the ACO's regional efficiency to converge benchmarks gradually between ACOs with higher and lower spending compared to their regions. We also further explained that with the use of a discount factor, we would no longer apply a negative regional adjustment. We also provided an overview of the steps for the calculation for the administratively-established benchmark update factor.

(2) Use of Accountable Care Prospective Trend in the Benchmark Update

As explained in the proposed rule, we are considering an approach that would transition from a three-way blend between the prospective ACPT and retrospectively determined regional and national growth rates (as described in section III.G.5.c. of the proposed rule) to an entirely prospectively set trend. This approach would further decouple benchmark updates from growth in realized FFS expenditures, thereby strengthening incentives for ACOs to participate in the Shared Savings Program and achieve savings.

OACT annually develops and publishes United States Per Capita Cost (USPCC) growth projections for Medicare spending. As described in section III.G.5.c. of the proposed rule, under the three-way blended update factor OACT would calculate an ACPT, based on a modification of the existing USPCC growth projections used annually for establishing Medicare Advantage rates. However, as discussed in the proposed rule, we envision that an ACPT, with some additional modifications as described below, would serve as the core component of

the administratively set benchmark update under the potential longer-term approach.

As we explained in the comment solicitation in the proposed rule, we are considering how to calculate and apply the ACPT in a manner that maintains a consistent national benchmark update trend across ACOs for a given performance year, independent of when the ACO's agreement period began. We are considering an approach under which we would establish an ACPT every 5 years which would apply during that 5-year window. For example, if we were to establish an average annual trend for the years 2025 through 2029, we would then calculate a new average annual trend for the years 2030 through 2034, then for 2035 through 2039, and so on for each subsequent period.[374] An ACO's update factor for a given performance year would be derived from the average annual trend established for the 5-year window that includes the applicable performance year.

For example, an ACO beginning its 5-year agreement period in 2025 would have a single update factor trend for all performance years under the agreement period. For illustration, Table V.D1 from the 2021 Medicare Trustees Report [375] projects overall per capita spending growth for Medicare Parts A and B at an annualized rate of 5.1 percent from a 2024 base year to what would be a fifth performance year in 2029. Note that this projected spending growth serves as an illustrative proxy for what a corresponding ACPT might show, though it is based on a different methodology that is not customized to the mix of spending categories included in Shared Savings Program benchmark calculations. In contrast, an ACO beginning its 5-year agreement period in 2027 would have one trend rate for its first 3 performance years (2027, 2028, and 2029) and another for its last 2 performance years (2030 and 2031), as the update factor would be reset every 5 calendar years. This update factor would not change for the duration of the 5-year period in response to changes to the OACT projection, with the exception of an adjustment for changes to the price and demographic components of the ACPT trend, or to account for extreme and uncontrollable circumstances. We noted that we would plan to continue to apply the update factor as a flat dollar, risk-adjusted amount, consistent with the methodology for the use of ACPT in a three-way blend described in section III.G.5.c. of the proposed rule.

We also noted that we are considering further refinements to calculating the ACPT as part of a longer-term approach for updating benchmarks using entirely administratively set update factors. For example, we are considering maintaining separate projections within the ACPT for price growth, volume/intensity growth, and demographic factors (with potential exceptions for certain service types such as Part B drugs, which are not currently projected using disaggregated growth assumptions). This disaggregation of these factors could be utilized in ACO benchmark updates (for service types where possible), as ACOs are anticipated to have impacts on volume/intensity growth but have minimal impact on price growth and demographic factors. Therefore, the ACPT volume-intensity trend would be held constant for the duration of the agreement period, but retrospective adjustments could be made annually to account for any differences between projected and actual price growth and demographic factors. This would mitigate the effects of unexpected changes in assignable beneficiary demographics, as well as of inflationary pressures or other price changes on ACOs benchmarks. We would also incorporate adjustments to the ACPT to account for changes in relative price levels across counties, as has been done in other ACO initiatives that use national trend projections, such as the Next Generation ACO Model.

By incorporating annual adjustments for changes in price and demographics, we expect that the administrative growth projection will exceed the observed volume/intensity growth, as ACOs generate savings relative to the growth projection. However, we are considering adding potential guardrails to the administrative growth projection in early years to ensure that forecasting error does not unfairly penalize ACOs or discourage participation. One option would be to phase-in the administrative trend over the first 5 years, increasing the weighting of the administrative trend component of the update in the three-way blend calculation from 33 percent in PY1 to 50 percent in PY2, 75 percent in PY3, and 100 percent thereafter. Another option would be to limit the contribution of forecasting error to savings and loss calculations during the first 5 years of the new methodology. For example, a floor could be set such that the national mean benchmark could not fall more than 2 percent below national mean FFS spending. We noted that CMS may consider applying either or both of these guardrail options as part of a prospectively-set update factor.

In section III.G.5.c. of the proposed rule, we proposed to adopt a prior savings adjustment with a 50 percent scaling factor for renewing and re-entering ACOs. In the comment solicitation, we explained that this proposed change together with the changes to the benchmark update described in the comment solicitation would act to limit the impact of an ACO's performance on its own benchmark. We also noted that increasing the 50 percent scaling factor for prior savings adjustments could be considered to further limit the impact of rebasing. The prospective update factor would remove this link within an agreement period and the prior savings adjustment would mitigate the impact of rebasing between agreement periods. We further explained that after benchmarks converge to a regional baseline (as discussed in section III.G.7.d. of the proposed rule), the link between an ACO's savings and its subsequent benchmark would be severed completely. We stated that we anticipated these changes would create and improve long-term incentives for ACOs to generate savings.

In the comment solicitation, we noted that we would also need to establish a process for considering additional factors when recalculating the ACPT prospective update factor every 5 years. We explained that one factor may be the size of the accrued wedge between benchmarks and realized FFS spending. It is vital that ACOs are permitted to retain savings in subsequent agreement periods for there to be a strong incentive to generate savings. Allowing a permanent wedge between benchmarks and FFS spending is also vital to giving ACOs flexibility to meet patient needs by providing care that has been traditionally unreimbursed under FFS, such as care management programs or services addressing social needs. Should this wedge grow excessive, however, the update trend may need to be slowed to recover more savings for the Medicare program and its beneficiaries. Over time, updated OACT ACPT projections would also come to reflect the impact of ACOs on spending, and therefore, we may need to use other external indices as factors in determining the preset benchmark update factor to ensure that

[374] ACPT 5-year growth projection trends include different growth rates for each year within the 5-year projection. However, for the purposes of simplicity, the overall average annualized growth rate over the 5-year period would be utilized, such that the growth rate is constant over each of the 5 years. Price and demographic projections would be considered at an annual level for the purposes of the adjustment for forecasting error.

[375] *https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf.*

ACOs continue to retain accrued savings.

We sought comment on these considerations for calculating an ACPT to be used as an administratively set benchmark update factor. We sought comment on the 5-year intervals for establishing an ACPT, and alternative approaches that would tie the ACPT to an ACO's agreement period. We also sought comment on approaches to accounting for price growth and demographic factors versus volume/intensity and considerations for guardrails to protect against projection error. Finally, we sought comment on approaches to updating the ACPT that would ensure it does not overly reflect ACOs' collective impact on spending.

(3) Discount Factor

As we explained in the comment solicitation, under the approach we are considering for implementing a common risk-adjusted regional benchmark (described in section III.G.7.d. of the proposed rule) that encourages participation by both historically efficient (spending below regional average) and inefficient (spending above regional average) ACOs, we believe there would need to be a period of gradual convergence in spending between efficient and inefficient ACOs, while allowing benchmarks for both to remain above realized FFS spending as ACOs generate savings. Therefore, we sought comment on the approach of subtracting a modest annual discount factor from the fixed 5-year ACPT growth trend based on the relative efficiency of the ACO. For example, if the projected ACPT trend was 5.1 percent annual growth, an ACO with a 0.2 percent discount factor would have a benchmark update factor based on a 4.9 percent annual growth rate (5.1 percent minus 0.2 percent). Overall, these discount factors would be intended to provide realistic targets that encourage participation by ACOs and providers and suppliers with spending above their regional average. Once in the program, these ACOs and providers and suppliers would have incentives to generate savings, and thus, gradually converge their spending more in line with historically lower spending ACOs.

We noted that to determine the discount that would be applied to an ACO's update factor, we would calculate a measure of the ACO's regional efficiency. We would compare the ACO's historical spending (the weighted-average spending for the ACO in benchmark year 3 to a regional benchmark (the weighted-average regional FFS expenditures for benchmark year 3). This calculation would be similar to the approach used to determine the difference between the average per capita expenditures for the ACO's regional service area, and the average per capita amount of the ACO's historical benchmark under § 425.601(a)(8)(ii)(A). The discount would vary according to the regional efficiency of each participating ACO but, importantly, would not grow if an ACO successfully lowers spending (as it would under the current regional adjustment methodology). Sample discount factors are shown in Table 84. If an ACO's historical spending was greater than its regional benchmark, we would apply a discount to the amount of the benchmark update, scaled such that a larger discount is applied for ACOs with increasingly higher spending (less efficient) compared to their regional benchmark. No discount would be applied to the update amount for ACOs with spending 2 percent or more below their regional benchmark. Applying larger discount factors to less efficient ACOs would converge benchmarks towards regionally consistent levels, allowing CMS to remove negative regional adjustments as discussed in section III.G.7.c.(4) of the proposed rule while still driving convergence.

TABLE 84: Sample Discount Factors for ACOs with Varying Regional Efficiency

Regional Efficiency	Discount Factor
ACO historical spending > 1.05 * regional benchmark	0.333%
1.00 * regional benchmark < ACO historical spending <= 1.05 * regional benchmark	0.200%
0.98 * regional benchmark < ACO historical spending <= 1.00 * regional benchmark	0.100%
ACO historical spending <= 0.98 * regional benchmark	0.000%

As we stated in the comment solicitation, we have observed that ACOs make significant changes in composition of ACO participant TINs during an agreement period, by adding and removing ACO participants. To account for ACO participant TIN changes, we would recalculate the ACO's discount factor for each performance year of the agreement period based on its regional efficiency using the composition of its ACO participant TINs for the applicable performance year. That is, we would use the ACO's certified ACO participant list for the performance year to determine the ACO's historical spending based on expenditures for the beneficiaries who would have been assigned to the ACO in benchmark year 3 and determine the ACO's regional service area for calculating the ACO's regional benchmark, and thus its regional efficiency.

We sought comment on this approach for calculating and applying a discount factor in determining the amount of an ACO's benchmark update. We sought comment on the intervals of the discount we described, and alternative approaches such as use of a sliding scale in determining the discount amount. We also sought comment on approaches to ensuring the discount is reflective of the ACO's regional efficiency, including the approach of recalculating the discount factor to reflect changes in an ACO's regional efficiency as a result of changes in the ACO's composition during its agreement period.

(4) Removal of Negative Regional Adjustments to the Benchmark

In accordance with § 425.601(a)(8), we currently apply a regional adjustment in establishing the ACO's historical benchmark, which is equal to a percentage of the difference between the average per capita amount of expenditures for the ACO's regional service area for BY3 and the ACO's historical benchmark.

In the comment solicitation, we explained that under the administratively-established benchmarking concept we would no longer apply negative regional adjustments to the benchmark, although positive regional adjustments would remain. Under this approach, ACOs with higher than average historical

spending would begin with a benchmark calculated solely using their historical experience. This would encourage providers and suppliers with higher historical spending relative to their region to participate in the Shared Savings Program, while continuing to reward ACOs with lower-than-average historical spending for their efficiency relative to their region. We explained that this approach would build on the policies proposed in section III.G.5.c.(5) of the proposed rule to mitigate the impact of the negative regional adjustment on ACOs, particularly those caring for high-risk populations.

As discussed in the comment solicitation in the proposed rule, we are also considering approaches for addressing a potential concern that efficient ACOs would be disincentivized from adding less efficient providers and suppliers as ACO participants because it would reduce their regional adjustment. One approach would be to scale an ACO's initial, larger positive regional adjustment based on the overlap in beneficiaries that would have been aligned to the ACO using the ACO's initial ACO participant list and its updated ACO participant list. In this way, an ACO with spending below its regional average would retain its advantage conferred by the regional efficiency adjustment under its initial ACO participant list (to the extent it retains those ACO participants) while also being able to pursue the expanded savings opportunity afforded by the new benchmarking approach by adding less efficient providers and suppliers to its ACO participant list.

We sought comment on this approach, and considerations related to removing the negative regional adjustment in establishing the ACO's historical benchmark under an administratively-established benchmark approach. We also sought comment on considerations for limiting disincentives for efficient ACOs to add less efficient providers and suppliers.

(5) Detailed Administratively-Established Benchmark Update Calculation

The following is a step-by-step example of the administratively-established benchmark update calculation on which we sought comment:

- *Step 1:* Calculate the historical benchmark according to the existing Shared Savings Program benchmarking methodology (including, if finalized, the proposed changes detailed in section III.G.5. of the proposed rule), without applying negative regional adjustments.
- *Step 2:* Risk-adjust the historical benchmark to account for changes in severity and case mix between BY3 and the performance year for each enrollment type.
- *Step 3:* Apply the update factor to the risk-adjusted historical benchmark for each enrollment type, calculated as follows:

++ Start with the overall OACT-projected Shared Savings Program ACPT 5-year projected trend [376] applicable for the ACO based on the start of its agreement period and the performance year for each enrollment type.[377] The update rate over an agreement period may include ACPT projected trends from more than one 5-year period if the ACO's agreement period does not align with the 5-year cycle for ACPT calculation.

++ Apply the average projected trend based on the number of years between BY3 and the performance year.

++ Apply any retrospective adjustments to the trend based on divergence between the price and demographic components of the ACPT projected trend and observed price trends and demographic changes. This retrospective adjustment would be calculated annually after the end of each performance year only for the price and demographic components (no such adjustment would be made for the volume-intensity component).

++ Subtract the relevant discount factor (as per the examples in Table 84, based on the regional efficiency of the ACO in BY3) from the adjusted trend for each year between BY3 and the performance year to determine the ACO's trend percentage.

++ Multiply the ACO's trend percentage by the average national ACPT value for assignment eligible beneficiaries (adjusted to reflect the ACO's relative risk in each eligibility category) to determine the flat dollar update amount.

++ Apply any guardrails as described in section III.G.7.c.(2) of the proposed rule.

++ Add the flat dollar update amount to the ACO's risk-adjusted historical benchmark for the applicable enrollment type.

- *Step 4:* Calculate a single per capita benchmark amount by taking a weighted average across each enrollment type.

d. Convergence to Regional Benchmarks; Post-Convergence Phase

As we explained in the proposed rule, this administratively-established benchmark approach would be partially intended to drive ACOs towards regional spending convergence, such that the Shared Savings Program could consider further benchmarking changes under which benchmarks would be established on a regionally consistent risk-adjusted basis across ACOs in the same area. This post-convergence phase would completely eliminate ratcheting effects by removing rebasing and would also decouple benchmarks from an ACO's historical spending, thereby creating a sustainable benchmarking approach that would support high ACO participation levels and reward ACOs for increased efficiency.

We noted that regionally consistent benchmarking has precedent in other CMS models and programs. Medicare Advantage benchmarks are established using beneficiary risk scores and the Medicare Advantage Ratebook of county risk-standardized benchmarks, as described in §§ 422.258 and 422.306. In the ACO REACH Model,[378] the baseline component of the benchmark will be calculated either entirely or in part using a rate book with county benchmark expenditures and beneficiary risk scores. The Shared Savings Program calculates risk-adjusted county FFS expenditures for individual calendar years using a comparable approach, as discussed in section III.G.5.d. of the proposed rule.

Under the administratively-established benchmark approach under consideration, ACO benchmarks in this post-convergence phase would be calculated based on a rate book of risk-standardized average per capita rates at the county level and beneficiary level risk scores. Crucially, the initial per capita county rates would reflect the average benchmark levels in the county, inclusive of the accrued wedge between benchmarks and realized spending, as opposed to reflecting average expenditures. An ACO's benchmark would be the product of its average beneficiary risk score, weighted by assigned beneficiary months, and its

[376] As described in section III.G.5.c. of the proposed rule, we proposed that OACT would develop a Shared Savings Program-specific ACPT to incorporate into the update factor calculation. This projected trend would vary from the USPCC projections designed for MA payment purposes in that adjustments would be made to make it applicable to ACO spending calculations, including adding back hospice and removing IME, DSH, and uncompensated care payments (as is already done for benchmarking under the Global and Professional Direct Contracting Model and will continue when the model transitions to the redesigned ACO REACH Model on January 1, 2023).

[377] The ACPT would include trends for Aged & Disabled (A&D) and End Stage Renal Disease (ESRD) beneficiaries. The Aged & Disabled trend would apply for the disabled, aged/dual eligible, aged/non-dual eligible enrollment types.

[378] See the ACO REACH Request for Applications at *https://innovation.cms.gov/media/document/aco-reach-rfa.*

average regional benchmark rate, calculated as the weighted average of the county rates, weighted by the number of months of experience contributed by assigned beneficiaries residing in each county. The administratively set update factor would continue to be applied to ACO benchmarks in the post-convergence phase to determine average benchmark growth. As an example, say an ACO has assigned beneficiaries that reside entirely in two counties (County A and County B), with 50 percent of the assigned beneficiary population in each county. If the rate book rate for County A is $1,300 per beneficiary per month (PBPM) and the rate for County B is $1,100 PBPM, then the ACO's average regional benchmark rate would be $1,200 PBPM. If the ACO's assigned beneficiaries have an average risk score of 1.5, then the risk-adjusted benchmark would be $1,800 PBPM, pending application of the update factor. This regionally consistent benchmarking approach would likely involve an annual determination of county rates tied to the publication of the rate book.

As we explained in the comment solicitation in the proposed rule, the convergence phase would be intended to converge benchmarks toward some level above realized spending, but below predicted spending absent ACOs, assuming ACOs generate savings. We also noted that we are considering several approaches for developing county per capita rates. One method under consideration would be to calculate risk-standardized average per capita expenditures and apply a scalar adjustment that accounts for prior savings or the accrued wedge. Alternatively, another approach could involve developing county rates by calculating a weighted average benchmark across ACO-assigned and unassigned beneficiary populations in the county. In either case, we would continue to use an administratively-established factor to update county rates over time; however, we anticipate the need for a process to monitor the size of the wedge within a region (the risk-adjusted difference between the benchmark and FFS spending) and to establish bounds that restrict regional rates from exceeding a certain level above FFS spending.

We further explained that we anticipate that the convergence phase would last between 5–10 years, depending on participation rates and the pace of spending convergence within regions. We noted that we expect ACO spending will converge within regions under the changes described in the comment solicitation because the incentives for providers and suppliers with high spending for their region to participate in ACOs and lower spending would be much stronger, and the ACOs in which those providers and suppliers participate would have strong savings potential. Convergence in risk-adjusted spending may also be fostered by improvements to the risk adjustment methodology. Convergence in spending would not have to be complete, however, to transition to a post-convergence phase in which benchmarks are set based on a common regional rate that is risk-adjusted for an ACO's aligned population characteristics. We noted that we would expect some continued variation in ACO spending, but the convergence to regional rates would still provide all ACOs an opportunity to lower spending below their benchmarks. Still, we acknowledged that the timing for transitioning to the post-convergence phase is important, as it may cause a significant shift in benchmarks for many ACOs as the baseline component shifts from population-specific to regionally consistent. In order to maintain participation, it would be essential that this phase does not occur until a sufficient portion of providers are below the administratively projected regional benchmark.

If the convergence phase takes longer than 5 years, we noted that we would need to address the potential rebasing effects for ACOs renewing for subsequent agreement periods under the new benchmarking approach. One approach would be to completely eliminate rebasing and use the historical benchmark period from an ACO's first agreement period under the new benchmarking approach for subsequent agreement periods until the post-convergence phase. This approach would most directly eliminate rebasing effects but would risk weakening the accuracy of the historical baseline expenditures as the number of years separating the baseline period and performance year increases. In prior rulemaking, we have acknowledged concerns about an approach that depends on older historical data in benchmark calculations (see, for example, February 2016 proposed rule, 81 FR 5832 through 5834, 5865 and 5866), including operational complications and potential biases that result from use of older historical data when the ACO's composition of providers and suppliers changes over time. These complicating circumstances may become more pronounced with a longer convergence period and a larger gap between the historical benchmark and performance period. An alternative approach would be to continue to use a baseline period of 3 years directly proceeding the start of the agreement period, but with ACO-specific adjustments to limit rebasing effects. As an example of this type of ACO-specific adjustment, we noted that we are considering approaches that would build on the proposal, discussed in section III.G.5.c. of the proposed rule, to add prior ACO savings into subsequent benchmarks, with weighting to address changes in ACO composition.

We sought comment on—

- Considerations for the design of a regionally consistent benchmarking approach, including how to set fair and accurate risk-standardized benchmarks, the process for annual updates to regional rates, and how to distinguish between enrollment types.
- Considerations for the required conditions and timing for reaching this post-convergence phase with the use of regionally consistent benchmarks, as well as incentives to promote ACO spending convergence within a region.
- Approaches to addressing rebasing effects for renewing and re-entering ACOs in subsequent agreement periods during the convergence phase.
- Considerations for converging to nationally consistent spending versus regionally consistent spending.

The following is a summary of the public comments received in response to the Comment Solicitation on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program and our responses:

Comment: The vast majority of commenters expressed support for the concept of utilizing a prospective, administratively set benchmark in the Medicare Shared Savings Program. These commenters expressed the need to address the ratchet effect, through which ACOs' benchmarks are impacted by the individual and collective savings generated by ACOs and noted that administratively-set benchmarks were an appropriate mechanism to address these effects. Several commenters noted that an administrative benchmarking approach would be a necessary step to achieve CMS' stated goals of substantial growth in the number of Medicare beneficiaries under accountable care relationships.

In the context of support for the overall approach, many commenters shared considerations for implementation of an administrative benchmarking approach. Additionally, numerous commenters urged CMS to engage with stakeholders in the

development of these new benchmarking methodologies.

Several commenters expressed concerns that a national administratively-set benchmark trend would not adequately account for regional variation in spending growth trends. These commenters urged CMS to consider regional adjustments to the administratively-set benchmark trends. One commenter recommended implementing a glidepath to administrative benchmarks to mitigate short-term windfall gains/losses due to regional spending variations or forecasting errors.

Commenters expressed differing views on the timing of a transition to an administrative benchmarking methodology. Several commenters expressed urgency in implementing this benchmarking methodology, citing the growing impact of the ratchet effect and a desire to grow the Medicare Shared Savings Program. Other commenters noted that while this administrative benchmarking methodology was an appropriate long-term goal, there was no urgent need to move to administrative benchmarks, noting that CMS is still able to set Medicare Advantage benchmarks based on FFS spending data in regions with high Medicare Advantage penetration. Two commenters specifically questioned the timing of introducing administrative benchmarks given volatility introduced by the COVID–19 pandemic.

Multiple commenters specifically commented on the possibility of applying a variable discount rate to the benchmark trend according to an ACO's risk-adjusted spending relative to its region. Most of these commenters supported this approach, stating that variable discount factors would allow for gradual convergence to a common regional benchmark while not discouraging ACO participation. One commenter was opposed, stating that discount factors were not appropriate for the Shared Savings Program.

Multiple commenters expressed support for the concept of allowing for retrospective adjustments to an administrative benchmark based on observed changes in regional prices and demographics only. These commenters noted such adjustments may address concerns about the accuracy of an administratively set benchmark. No commenters expressed concerns about such price adjustments.

Many commenters indicated that the development of a wedge in which the administratively-set benchmark remains at a level above observed FFS spending would be critical to the success of this benchmarking approach. Some of these commenters expressed concern that this wedge may be reduced in the future, either through future rulemaking or congressional action. These commenters urged CMS to provide assurances that an administrative benchmarking approach would remain stable over time and provide transparency into what would lead to changes in the benchmark calculation.

Several commenters encouraged CMS to consider how an administrative benchmarking approach would interact with the Medicare Advantage program. These commenters urged CMS to utilize administrative benchmarking to achieve ''parity'' between FFS and Medicare Advantage reimbursement, but did not specify what this would entail. One commenter suggested that CMS consider utilizing price trends in Medicare Advantage in calculating the administrative benchmark.

One commenter expressed concern that an administrative benchmark based on the USPCC may artificially inflate benchmarks, given this commenter's assertion that the USPCC has systemically overestimated spending in the past. This commenter also encouraged CMS to remove shared savings payments from the calculation of any administrative benchmark trend.

One commenter urged CMS to consider whether legislative changes to the Shared Savings Program's statutory authority would be needed to allow for an administrative benchmarking approach, and whether CMS would be able to set benchmarks based on factors other than cost trends in FFS Medicare under the existing authority.

Another commenter suggested that a separate benchmarking approach would be required for very high cost, high needs populations, and questioned whether converging to a common regional risk-adjusted benchmark would be possible in this patient population. Two commenters encouraged CMS to consider alternative payment methodologies such as a capitated primary care payment in conjunction with an administrative benchmarking approach. Additionally, while not in response to the administrative benchmarking request for information but the proposed rule generally, one commenter cited the recent National Academies of Sciences, Engineering, and Medicine (NASEM) report [379] and suggested CMS use the authority in section 1899(i) of the Act to include a hybrid payment—part fee-for-service and part prospective capitated payment—in the Shared Savings Program to better support primary care.

Response: We appreciate these thoughtful comments in response to our comment solicitation on incorporating an administrative benchmarking methodology in the Shared Savings Program. We will consider these comments in the development of policies for future rulemaking. We note that some of these comments are similar to those received in response to our proposal to incorporate the ACPT into the Shared Savings Program. In response to both the proposal to incorporate the ACPT into the Shared Savings Program and the comment solicitation on incorporating an administrative benchmarking approach, commenters expressed overall support for the ACPT, but shared concerns that basing the ACPT solely on national spending trends may not adequately account for geographic variation in spending trends that are outside of ACOs' control. Commenters recommended applying regional adjustments to the ACPT. However, comments received in response to the comment solicitation also addressed the use of variable discount factors applied to the ACPT and convergence to a regionally consistent risk-adjusted rate. Most commenters expressed support for the use of variable discount factors as a means to drive gradual convergence to a common regional benchmark. Although these comments are outside the scope of the proposed changes to the benchmarking methodology discussed in section III.G.5.c.(3), we may consider them in the development of policies for future rulemaking. Please see section III.G.5.c.(3) of this final rule for CMS' response to comments on the proposal to incorporate the ACPT as part of a three-way blended update factor.

e. Responses to Comment Solicitation on Addressing Health Equity Through Benchmarking

In the CY 2023 PFS proposed rule (87 FR 46217 and 46218), we explained that consistent with the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985), we are committed to advancing equity in health and healthcare for all individuals and addressing inequities that exist in our policies and programs that serve as barriers to equal opportunity. The term ''equity'' is defined in E.O. 13985 as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment . . . .''

[379] *https://nap.nationalacademies.org/read/25983/chapter/1.*

Benchmarks based on historically observed spending may be inequitable to the extent that historical patterns reflect existing inequities in both access to care and the provision of care. We are interested in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. Direct increases to benchmarks for historically underserved populations would grant additional financial resources to health care providers accountable for the care of these populations, and may work to offset historical patterns of underspending that influence benchmark calculation. Furthermore, setting payment in excess of current spending for groups experiencing disadvantage would incentivize ACOs to attract those groups with care and enhancements valued by these beneficiaries. Pairing such benchmark changes with monitoring of use of resources, quality, and outcomes can ensure that increased benchmarks are being used to address care inequities, rather than solely generating increased shared savings potential for ACOs benefitting from positive benchmark adjustments.

In the proposed rule, we explained that the redesigned ACO REACH Model [380] will be implementing a benchmark adjustment to address historical health inequities within CMS ACO initiatives, with the intent of incentivizing ACOs to seek out and form relationships with historically underserved beneficiaries. The ACO REACH benchmark adjustment is calculated at the beneficiary level, and provides for a $30 per beneficiary per month (PBPM) increase to an ACO's benchmark for each assigned beneficiary classified as being in the top decile of underserved beneficiaries across all beneficiaries in the ACO REACH Model. The adjustment is designed in a budget neutral manner, in which benchmarks will be reduced by a smaller $6 PBPM adjustment for each assigned beneficiary classified as being in the bottom five deciles. Beneficiaries will be stratified using a composite measure that incorporates a combination of ADI (percentile score from 1–100) and Dual Medicaid Status (Medicare only vs. Full or Partial Dual Eligibility). The area-level measure (Area Deprivation Index [381]) captures local socioeconomic factors correlated with medical disparities and underservice, while the beneficiary level measure (Dual Medicaid Status) captures economic challenges directly affecting individual beneficiaries' ability to access high-quality care. Because ADI is measured as a percentile (continuous variable), while Medicaid Status is a binary metric, a simple blending of the variables would underweight the ADI. Therefore, CMS will calculate the measure by starting with the ADI for a given beneficiary's census block group of residence (scored from 0–99 based on percentile relative to the nation), and applying a 25-point increase to the score for dually eligible beneficiaries. For example, a dually eligible beneficiary residing in a census block group with an ADI in the 75th percentile would receive a score of 75 + 25, for a total of 100.

Each ACO will then receive a net benchmark adjustment based on the number of its assigned beneficiaries in each category. For example, an ACO with 100 beneficiaries scoring in the top decile and 500 beneficiaries in the bottom five deciles in a given month would receive a net neutral benchmark impact for that month [($30 PBPM × 100) − ($6 PBPM × 500) = 0].

The ACO REACH health equity benchmark adjustment addresses inequity in benchmarks calculated primarily using historical expenditures, where historical underspending for underserved beneficiaries informs benchmarks. We noted, however, that in the context of the administratively-established benchmarking approach outlined in the comment solicitation in section III.G.7.a.–d. of the proposed rule, our intent would be to converge spending to the point where benchmarks can be calculated on a regionally consistent basis, which would address equity concerns associated with entrenched historical underspending. By utilizing risk-standardized regional rates to derive benchmarks, rather than blends of historical and regional spending that can entrench inappropriately low levels of spending for populations with unmet needs, the new benchmarking approach would facilitate setting benchmarks above current levels of spending for ACOs caring for underserved populations. Such adjustments could be implemented within the estimation of the predictive model of spending used for risk adjustment (the CMS–HCC model) or in a post-estimation benchmark adjustment as in ACO REACH so that benchmarks would support optimal rather than current spending for historically marginalized groups. These adjustments would not only act to correct resource disparities but also establish incentives for ACOs to attract underserved groups with enhanced care.

We also explained that these and other approaches could be employed to preserve (if not expand) existing payment differentials that set payment higher for certain providers and suppliers. Equity-motivated benchmark adjustments could be implemented, for example, to support additional funding for safety net providers (for example, CAHs, RHCs, and FQHCs). In other cases, add-on payments, such as DSH and IME, might continue to be carved out of ACO benchmarks and performance year expenditures, as they are now. We sought comment on other policy adjustments that should be considered for benchmark setting in the post-convergence phase.

We sought comment on—

- Approaches, generally, to addressing health inequities via the benchmark methodology for the Shared Savings Program, and specifically to incentivize ACOs to serve historically underserved communities.
- Considerations for what data would need to be collected on Medicare beneficiaries and their communities (for example, need for and access to health care providers, transportation, and social services) and what factors should be considered to identify underserved communities and adjust ACO benchmarks.
- Considerations for including a health equity benchmark adjustment in the Shared Savings Program in the near term comparable to the equity adjustment being tested within the ACO REACH Model.
- Considerations for addressing health inequities in the context of the benchmarking concept outlined in the comment solicitation in section III.G.7.a.–d. of the proposed rule.
- Considerations for monitoring and program integrity tools that would track the use of any health equity benchmark adjustments for the intended purposes.
- Considerations for whether benchmark adjustments for ACOs that include CAHs, RHCs, FQHCs, and REHs as ACO participants would improve care for rural and underserved populations and increase participation by these providers and suppliers in the Medicare Shared Savings Program.

[380] See the ACO REACH Request for Applications at *https://innovation.cms.gov/media/document/aco-reach-rfa.*

[381] The University of Wisconsin Neighborhood Atlas website (*https://www.neighborhoodatlas.medicine.wisc.edu/*) Area Deprivation Index was developed by researchers at the University of Wisconsin based on a measure developed by the Health Resources and Services Administration (HRSA) over 3 decades ago. It has been adapted to the Census Block Group level and includes factors measuring income, education, employment, and housing quality, which have been linked to a number of healthcare outcomes, to rank neighborhoods by socioeconomic disadvantage.

The following is a summary of the public comments received in response to the Comment Solicitation on Addressing Health Equity Through Benchmarking and our responses:

Comment: The vast majority of commenters expressed support for exploring methodologies to address health equity via benchmarking changes. Specifically, many of these commenters noted that benchmark adjustments could be an effective tool to redirect resources to ACOs serving underserved communities.

Multiple commenters commented specifically on the health equity benchmark adjustment approach utilized in ACO REACH. Several of these commenters expressed support for using a similar methodology in implementing a health equity benchmark adjustment in the Shared Savings Program. However, other commenters expressed concern regarding the ''budget-neutral'' approach adopted in ACO REACH, whereby higher benchmarks for underserved populations were offset by lower benchmarks for other populations. These commenters noted that benchmark adjustments for underserved populations should not negatively impact benchmarks for ACOs serving other populations.

Several commenters specifically encouraged CMS to consider equity-motivated benchmark adjustments that would provide higher benchmarks to ACOs that include safety net providers, such as CAHs, FQHCs, RHCs, and REHs. One commenter suggested that benchmarks should include explicit adjustments for ACOs serving rural areas. Another commenter urged CMS to explore regulatory opportunities that would expand its authority to pay providers and suppliers differently depending on the degree of social deprivation in their community and explore obtaining authority from Congress to create additional payment streams to put these communities on a level funding basis with other communities.

One commenter expressed concerns with the potential use of the Area Deprivation Index (ADI) to identify underserved populations, and specifically noted that ADI does not incorporate race or ethnicity variables. This commenter recommended CMS consider using the Social Vulnerability Index because that index includes race as a variable which may account for the impact of structural racism on health care utilization and outcomes. Another commenter recommended that CMS encourage standardization of the collection of social determinants of health data, which could allow for more effective equity-motivated benchmark adjustments.

One commenter observed that CMS has recently rolled out many health equity related initiatives, and recommended observing the impacts of these policies, including the health equity benchmark adjustment being tested in the ACO REACH Model, prior to proposing new health equity initiatives. Another commenter suggested that any health equity motivated changes to the Shared Savings Program be considered holistically across multiple program features such as quality metrics and risk adjustment rather than focused on benchmarking alone.

Response: We appreciate these thoughtful comments in response to our comment solicitation on addressing health equity via benchmarking in the Shared Savings Program. We will consider these comments in the development of policies for future rulemaking.

H. Medicare Part B Payment for Preventive Vaccine Administration Services

1. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and its administration for the specified preventive vaccines—the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. Under sections 1833(a)(1)(B) and 1833(b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. Payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC). We note that many other preventive vaccine products, such as the shingles vaccine, are not specified for Medicare Part B coverage under section 1861(s)(10) of the Act, and are instead covered and paid for under Medicare Part D.

Section 1861(s)(10)(A) of the Act, as amended by section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), includes the COVID–19 vaccine and its administration in the same subparagraph as the influenza and pneumococcal vaccines and their administration. We implemented this change in the interim final rule with comment period titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' published in the November 6, 2020, **Federal Register** (85 FR 71142, 71145 through 71150) (hereafter referred to as ''the November 2020 IFC''). In the November 2020 IFC, we established that payments for COVID–19 vaccines and vaccine administration would be made in the same manner as payments for the influenza and pneumococcal vaccines. In section III.H.5. of this final rule, we are finalizing our proposal to permanently codify regulatory changes published in the November 2020 IFC.

2. Refinement to the Payment Amount for Preventive Vaccine Administration

a. Background for Medicare Part B Payment for Administration of Influenza, Pneumococcal, HBV Vaccines

As we discussed in the CY 2023 PFS proposed rule (87 FR 46218 through 46219), vaccine administration services described under section 1861(s)(10) of the Act are not technically valued or paid under the PFS, as they are not included within the statutory definition of physicians' services in section 1848(j)(3) of the Act. Prior to CY 2022, we had based payment rates for the administration of these preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that we use to establish payment rates for the PFS. Payments for the administration of the preventive vaccines by these suppliers are geographically adjusted based on the location of where the service was performed. Under the Outpatient Prospective Payment System (OPPS), we assign a payment rate for administering these preventive vaccines and the payment rates are applicable for preventive vaccine administration services by hospitals and home health agencies. Certain other types of providers and suppliers, such as RHCs, FQHCs and critical access hospitals (CAHs), are paid based on reasonable cost for vaccine administration.

We noted that a discussion is provided in the CY 2022 PFS final rule on the history of the valuation of the three HCPCS codes, G0008, G0009, and G0010, which describes the services to administer an influenza, pneumococcal, and HBV vaccine, respectively (86 FR 65180 through 65182). We explained that we generally had established payment rates for the three codes based on a direct crosswalk to the PFS

payment rate for CPT code 96372 *(Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular).*

Additionally, we stated that using this methodology resulted in reductions in the payment rates for the preventive vaccine administration services over several years and raised concerns from interested parties. Therefore, we attempted to address the reduction in payment rates for these vaccine administration HCPCS codes in the CY 2020 and CY 2021 PFS final rules (84 FR 62798 and 85 FR 84626 through 84628, respectively) by maintaining the CY 2019 payment rate for all three codes.

We explained that in rulemaking for the CY 2022 PFS, we continued efforts to establish payment for vaccine administration services on a long-term basis. In the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining the payment amount for vaccine administration services. In the CY 2022 PFS final rule (86 FR 65183 through 65187), we discussed the feedback received from a wide variety of interested parties in response to our comment solicitation. In that rule, we explained that we agreed with commenters on the need to establish stable payment rates that consider the costs associated with administering the preventive vaccines included in the Part B preventive vaccine benefit. In particular, we agreed that the payment rates for administration of the influenza, pneumococcal and hepatitis B vaccines are too low and need to be adjusted to reflect the costs incurred by healthcare providers. Furthermore, we agreed with commenters who stated that we should decouple payment for these vaccine administration services from the crosswalk to the PFS and treat them independently.

Additionally, we explained in the CY 2022 PFS final rule (86 FR 65185) that, based on the history and status of payment for preventive vaccine administration and given the concerns gathered through the comment solicitation, we believed that we needed to act expeditiously to update payment rates for the administration of preventive vaccines paid under Medicare Part B, effective January 1, 2022. In addition, we believed that the timing was appropriate for establishing a predictable payment rate for preventive vaccine administration since the PHE had ignited a hypervigilance for infectious diseases.

Therefore, for CY 2022, we finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine covered under the Medicare Part B preventive vaccine benefit at section 1861(s)(10) of the Act. We explained that since the administration of the preventive vaccines described under section 1861(s)(10) of the Act are finalized independent of the PFS, these payment rates will be updated as necessary independently of the valuation of any specific codes under the PFS.

b. Background for Medicare Part B Payment for Administration of COVID–19 Vaccines

As discussed in the CY 2023 PFS proposed rule (87 FR 46219), under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine and its administration through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website.[382] We noted that a detailed history on how the initial payment rates for the administration of the COVID–19 vaccines were determined and how the payment policy evolved to a rate of $40 per dose is provided in the CY 2022 PFS final rule (86 FR 65181 and 65182).

We noted that in the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining a payment amount for preventive vaccine administration. As part of the comment solicitation, we requested feedback specifically related to the circumstances and costs associated with furnishing the COVID–19 vaccines to ensure we took these into consideration when determining our payment policy. In the CY 2022 PFS final rule (86 FR 65185), we discussed the feedback received in response to our comment solicitation with regard to the COVID–19 pandemic. In that rule, we recognized that the PHE has posed and continues to pose unique challenges for vaccination providers, particularly with respect to the administration of vaccines for COVID–19. For example, we stated that we anticipate that healthcare providers will continue to experience unusual costs associated with staffing, scheduling, and reporting requirements as increasing numbers of patients receive additional doses and boosters of the COVID–19 vaccines in the near future, and as health care providers adapt their vaccine delivery infrastructure accordingly. However, we explained that after the PHE, we anticipate that these costs will go down as patient volumes stabilize and as healthcare providers incorporate tasks such as scheduling and reporting into their routine clinical practice. For example, while we may see annual vaccination for COVID–19 similar to influenza, these vaccinations may happen in a more predictable manner, which would provide healthcare settings more time and ability to plan ahead for future vaccination needs. In addition, we noted that healthcare providers will have already made certain capital investments associated with the COVID–19 vaccines, such as ultra-cold storage freezers and software upgrades, during the course of the PHE, and thus, after the PHE such investments will no longer represent a significant additional cost over and above the costs of administering other preventive vaccines. For example, we believe recurrent staffing costs for COVID–19 vaccines may mirror the staffing needs for the administration of the yearly influenza vaccine. At the same time, we recognized that the formal termination of the PHE will not necessarily coincide with an immediate return to pre-pandemic circumstances, and that some of the additional costs mentioned above may persist while conditions normalize. For those reasons, we believed that it was appropriate to establish a single, consistent payment rate for the administration of all Part B preventive vaccines following the end of the calendar year in which the PHE expires. That is, we finalized last year that, effective January 1 of the year following the year in which the PHE ends, the $40 payment rate for administration of the COVID–19 vaccines would be adjusted to align with the payment rate for the administration of other Part B preventive vaccines (86 FR 65185). While the above information is presented for background purposes, we direct readers to section III.H.4.e for the most current policies on this matter, as finalized in this rule.

c. Adjustment to the Payment Amount for Administration of Preventive Vaccines for Geographic Locality

In the CY 2023 PFS proposed rule (87 FR 46219 through 46220), we stated that our method of paying for the administration of preventive vaccines has varied over time. We explained that

[382] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

prior to March 1, 2003, we paid for the administration of an influenza, pneumococcal, or HBV vaccine, at the same rate as CPT code 90782 for the year corresponding to the date of service on the claim.[383] For dates of service on or after March 1, 2003 through December 31, 2021, the vaccine administration payment rates for an influenza, pneumococcal, or HBV vaccine were established through notice-and-comment rulemaking using a crosswalk to the payment rate for similar services paid under the PFS, such as, CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*) or CPT code 36000 (*Introduction of needle or intracatheter, vein*). Using the direct crosswalk to a similar service under the PFS requires applying the PFS payment calculation. This formula that uses a HCPCS code's relative value units (RVUs) for work, practice expense (PE), and malpractice (MP) adjusted by the location where the service is furnished (that is, geographic practice cost indices (GPCIs)). The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the average national costs for furnishing the service. Thus, in order to calculate the payment for the vaccine administration codes, the work, PE, and MP RVUs are adjusted by the GPCIs to reflect the variations in the costs of furnishing the services.

For CY 2022, we decoupled payment for these vaccine administration services from the PFS crosswalk and finalized a payment rate of $30 for the administration of an influenza, pneumococcal, or HBV vaccine and a payment rate of $40 for the administration of COVID–19 vaccines. However, in the CY 2022 PFS final rule, we inadvertently neglected to address a geographic adjustment policy for these payment rates and instead, noted only that payments would be geographically adjusted. We noted when we posted the CY 2022 payment rates for preventive vaccine administration to the seasonal influenza web page, we posted locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rate.[384] Similarly, when we posted the CY 2022 payment rates for the COVID–19 vaccine administration to the COVID–19 vaccine web page, we posted locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rate.[385]

In the CY 2023 PFS proposed rule (87 FR 46219 through 46221), we discussed our proposal for a geographic adjustment policy that would apply to preventive vaccine administration services for CY 2023 and subsequent years. We noted that we believe that it is appropriate to adjust the payment amount for the administration of preventive vaccines to reflect cost differences for each geographic locality. For example, suppliers' costs for rent or employee wages could vary significantly across different geographic areas. We also noted that we believe the geographic variation in costs of administering preventive vaccines provided by suppliers such as physicians, NPPs, and mass immunizers is similar to the geographic variation in the cost of physicians' services paid under the PFS.

Since we have decoupled payment for these vaccine administration services from the PFS crosswalk and finalized a payment rate for them, we noted that we believe the next step in establishing appropriate payment for preventive vaccine administration services independent of the PFS would be to consider a more independent approach to geographic payment adjustment. The PFS GPCIs reflect cost differences for each geographic locality for each of the three distinct components of PFS services (work, PE, and MP). In contrast, the payment rate we have established for administration of the flu, pneumococcal, and HBV preventive vaccines is a flat rate payment of $30, and for the administration of COVID–19 vaccines is a flat rate payment of $40. As such, a single adjustment factor could be used to apply the geographic locality adjustment for these services. In addition to calculating the three component GPCIs (work, PE and MP) to adjust payment under the PFS, under section 1848(e)(2) of the Act, we also calculated a Geographic Adjustment Factor (GAF) for each fee schedule area and, we proposed to use this GAF described in § 414.26 to geographically adjust payment for preventive vaccine administration services beginning for CY 2023. Specifically, we proposed to use the GAF to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas. The GAF is calculated using the three component GPCIs under the PFS (work, PE, and malpractice), and is calculated for each PFS fee schedule area as the weighted composite of all three GPCIs for each fee schedule area using the national GPCI cost share weights. The GAF, which is described under our regulation at § 414.26, was further discussed in section II.D. of the proposed rule, and the specific proposed GAF values for each fee schedule area are posted in Addendum D to the proposed rule.

We discussed in the proposed rule that we also considered continuing to adjust the payment amount for administration of preventive vaccines by applying the PFS GPCIs to reflect cost differences for each geographic area. However, to effectuate this adjustment, this method would require a crosswalk to the RVUs established under the PFS for a CPT code that describes a similar service and is reflective of the mix of work, PE and MP for preventive vaccine administration services. Having recently disconnected payment for preventive vaccine administration services from the PFS through rulemaking as explained above, we did not believe it would be appropriate to continue connecting these payments to the PFS in this way for purposes of geographic adjustment.

We proposed use of the GAFs to adjust payment for the preventive vaccine administration services for geographic cost differences beginning for CY 2023. As we discussed in the proposed rule and in the CY 2022 PFS final rule (86 FR 65180 through 65194), we engaged the preventive vaccine community and established a stable payment amount for preventive vaccine administration that is based on resource costs. Since calculation of the GAFs incorporates the fundamental relative cost structure of the PFS GPCIs, but is a single factor that is weighted by the overall relative share of the three PFS component GPCIs, we noted that we believe application of the single GAF to geographically adjust the payment rate for preventive vaccine administration services based on costs in a given locality would be a more appropriate, streamlined approach to geographic adjustment that results in similar payment. Additionally, we explained that this method avoids the need to refer to the component RVUs for any particular reference service that is valued under the PFS, and thus gets us closer to updating the preventive vaccine administration rates independent of the PFS.

We proposed to amend our regulation at § 410.152 to codify the use of the GAFs for each PFS fee schedule area to adjust payment amounts for the preventive vaccine administration services (influenza, pneumococcal,

[383] Pub. 100–04, Chapter 18, Section 10.2.5.2. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c18pdf.pdf.*

[384] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.*

[385] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

HBV, and COVID–19) to reflect the cost differences in furnishing these services in different fee schedule areas. We noted that as proposed, beginning January 1, 2023, we would apply the GAF to the $40 payment amount for COVID–19 vaccine administration service so long as the emergency use authorization (EUA) declaration is still in place.

We invited public comment on the proposal to adjust the payment amount for the administration of preventive vaccines for geographic cost variations using the GAF. We also welcomed comments on any other factors that could be used to make the payment adjustment to reflect geographic cost differences.

We also proposed to amend our regulations to codify the payment amount established for administration of preventive vaccines in the CY 2022 PFS final rule and the proposed method for adjusting this rate for cost differences in each geographic locality.

In the CY 2023 PFS proposed rule (87 FR 46221), we noted that § 410.152(h) currently contains outdated payment policies for pneumococcal vaccine administration. Therefore, we proposed to revise § 410.152 by replacing the current paragraph (h) to reflect the following:

- Effective January 1, 2022, the established payment amount under Medicare Part B for administration of influenza, pneumococcal, and HBV vaccines is $30. For preventive vaccines administered January 1, 2022 through December 31, 2022, payments under Medicare Part B for administration of preventive vaccines are adjusted to reflect geographic cost variations using the GPCIs established under the PFS and the RVUs for a designated reference code under the PFS. Beginning January 1, 2023, we would adjust the payment amount for the administration of preventive vaccines for geographic cost variations using the GAF described in § 414.26.
- Effective January 1, 2022, the established payment amount under Medicare Part B for administration of COVID–19 vaccines is $40. For COVID–19 vaccines administered January 1, 2022 through December 31, 2022, payments under Medicare Part B for administration of COVID–19 vaccines are adjusted to reflect geographic cost variations using the GPCIs established under the PFS and the RVUs for a designated reference code under the PFS. Beginning January 1, 2023, we would adjust the payment amount for the administration of COVID–19 vaccines for geographic cost variations using the GAF described in § 414.26.
- Effective January 1 of the year following the year in which the PHE ends, the payment rate for administration of the COVID–19 vaccines will be adjusted to align with the payment amount for the administration of other Part B preventive vaccines.

We solicited comment on the proposals and the proposed amendments to the regulation text.

The following is a summary of the public comments received on the adjustment to the payment amount for administration of preventive vaccines for geographic locality provisions and our responses:

Comment: Commenters were very supportive of the proposal to adjust the payment amount for the administration of COVID–19 vaccines for geographic cost variations using the GAF beginning January 1, 2023. One commenter specified that they are supportive of the proposed adjustment, so long as it does not result in a reduction in reimbursement from current levels.

Response: We are grateful to commenters for expressing their support for this proposal. With regard to the comment that is supportive of basing the adjustment on the PFS GAF instead of the GPCIs as long as the change does not result in a reduction in payment, we clarify that this change from using the PFS GPCIs to the GAF is technical in nature. Since the data inputs are generally the same, changes in payment amounts would be minimal for any particular service, and insignificant in the aggregate. For example, using the COVID–19 vaccine administration payment amount of $40, the average adjusted rate using the 2022 GAF is $40.99 and using the 2022 GPCIs is $41.09.

After consideration of public comments, we are finalizing use of the GAF, described under § 414.26, for each PFS fee schedule area to adjust payment amounts for the preventive vaccine administration services (influenza, pneumococcal, HBV, and COVID–19) to reflect cost differences in furnishing these services in each of the PFS areas as proposed. We are also finalizing revisions to the regulation at § 410.152 to reflect this payment policy as proposed.

The following is a summary of the public comments received on the proposals to revise § 410.152 to reflect updated payment policies for preventive vaccine administration, followed by our responses:

Comment: One commenter emphasized that preventive vaccines have been shown to lower overall costs of health care, and they thus requested a one-time increase in payment amounts for all Part B vaccines, as an incentive to providers to administer these critical vaccines promptly and efficiently. Other commenters mentioned the historical decline in payment rates for vaccine administration, as we discussed in the CY2022 PFS final rule (86 FR 65180 through 65182), and they explained that higher rates of payment are needed to encourage providers to continue vaccination services in the future. Other commenters called generally for increases in payments and other incentives under the Part B preventive vaccine benefit, in order to cover the resources that providers need to administer vaccines, and thereby increase adult vaccination rates.

Other commenters suggested that CMS make more significant changes to the Part B preventive vaccine benefit. A number of commenters requested that CMS increase, or at least consider increasing, the vaccine administration payment for all Part B vaccines to $40, in order to incentivize providers to increase vaccine administration and support their overhead costs related to vaccines. Other commenters generally asked that CMS continue to review the proposed vaccine administration payment rates over time to ensure that the rates accurately reflect current health care costs, and therefore serve as adequate incentives to encourage all types of providers to continue providing vaccination services in a variety of settings. Several commenters voiced strong support for the addition of vaccine counseling under the Part B preventive vaccine benefit. Some commenters requested that the Part B vaccine benefit cover all Medicare-covered vaccines, including those currently covered under Part D, while others commented that the Part B vaccine benefit should include all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). One commenter requested that CMS adopt a site-neutral payment policy for Part B preventive vaccine administration, and that those payments should align with the current OPPS payment rates for vaccine administration. A few commenters requested that CMS clarify the difference between vaccine administration coverage under Medicare Parts B and D, and another commenter requested that CMS consider expanding the Part B vaccine benefit to other settings, like RHCs and FQHCs. One commenter requested that CMS update Medicare Part D vaccine administration payment rates to match Part B vaccine administration payment rates, since

both services are very similar, and since CMS' discussion regarding reductions in Part B vaccine administration payment rates (most recently at 86 FR 65184 through 65186) applies similarly to those in Part D. This commenter also noted that CMS guidance recommends that Part B and Part D vaccine administration payments should consider the same factors. Another commenter asked that CMS consider new, non-cost-based payment methodologies for vaccine benefits that would more effectively capture the value of vaccinations and maximize vaccination rates; however, the commenter did not recommend a specific alternative payment methodology.

Response: We did not make any proposals in the CY 2023 PFS proposed rule regarding expanding the Part B preventive vaccine benefit to additional vaccines, which would require a statutory change, or to pay for the current Part B preventive vaccines via any new methodologies. We have also not made any proposals regarding vaccine administration payments in Part D. We direct commenters to the CY 2023 OPPS proposed rule (87 FR 44575 through 44577) for a discussion on COVID–19 vaccine administration payments in the hospital outpatient setting, where a different payment methodology is currently used.

After consideration of the public comments, we are finalizing our proposal to revise § 410.152 by replacing the current paragraph (h) to reflect that, for preventive vaccines administered January 1, 2022 through December 31, 2022, payments under Medicare Part B for administration of preventive vaccines are adjusted to reflect geographic cost variations using the GPCIs established under the PFS and the RVUs for a designated reference code under the PFS, and beginning January 1, 2023, the payment amount for the administration of preventive vaccines for geographic cost variations will be adjusted using the GAF described in § 414.26.

We are also finalizing our proposal to revise § 410.152 to reflect that, effective January 1, 2022, the established payment amount under Medicare Part B for administration of COVID–19 vaccines is $40, and effective January 1 of the year following the year in which the PHE ends, the payment rate for administration of the COVID–19 vaccines will be adjusted to align with the payment amount for the administration of other Part B preventive vaccines. We note in section III.H.4.d.i. of this final rule, we are finalizing our proposal to clarify that this policy will be dependent on the declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), that is, EUA declaration for drugs and biological products.

d. Annual Adjustment to the Payment Amount for Administration of Preventive Vaccines to Reflect Changes in Cost

As discussed in the CY 2023 PFS proposed rule (87 FR 46221 through 46222), as part of the comment solicitation in the CY 2022 PFS proposed rule, we requested feedback on whether CMS should use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis. Some commenters provided feedback in response to this specific inquiry. One commenter suggested that incremental updates should be made to the payment rate each year. Another commenter stated that annual updates to the vaccine administration payment rates based on OPPS claims data would be a reliable and data-based method for updating the payment rate and would prevent the issues that have occurred in the past with the crosswalk under the PFS to CPT code 96372. In response to those comments, we stated that we would continue to seek feedback on an appropriate mechanism for updating these payments on a yearly basis by, for example, applying an annual inflation factor, for example the increase in the MEI, to the payment rate in order to reflect increases in costs faced by providers and suppliers that furnish the service; and that we plan to address updating the payment rate for Part B preventive vaccine administration in future rulemaking.

We noted that we believed finalizing a $30 payment amount adjusted for geographic locality for the service to administer preventive vaccines in CY 2022 was the first step in the development of a Part B payment methodology that provides predictable payment to the providers/suppliers furnishing these vaccines. Therefore, we discussed how we would annually update the $30 payment amount to account for changes in costs associated with furnishing the service.

To account for the change in costs of administering preventive vaccines, we proposed to update the payment amount (that is, $30) established in the CY 2022 PFS final rule for the administration of preventive vaccines based upon the annual increase to the MEI. The MEI is defined in section 1842(i)(3) of the Act and is used to update payment amounts in other healthcare settings. For example, the MEI is used to update the non-drug component of the OTP payment bundle and is also used to update the fixed-dollar payment amount for the originating site facility fee for Medicare telehealth services. The MEI is a fixed-weight input price index that reflects the physicians' own time and the physicians' practice expenses, with an adjustment for the change in economy-wide, private nonfarm business total factor productivity. We noted that the MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264) and the proposal to rebase and revise the MEI for CY 2023 is discussed in section II.M. of the proposed rule (87 FR 46041–46055). At the time of the CY 2023 PFS proposed rule, the available forecast of the increase in the MEI for CY 2023 was 3.8 percent based on the proposed 2017-based MEI. We also noted that the CY 2023 MEI increase factor for the final rule would be based on historical data through the 2nd quarter of 2022.

As discussed in the proposed rule, in developing the proposed method to update the payment amount for administering preventive vaccines, we considered other potential update factors, such as the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*). The Consumer Price Index for All Items (CPI–U) is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. However, we concluded that a healthcare-specific update factor, such as the MEI, would be more appropriate for suppliers that administer preventive vaccines than the CPI–U, which measures general inflation, as the MEI would more accurately reflect the change in the prices of goods and services included in the vaccine administration service. We also considered using a labor-specific series for the inflation factor since a main source of the expenses related to the administration of vaccines are related to the staff who administer them. For example, we considered the Employment Cost Index (ECI)—Wages and salaries for All Civilian workers in Hospitals or the ECI—Wages and salaries for All Civilian workers in Health care and social assistance. However, we concluded that an update factor that considers other costs, such as the MEI, would be more appropriate for suppliers that administer preventive vaccines than the ECI.

We noted that under the proposal, beginning January 1, 2023 we would update the $40 payment amount for

COVID–19 vaccine administration based upon the proposed 2017-based MEI so long as the EUA declaration is still in place.

Accordingly, we proposed to annually update the payment amount for administration of preventive vaccines based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We proposed to codify this proposal in tandem with the revisions discussed in section III.H.2.c. of the proposed rule under § 410.152. We invited public comment on the proposal. We also welcomed comments on potential approaches to updating payment rates for administration of preventive vaccines other than the MEI that could be used as an annual adjustment to account for the change in costs associated with administering preventive vaccines.

The following is a summary of the public comments received on the annual adjustment to the payment amount for administration of preventive vaccines to reflect changes in cost provisions and our responses:

Comment: All commenters supported an annual increase to the Part B preventive vaccine administration payment amount to reflect changes in cost faced by providers and suppliers that furnish the service. The majority of the commenters supported the proposal to annually adjust the Part B preventive vaccine administration payment amount based upon the annual increase in the MEI. However, several commenters noted that, while they are in favor of an annual payment update for vaccine administration rates with the MEI, they expressed concerns with the CY 2023 PFS proposed rule's suggested changes to the MEI calculation (87 FR 46041–46055). Two commenters supported conditional use of the proposed rebased and revised MEI if CMS considered their suggested recommendations. Two other commenters recommended that CMS not rely on the proposed rebased and revised MEI because of their concerns, but they did not offer an alternative policy. One commenter requested that CMS periodically review the cost of vaccine administration to ensure that the MEI is adequately reflecting annual increased costs.

Response: We direct those with concerns about the proposed changes to the MEI calculation to section II.M of this final rule. While we acknowledge those concerns, CMS believes that the MEI remains the most appropriate measure by which to annually adjust Part B preventive vaccine administration payments. After consideration of the public comments, we are finalizing our proposed policy. That is, beginning January 1, 2023 and in subsequent years, the payment amount for administration of preventive vaccines will be annually updated based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We are also finalizing revisions to the regulation at § 410.152 to reflect this payment policy as proposed.

We note that, in section II.M. of this final rule, we are finalizing the 2017-based MEI for CY 2023, with technical modifications based on public comments. The CY 2023 MEI update is 3.8 percent, based on historical data through the 2nd quarter of 2022 of the finalized 2017-based MEI.

e. Summary of Final Payment Policies and Implementation

In summary, beginning January 1, 2023 and in subsequent years, we are finalizing our proposal to annually update the payment amount for the administration of Part B preventive vaccines based upon the increase in the MEI. Additionally, we are finalizing our proposal to adjust this payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered using the GAF. These adjustments will apply to HCPCS codes G0008, G0009, G0010, and CPT codes that describe the service to administer COVID–19 vaccines [386] effective January 1, 2023.

Since the CY 2023 MEI update is 3.8 percent, the CY 2023 payment amount for influenza, pneumococcal, and HBV vaccine administration is $31.14 ($30.00 × 1.038 = $31.14). This amount will be geographically adjusted based upon the fee schedule area where the preventive vaccine is administered using the GAF. To facilitate these new payment rules, CMS plans to release subregulatory guidance to implement a new national fee schedule for Part B preventive vaccine administration. With regard to COVID–19 vaccine administration, for CY 2023 the payment amount is $41.52 ($40.00 × 1.038 = $41.52), through the end of the calendar year in which the current EUA declaration for drugs and biologicals with respect to COVID–19 remains in place. Thereafter, the payment amount for COVID–19 vaccine administration will be adjusted to align with the payment rate for the other Medicare Part B preventive vaccines. Please see section III.H.4 of this final rule for more information on final policies regarding COVID–19 vaccine administration.

3. In-Home Additional Payment for Administration of COVID–19 Vaccines

a. Background

On June 9, 2021, we announced a new add-on payment with a national rate of approximately $35.00 when a COVID–19 vaccine is administered in the home, and on August 24, 2021, we expanded the circumstances under which the in-home add-on payment is available.[387] [388] Under this policy, providers and suppliers that administer a COVID–19 vaccine in the home under certain circumstances can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes [389] along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). The total national average payment to providers and suppliers administering a COVID–19 vaccine in the home is $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home), and both payments are geographically adjusted using PFS GPCIs as discussed in section III.H.2.c. of this final rule. In the CY 2022 PFS final rule (86 FR 65187 and 65188), we provided a detailed explanation on how the payment amount was established. In announcing the add-on payment for in-home COVID–19 vaccine administration, we noted that we established these policies on a preliminary basis to ensure access to COVID–19 vaccines during the public health emergency and that we will continue to evaluate the needs of Medicare patients and these policies, and address them in the future, as needed.

In the CY 2022 PFS proposed rule (86 FR 39224 through 39226), we included a comment solicitation to collect feedback on these policies and potential future changes. As part of the comment solicitation, we requested feedback related to our definition of ''home,'' program integrity concerns, changes that we should consider, costs associated

[386] The current list of effective COVID–19 vaccine administration codes is available on the CMS web page: *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[387] *https://www.cms.gov/newsroom/press-releases/biden-administration-continues-efforts-increase-vaccinations-bolstering-payments-home-covid-19.*

[388] *https://www.cms.gov/newsroom/press-releases/cms-expands-medicare-payments-home-covid-19-vaccinations.*

[389] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

with administering COVID–19 vaccines in the home, and whether outside of a PHE there is a need to vaccinate people in the home rather than going to a health care provider or supplier. In the CY 2022 PFS final rule (86 FR 65188 through 65190), we discussed the feedback received and that commenters overwhelmingly recommended that we continue making the additional payment beyond the end of the PHE, with many also supporting extending the payment to other preventive vaccines, either permanently or until the end of the PHE. Commenters emphasized the importance of increasing vaccination rates and making vaccines available to vulnerable homebound beneficiaries who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources.

In that rule, we agreed with commenters that the added costs and compelling needs required CMS to adopt the in-home add-on payment rate for COVID–19 vaccine administration. In addition, we stated that since we did not expect those needs or costs to diminish immediately with the end of the PHE, we believed it would be appropriate to leave the in-home add-on payment rate in place through the end of the CY in which the PHE ends. For example, we anticipated that additional COVID–19 vaccine booster doses will be needed. In addition, we believed that that this policy would set clear expectations for vaccine providers and suppliers and allow for a more gradual transition to a permanent payment policy.

Therefore, we finalized continuation of the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances until end of the calendar year in which the PHE ends. As we discussed in the CY 2022 PFS final rule, extending the availability of the in-home add-on payment past the end of the PHE maximizes access to COVID–19 vaccines for vulnerable homebound beneficiaries during the gradual return to normal conditions following the formal termination of the PHE. We also explained that this extension of payment past the end of the PHE affords CMS the opportunity to monitor vaccine uptake data (86 FR 65189).

b. Conditions for Billing HCPCS Code M0201

In establishing the additional payment for COVID–19 vaccine administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. In the CY 2022 PFS final rule, we provide a detailed discussion on how we established the certain conditions under which the code can be used, and the situations we contemplated to arrive at our final payment policy (86 FR 65187 and 65188).

For purposes of this add-on payment for in-home COVID–19 vaccine administration, the following requirements apply when billing for HCPCS code M0201: [390] [391]

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:
  - ++ They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;
  - ++ They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or
  - ++ They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID–19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be:
  - ++ A private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter);
  - ++ An apartment in an apartment complex or a unit in an assisted living facility or group home (including assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program);
  - ++ A patient's home that is made provider-based to a hospital during the PHE for COVID–19; or
  - ++ Communal spaces of a multi-unit or communal living arrangement.
- A home cannot be:
  - ++ An institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[392]

The COVID–19 vaccine must be administered inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. HCPCS code M0201, as noted in the code descriptor, can be billed only once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.

c. Changes for CY 2023

As discussed in the CY 2023 PFS proposed rule (87 FR 46223), subsequent to the CY 2022 PFS final rule, we received suggestions from interested parties that this in-home add-on payment should be applied more broadly to all preventive vaccines, and concerns that discontinuation of the payment would negatively impact access to preventive vaccines for vulnerable homebound beneficiaries. We noted that while we agreed with these concerns, we also believed that we need to learn more about the populations served through the current in-home add-on payment, and other potential populations that may not have been able to access a COVID–19 vaccine despite the availability of the in-home add-on payment, to understand the barriers they face in receiving vaccinations in their home versus in the community. We also noted the need to consider potential program integrity concerns.

We discussed continuing the additional payment for at-home COVID–19 vaccinations for another year to provide us time to track utilization and trends associated with its use to inform the policy for CY 2024. We noted that we are not extending the policy to include the other preventive vaccines and explained that one of the reasons we established this rate is to account for the post-administration time that the health care professional must spend in the home to monitor the patient after

[390] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[391] *https://www.cms.gov/files/document/vaccine-home.pdf.*

[392] 42 CFR 409.42(a).

administration of the COVID–19 vaccine. Administration of the COVID–19 vaccine typically involves monitoring the patient for at least 15–30 minutes post-injection, which is not the general administration protocol for other vaccines. We also noted that the in-home add-on payment helps to account for the costs associated with special handling of the vaccine and the extra time spent with the patient when a vaccine is administered in the home.

Therefore, for CY 2023, we proposed to continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under the certain circumstances described in section III.H.3.b of the proposed rule. We also proposed to adjust this payment amount for geographic cost differences as we do the payment for the preventive vaccine administration service. That is, for CY 2023, we would adjust this payment amount to reflect cost differences for the geographic area based upon the fee schedule area where the COVID–19 vaccine is administered using the GAF. In addition, for CY 2023, we discussed in the proposed rule that we would update the $35.50 by the CY 2023 MEI consistent with the proposal for the other preventive vaccine administration services. We noted that we believe this policy will continue to provide access to beneficiaries who would otherwise have difficulty getting vaccinated, while we continue to monitor utilization and receive information to be considered in developing our policy for the future. We welcomed comments and suggestions on steps we could take related to program integrity and beneficiary protections associated with payments for administering preventive vaccines in the home, including the COVID–19 vaccine and other preventive vaccines under Medicare Part B.

The following is a summary of the public comments received on the in-home additional payment for administration of COVID–19 vaccines provisions and our responses:

Comment: Many commenters supported continuation of the in-home additional payment for COVID–19 vaccine administration. Commenters largely echoed the positive comments summarized in the CY 2022 PFS final rule (86 FR 65189 and 65190). They explained that, over the past calendar year, this policy has provided critical expanded access to COVID–19 vaccines for vulnerable beneficiaries living in rural areas, for those who are homebound or lack transportation, or for those who have a condition that would put them at high risk for contracting severe COVID–19. Commenters pointed out that this policy has also helped those with chronic illnesses and those with mental and physical limitations that severely curtail their mobility and/or their ability to seek vaccination administration outside the home. In addition to general support for the policy, commenters were also very supportive of updating the in-home additional payment both annually and for geographic location, via the MEI and GAF respectively.

In addition to the positive feedback received, we received many comments that requested that this in-home benefit be expanded. Similar to the feedback described in CY 2022 PFS final rule (86 FR 65188 through 65190), many commenters recommended that CMS extend the in-home additional payment to the other preventive vaccines covered under Part B, additional vaccines covered under Medicare, and all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines. Several commenters expressed their hope that the in-home additional payment continue indefinitely. One commenter requested that CMS allow home care providers to receive the additional in-home payment when administering the COVID–19 vaccine alongside an Evaluation and Management (E/M) visit. These commenters emphasized the importance of increasing vaccination rates and making vaccines available to the multiple types of vulnerable beneficiaries mentioned above.

Response: We thank all commenters for their feedback on the in-home additional payment for COVID–19 vaccine administration. At this time, we are finalizing our proposal to continue the in-home additional payment as proposed for CY 2023. While we did not make any proposals about expanding this payment to other vaccines or to home care providers when administering the COVID–19 vaccine alongside an E/M visit, we are carefully reviewing all of the aforementioned comments as we consider potential policy changes regarding in-home vaccine administration payments in the future. After consideration of the public comments, we are finalizing our proposed policies for CY 2023 to continue the in-home additional payment for the administration of COVID–19 vaccines, to adjust payments for these services based on the PFS GAF, and to update the payment by the CY 2023 MEI. Therefore, for CY 2023 the in-home additional payment amount for COVID–19 vaccine administration described by HCPCS code M0201 is $36.85 ($35.50 × 1.038 = $36.85), and payment for these services will be adjusted for geographic cost differences using the relevant PFS GAF.

4. Clarification on Policies for COVID–19 Vaccine and Monoclonal Antibody Products

a. Background

Under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), the Secretary can declare a public health emergency (PHE) if he determines that: (1) a disease or disorder presents a PHE; or (2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. A PHE declaration allows the Secretary to take certain actions in response to the PHE. In addition, a PHE declaration under section 319 of the PHS Act can be a necessary step in authorizing the Secretary to take a variety of discretionary actions to respond to the PHE under the statutes HHS administers.[393] If the criteria under section 564 of the FD&C Act are met, the Secretary may make a declaration that the circumstances exist justifying an emergency use authorization (EUA) of unapproved drugs, devices, or biological products, or of approved drugs, devices, or biological products for an unapproved use.[394]

On January 31, 2020, under section 319 of the PHS Act, the Secretary determined that a PHE as a result of confirmed cases of 2019 Novel Coronavirus existed nationwide and had existed since January 27, 2020 (hereafter referred to as the PHE for COVID–19). The Secretary has since renewed this declaration for successive 90-day periods, most recently on October 13, 2022.[395] On March 27, 2020, the Secretary declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section (85 FR 18250 through 18251). This latter declaration enabled the Commissioner of Food and Drugs to issue an EUA for a drug or biological product if the Commissioner reasonably concludes that, among other criteria, based on the totality of available scientific evidence, the product may be

[393] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/PHE-Questions-and-Answers.pdf.*

[394] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.*

[395] *https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.*

effective in diagnosing, treating or preventing such disease or condition, and the product's known and potential benefits when used to diagnose, prevent, or treat such disease or condition, outweigh its known and potential risks.

b. Timing Distinction Between Section 319 of the PHS Act and Section 564 of the FD&C Act Declarations

As discussed in the CY 2023 PFS proposed rule (87 FR 46224), declarations under section 319 of the PHS Act generally last for 90 days, but may be extended [396] by the Secretary. After each extension, the declaration lasts for 90 days or until the Secretary declares the emergency no longer exists, whichever occurs first. In contrast, an emergency declaration pursuant to section 564 of the FD&C Act (an ''EUA declaration'') continues until specifically terminated.[397] An EUA declaration may remain in effect beyond the duration of the section 319 PHE declaration. When an EUA declaration is to be terminated, notice of termination will be published in the **Federal Register** that provides a reasonable period of advance notice to the public that the EUA declaration is being terminated, to permit manufacturers, health care facilities, providers, patients, and other interested parties to transition away from EUA products and the policies that support them.

c. Medicare Part B Coverage and Payment of COVID–19 Vaccine and Therapeutic Monoclonal Antibody Products

At the time of drafting this final rule, four COVID–19 vaccines are authorized or approved for use in the US to prevent COVID–19.[398] FDA has approved licensure of Pfizer-BioNTech and Moderna COVID–19 mRNA vaccines for use in certain individuals, but there are also individuals for whom these vaccines continue to be available under an EUA. FDA has limited the authorized use of the Janssen-manufactured COVID–19 viral vector vaccine to individuals 18 years of age and older for whom other FDA-authorized or licensed COVID–19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID–19 vaccine because they would otherwise not receive a COVID–19 vaccine. Since the publication of the proposed rule, FDA has issued an EUA for emergency use of the Novavax COVID–19 Vaccine, Adjuvanted for individuals 12 years of age and older. In addition, there are other COVID–19 vaccines that are not licensed or authorized under an EUA, but are in Phase 3 clinical trial.[399]

Regarding availability of COVID–19 monoclonal antibody products, there are no monoclonal antibody products approved for the treatment or prevention of COVID–19. There are three authorized monoclonal antibody COVID–19 products; two are authorized for the treatment of COVID–19 (one specifically for use in hospitalized patients) and one is authorized as pre-exposure prophylaxis for prevention of COVID–19.[400]

In the November 2020 IFC, we discussed how we believed it is appropriate for Medicare to consider any EUA under section 564 of the FD&C Act issued for a COVID–19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a vaccine to be described in section 1861(s)(10)(A) of the Act (85 FR 71145 through 71148). That is, even though section 3713 of the CARES Act refers to a COVID–19 vaccine ''licensed under section 351 of the PHS Act,'' CMS could consider any vaccine for which FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, to be eligible for Medicare coverage and payment.

Subsequent to the November 2020 IFC and as discussed in the CY 2022 PFS final rule (86 FR 65190 through 65194), when COVID–19 monoclonal antibody products were granted EUAs during the PHE for COVID–19, we made the determination to cover and pay for them under the Part B vaccine benefit in section 1861(s)(10) of the Act. This determination effectively extended the policy decision for COVID–19 vaccines to COVID–19 monoclonal antibody products, that is, that an EUA under section 564 of the FD&C Act issued for a COVID–19 monoclonal antibody product during the PHE is tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a COVID–19 monoclonal antibody product to be described in section 1861(s)(10)(A) of the Act.

As we discussed in the CY 2023 PFS proposed rule (87 FR 46225), the decision to cover and pay for monoclonal antibody products used to treat COVID–19 under the Part B vaccine benefit prioritized access to these products during the COVID–19 pandemic by allowing almost all Medicare enrolled providers and suppliers, as permitted by State law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care. Covering and paying for these services under the Part B vaccine benefit also means that beneficiaries are not responsible for any cost sharing for the product or the service to administer it.

We noted that under the Part B preventive vaccine benefit, Medicare pays for the vaccine product (when such product is not free to the provider/supplier, as is the case for COVID–19 vaccines as of the publication of this rule) and its administration. Typically, payment for the vaccine product is made at 95 percent of the AWP, but some healthcare settings, such as RHCs, are paid at 100 percent of their reasonable cost. Typically, payment for the administration of the preventive vaccine shots is approximately $30 per dose, but again, some healthcare settings are paid at 100 percent of their reasonable cost. We also noted that in contrast to vaccine shots, payment for administration of COVID–19 monoclonal antibody products under the Part B preventive vaccine benefit depends on the route of administration, and whether the product is furnished in a healthcare setting or in the beneficiary's home. As discussed in more detail in the CMS COVID–19 Monoclonal Toolkit, payment for administration of monoclonal antibodies can range from $150.50 to $750.00. [401]

We noted in the CY 2023 PFS proposed rule that in the CY 2022 PFS final rule (86 FR 65179 through 65193) we discussed several steps CMS has taken to promote broad and timely access to COVID–19 vaccines and monoclonal antibody products used to treat COVID–19 paid for under the Part B preventive vaccine benefit, during the PHE for COVID–19. We specifically discussed the unique circumstances providers and suppliers face when administering COVID–19 vaccines and recognized the difficulty to predict when resource costs relating to COVID–19 vaccination will align with those for

[396] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[397] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.*

[398] Viewed 9/18/2022. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#about-vaccines.*

[399] Viewed 9/18/2022. *https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine.*

[400] Viewed 9/18/2022. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[401] *https://www.cms.gov/monoclonal.*

other vaccinations after the PHE ends, as we believe the scale of this PHE is unique in Medicare payment history. Therefore, last year, we finalized the policy to maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the PHE ends. That is, we finalized for CY 2022, effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate that aligns with the per dose payment rate for administration of other Part B preventive vaccines (86 FR 65186). While this information is presented for background purposes, we direct readers to section III.H.4.e below for the most current policies on this matter, as finalized in this rule.

We also noted in the CY 2023 PFS proposed rule that in the CY 2022 PFS final rule, we contemplated how to cover and pay for COVID–19 monoclonal antibody products following the end of the PHE for COVID–19, including whether we should align their payment and coverage with other biologicals (86 FR 65190 through 65194). After review of the comments received, we agreed with commenters who recommended CMS transition to treating monoclonal antibody therapies used to treat COVID–19 as biologicals that are paid using methodologies under section 1847A of the Act following the end of the calendar year in which the PHE expires. We noted that Medicare considers other monoclonal antibody products—that is, monoclonal antibody products used in the treatment of other health conditions—to be ''biologicals,'' and Medicare pays for them based on the methodology in section 1847A of the Act when they are furnished in physician offices or ambulatory infusion clinics, and under a similar methodology under the hospital OPPS. We explained that for these care settings, we typically rely on the applicable AMA CPT codes to describe and pay for drug administration services performed by providers and suppliers.

We further noted that in the CY 2022 PFS final rule, we explained that the public health needs that prompted coverage of monoclonal antibody products used to treat COVID–19 paid for under the Medicare Part B vaccine benefit will gradually stabilize following the end of the PHE, and that extending the current payment approach to the end of the year will give healthcare providers adequate time to prepare for the change in payment methodology while continuing to maximize access to beneficiaries, including those who receive these treatments in the home. In addition, we stated that since we do not expect those needs or costs to diminish immediately with the end of the PHE, we believe it would be appropriate to continue to provide payment and coverage for COVID–19 monoclonal antibody therapies under the Medicare Part B vaccine benefit in place through the end of the CY in which the PHE ends, when such treatments are used consistent with the scope and conditions of authorization in the relevant EUA (while in effect). In the CY 2022 PFS final rule, we recognized that once an EUA declaration is terminated,[402] EUAs issued under that declaration will no longer remain in effect,[403] which may affect the availability of some products either for the diagnosis, treatment, or prevention of COVID–19, because they will need to have the requisite marketing authorization to remain on the market. To the extent there are products that would no longer have the requisite marketing authorization to remain on the market after a revocation of an EUA, we believe a transition period would be appropriate to allow for adjustments, as needed, to care plans that included such products (86 FR 65192).

d. Clarification of Medicare Part B Policies

In the CY 2023 PFS proposed rule (87 FR 46225 through 46226) we stated that in light of the timing distinctions between a PHE declared under section 319 of the PHS Act and an EUA declaration under section 564 of the FD&C Act, we reconsidered the policies finalized in the CY 2022 PFS final rule and believe a clarification is necessary. We noted that throughout our discussions and specifically in policy statements related to payment and coverage for COVID–19 vaccines and monoclonal antibody products, we have used phrases such as, ''through the end of the calendar year in which the PHE ends'' and ''effective January 1 of the year following the year in which the PHE ends.'' While we acknowledged that the intent at the time was to refer to the declaration under section 319 of the PHS Act, we reconsidered this position in light of the fact that the March 27, 2020 EUA declaration under section 564 of the FD&C Act is distinct from, and not dependent on, the PHE declaration under section 319 of the PHS Act. We explained an EUA for a drug or biological product issued pursuant to the March 27, 2020 EUA declaration may remain in effect beyond the duration of the section 319 declaration if all statutory conditions are met.[404] On further consideration, we discussed in the proposed rule that we believe that our goal to promote broad and timely access to COVID–19 vaccines and COVID–19 monoclonal antibody products, will be better served if our policies with respect to payment for these products, as addressed in the November 2020 IFC and CY 2022 PFS final rule, continue until the EUA declaration for drugs and biological products (see 85 FR 18250) is terminated. Therefore, we proposed to clarify our policies as stated below. Table 85 displays the CY 2023 Part B payment for preventive vaccine administration if the EUA declaration continues into CY 2023 and Table 86 displays the CY 2023 Part B payment for preventive vaccine administration if the EUA declaration ends on or before December 31, 2022.

i. COVID–19 Vaccines and Their Administration

In the CY 2023 proposed rule, we proposed that CMS would maintain the current payment rate of $40 per dose, updated by the increase in the MEI and adjusted by the PFS GAF as discussed above, for the administration of the COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, we proposed that the payment rate for COVID–19 vaccine administration would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines.

ii. In-Home Administration of COVID–19 Vaccines

In the CY 2023 proposed rule, we noted the policy finalized for in-home administration of COVID–19 vaccines in the CY 2022 PFS final rule. That is, in CY2022, we finalized that CMS will continue the additional payment of $35.50 for COVID–19 vaccine administration in the home under certain circumstances through the end of the calendar year in which the PHE ends. However, in section III.H.3 of this final rule, we discuss finalizing the proposal to continue the in-home

[402] Subsequent to the issuance of the final rule, we found that we incorrectly stated 'once the COVID–19 PHE declaration is terminated.' The correct statement is 'once the EUA declaration is terminated.'

[403] *https://www.fda.gov/media/97321/download.*

[404] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.*

additional payment of $35.50 for administering COVID–19 vaccines for CY 2023. We are also finalizing our proposals to update this payment amount by the CY 2023 MEI and to adjust it by the PFS GAF. Therefore, for CY 2023, the in-home additional payment amount for COVID–19 vaccine administration described by HCPCS code M0201 is $36.85 ($35.50 × 1.038 = $36.85).

We note that we have finalized the policy to continue to pay the additional in-home payment for the entire duration of CY2023. Consequently, this finalized policy for CY2023 will allow for the additional in-home payment regardless of the status of the current PHE or the EUA declaration. Therefore, for CY2023, the additional in-home payment will not be affected by either the end of the PHE or the termination of the EUA declaration.

iii. Monoclonal Antibody Products Used for Treatment or for Post-Exposure Prophylaxis of COVID–19

We proposed to continue to pay for COVID–19 monoclonal antibody products under the Medicare Part B vaccine benefit through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated. Until the end of the calendar year in which the EUA declaration for drugs and biological products is terminated, we proposed to maintain the payment rate for administering a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19 in a healthcare setting, as well as the payment rates for administering a COVID–19 monoclonal antibody product in the home as described on the CMS COVID–19 Monoclonal Toolkit.[405] Effective January 1 of the year following the year in which the EUA declaration for drugs and biological products ends, CMS would pay physicians and other suppliers for covered COVID–19 monoclonal antibody products used for the treatment or for post-exposure prophylaxis of COVID–19 as biological products paid under section 1847A of the Act; healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID–19 monoclonal antibody therapies similar to the way they are paid for administering other complex biological products (86 FR 65192).

As we explained, since an EUA for a drug or biological product issued pursuant to the March 27, 2020 EUA declaration may remain in effect beyond the duration of the section 319 declaration, we contemplated our payment policies for COVID–19 monoclonal antibody products. Since we do not know when the HHS Secretary would terminate the March 27, 2020 EUA declaration, we noted that we believe that we need to give notice on how these proposals would impact payments for administering COVID–19 monoclonal antibody products in the event the EUA declaration continues in CY 2023. Therefore, beginning January 1, 2023, we proposed to apply the GAF to the payment amount for the administration of monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID–19 so long as the EUA declaration is still in place. We noted that we believe it is appropriate to continue to adjust this payment amount to reflect cost differences for each geographic area, and proposed to do so using the GAFs as for other COVID–19 vaccine administration services (please see section III.H.2.c. of this final rule).

Regarding an update based upon the MEI beginning January 1, 2023, we did not extend the proposal to update the payment amount for the administration of these products. We noted that we believe that the payment amounts established for the administration of monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID–19 were approximations intended to reflect resource costs associated with furnishing these particular services during the pandemic response and generally corresponding to the timeframe the EUA declaration is effective. We also noted that some of the resource costs reflected in those rates, such as costs to establish the necessary operational infrastructure, may dissipate over time, even as the pandemic persists. Consequently, we discussed that we did not believe it would be appropriate to establish annual updates to reflect increased costs that would likely be offset to some extent by reduced costs given the more established infrastructure and delivery approaches. We pointed out, too, that the current payment rates effective during the years in which the PHE continues correspond with OPPS New Tech payment amounts that are intended to serve as estimates of overall costs, in contrast to more finely tuned amounts that are typically subject to annual updates (increases or reductions) to reflect greater efficiency. Therefore, we proposed to maintain the current rates for CY 2023 for administration of a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19, and to not update these rates based on the increase in the MEI.

e. Monoclonal Antibody Products Used as Pre-Exposure Prophylaxis for Prevention of COVID–19

As discussed in the CY 2023 PFS proposed rule (87 FR 46226 through 46227) and section III.H.4.c of this final rule, there are no monoclonal antibody products approved by the FDA for the treatment or prevention of COVID–19 as of the publication of this proposed rule. However, we noted in the proposed rule that there are currently three COVID–19 products authorized under an EUA; two are authorized for the treatment of COVID–19, and one is authorized as pre-exposure prophylaxis for prevention of COVID–19.[406] The monoclonal antibody product for use as pre-exposure prophylaxis prevention of COVID–19 was granted an EUA subsequent to the CY 2022 PFS final rule. Therefore, we explained that our policies regarding coverage of COVID–19 monoclonal antibody products as finalized in the CY 2022 PFS final rule did not address monoclonal antibody products used as pre-exposure prophylaxis for prevention of COVID–19. Nevertheless, we noted that when this COVID–19 monoclonal antibody pre-exposure prophylactic product was granted an EUA, we promptly provided payment and coverage for it under the Part B vaccine benefit in section 1861(s)(10) of the Act as we have done for the other COVID–19 monoclonal antibody products.[407]

We recognized that there are certain individuals for whom these pre-exposure prophylactic products may be their only preventive option against COVID–19. These individuals would include, for example, those who are not currently infected with COVID–19, who have not had a known recent exposure to an individual infected with COVID–19, and for whom vaccination with any available COVID–19 vaccine is not recommended due to a history of severe adverse reaction (for example, severe allergic reaction) to a COVID–19 vaccine(s) and/or COVID–19 vaccine component(s). Therefore, we proposed to clarify that our policy of coverage and payment under the Part B vaccine

[405] *https://www.cms.gov/monoclonal.*

[406] Viewed 5/6/2022. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[407] *https://www.cms.gov/monoclonal.*

benefit for monoclonal antibody products includes those used as pre-exposure prophylaxis for prevention of COVID–19. In addition, to ensure the aforementioned beneficiaries have access to COVID–19 pre-exposure prophylactic products, we proposed to continue the existing policy to pay for these products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

Since we proposed to pay for pre-exposure prophylaxis monoclonal antibody products for COVID–19 under the Part B vaccine benefit, we also proposed to apply the PFS GAF to geographically adjust the payment amount for the administration of those monoclonal antibody products, effective January 1, 2023. However, we did not propose to update the payment amount with the MEI beginning January 1, 2023. The payment amounts established for the administration of monoclonal antibody products used as pre-exposure prophylaxis for COVID–19 were intended to account for resource costs associated with pandemic response, and like the payment amounts for administration of other COVID–19 monoclonal antibody products, reflects an approximation. Therefore, we proposed to maintain the current amount without a specified update mechanism, but also sought comment on how best to consider refining rates for administration of this specific kind of product in the future. We solicited comment on these proposals.

The following is a summary of the public comments received on the clarification on policies for COVID–19 vaccine and monoclonal antibody products provisions and our responses:

Comment: Many commenters supported our proposal to continue the $40 payment rate, updated by the MEI, for COVID–19 vaccine administration through the end of the year in which the EUA declaration for drugs and biologicals is terminated. Several commenters supported our proposal to align the payment rate for administration of the COVID–19 vaccines with the payment amount for the administration of other Part B preventive vaccines, effective January 1 of the year following the year in which the EUA declaration ends.

However, many commenters stated that the vaccine administration rate for other Part B preventive vaccines, that is, $30 updated annually by the increase in the MEI, is not adequate payment for the administration of the COVID–19 vaccine, even after HHS ends its EUA declaration for drugs and biological products with respect to COVID–19. Some commenters called for CMS to continue the higher payment rate for COVID–19 vaccine administration for additional years or even indefinitely, and provided several reasons they believe the higher payment amount should remain: continued physician effort needed to navigate the many COVID–19 vaccine options; need to ensure broad and equitable access to COVID–19 vaccines; the possible need for additional booster or vaccine doses even after the end of the PHE; the costs involved in monitoring those who receive the COVID–19 vaccines for 15–30 minutes after it is administered; staffing shortages; supply challenges; the need to educate patients on the value of vaccines, vaccine effectiveness and safety, and to combat vaccine misinformation; unique reporting needs for COVID–19 vaccines; unique storage requirements for many COVID–19 vaccines; the potential for new COVID–19 variants to emerge; and the possibility of new vaccines being approved. Commenters also explained that a transition away from emergency-period policies can cause operational and administrative challenges for those who furnish the vaccines, which may result in health care access issues for Medicare beneficiaries.

One commenter stated that, instead of a reduction, an increase is needed to the COVID–19 vaccine administration rate, due to the still-changing circumstances surrounding COVID–19 vaccines and their administration, as described above. Finally, several commenters requested that CMS provide clear guidance and sufficient notice in anticipation of any transition in payment amounts for COVID–19 vaccine administration.

Response: We thank all commenters for their attention to this important issue regarding COVID–19 vaccinations. The CY 2022 PFS final rule (87 FR 65184 through 65186) contains an extensive discussion on our rationale for setting the $40 COVID–19 vaccine administration rate during the PHE, and for aligning the COVID–19 vaccine administration rate with the rate for administration of the other Part B preventive vaccines after the end of the PHE. We acknowledge the unique and unusual circumstances that still surround the COVID–19 vaccine landscape, as described by the commenters, and we recognize the higher resource load that those administering vaccines still need in order to provide those vaccinations. We believe that our proposal to continue the higher COVID–19 vaccine administration rate through the end of the year in which the EUA declaration ends, rather than immediately aligning the COVID–19 vaccine administration rate with the rate for the other Part B preventive vaccinations after the PHE ends, will provide an appropriate transition period to recognize the potential continuation of higher resource needs, and to assist those administering COVID–19 vaccines as they continue to furnish them. We will continue to review payment policies for the Part B preventive vaccine benefit in the coming years, as circumstances continue to evolve regarding COVID–19 specifically, and with regard to public health in general. When the transition to a calendar year post-EUA declaration does arrive, CMS certainly plans to provide sufficient notice and thorough guidance regarding the transition to both providers and beneficiaries.

Comment: Commenters were all supportive of our proposal to continue the in-home additional payment for administering COVID–19 vaccines through CY 2023, regardless of the status of the PHE or EUA declaration. As discussed above in section III.H.3.c. of this final rule, commenters expressed that this additional payment has had a positive effect on vaccination rates among vulnerable populations, and commenters believe this beneficial effect will continue in CY 2023.

Response: We thank commenters for their support. As discussed above in section III.H.3.c. of this final rule, we are finalizing the in-home additional payment for COVID–19 vaccine administration as proposed.

Comment: Commenters were supportive of our proposals to cover and pay for monoclonal antibody products used for treatment or post-exposure prophylaxis of COVID–19 under the Part B preventive vaccine benefit through the end of the year in which the EUA declaration for drugs and biologicals is terminated. These commenters supported our proposal to geographically adjust monoclonal antibodies payments for the administration of COVID–19 monoclonal antibodies via the GAF beginning January 1, 2023 and they generally supported our proposals regarding the proposed payment adjustments for CY 2023. Additionally, these commenters supported coverage and payment of monoclonal antibodies used for the treatment or for post-exposure prophylaxis of COVID–19 as biological products paid under section 1847A of the Act where healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and

payment rates, beginning January 1 after the year the EUA declaration is terminated. These commenters thanked CMS for the transition guidance provided to date.

However, several commenters objected to the proposal to end our current payment policies for monoclonal antibody products used for treatment or post-exposure prophylaxis of COVID–19. These commenters stated that, even following the year in which the EUA declaration terminates, healthcare providers will need extensive resources to provide care and COVID–19 monoclonal antibody treatments to COVID–19 patients, including extra Personal Protective Equipment (PPE) and airflow protections. Some commenters also objected to our proposal to refrain from an annual update to the payment amount for administration of these products based upon the increase in the MEI, as they believe that an update is needed to maintain appropriate reimbursement for these critical COVID–19 therapies.

Several commenters requested that CMS provide sufficient notice and clear guidance before a payment transition begins for COVID–19 monoclonal antibody products, and that CMS consider ways to minimize out-of-pocket costs for beneficiaries who will begin being charged cost-sharing (Part B deductible and copayment) amounts for these therapies. Another commenter asked CMS to create and maintain a payment mechanism for future EUAs for monoclonal antibody treatments that are authorized by FDA against future COVID–19 variants and/or any future public health emergencies, and that the policy should particularly address vulnerable beneficiary populations.

Response: We acknowledge the unique and unusual circumstances that still surround the COVID–19 landscape, as described by the commenters, and we recognize the higher resource load that healthcare providers still face when administering COVID–19 monoclonal antibodies to beneficiaries. We continue to believe that our proposal to continue payment and coverage of COVID–19 monoclonal antibodies under the Part B preventive vaccine benefit until the end of the CY in which the EUA declaration ends, rather than the end of the CY in which the PHE for COVID–19 ends, will appropriately mitigate the commenters' concerns. We will continue to assess the fluid circumstances of the COVID–19 pandemic in considering whether further policy changes are warranted through additional rulemaking. When the transition to a calendar year post-EUA declaration does arrive, we plan to notify vaccine providers and beneficiaries, and we expect to issue information and guidance in advance of the transition in payment policies, including information on payment policies and applicable beneficiary cost-sharing.

Regarding comments expressing concern that the payment amount for COVID–19 monoclonal antibody administration needs to be updated for CY 2023 to maintain appropriate payment, we believe the current payment amounts continue to be appropriate for these services through the period they will remain in effect. As discussed above, these payments are approximations intended to reflect resource costs associated with furnishing these particular services during the COVID–19 pandemic response, and they generally correspond to the timeframe in which EUA declaration is effective. We continue to believe that some of the resource costs reflected in those rates, such as costs to create needed operational infrastructure in health care settings for administering COVID–19 monoclonal antibodies, may dissipate over time, even as the need for COVID–19 treatments continues. Therefore, we are not persuaded that it would be appropriate to establish annual updates to reflect increased costs over time, given the temporary nature of these payment rates, and since cost increases would likely be offset by the reduced costs of infrastructures established by those furnishing these products.

After consideration of public comments, we are finalizing the proposed policy. That is, in the event the EUA declaration continues into CY 2023, CMS will maintain the current payment rates for administration of a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19, and apply the GAF to geographically adjust the payment amount. The payment rates will not be updated for CY 2023 based on the increase in the MEI. In the event the EUA declaration ends in CY 2022, beginning January 1, 2023 CMS will pay physicians and other suppliers for covered COVID–19 monoclonal antibody products used for the treatment or for post-exposure prophylaxis of COVID–19 as biological products paid under section 1847A of the Act; healthcare providers and practitioners will be paid to administer these products under the applicable payment system, and using the appropriate coding and payment rates, similar to the way they are paid for administering other complex biological products. These payment amounts are displayed in Tables 85 and 86.

Comment: One commenter requested that CMS clarify the reasoning for a lower payment rate of $550.50 per administration for in-home intravenous (IV) injections of monoclonal antibodies, as they believe that the resources needed to provide this therapy in the home are similar to those needed for infused therapies which are paid $750.00 per administration.

Response: In determining appropriate payment amounts for the administration of monoclonal antibody products for COVID–19, CMS considers the costs associated with the route of administration and how long each method takes to administer, post-administration practitioner monitoring time, and the rates that correspond for similar services under the OPPS New Technology Ambulatory Payment Classification (APC). Effective February 11, 2022, CMS established separate coding and payment for administering COVID–19 monoclonal antibody products through IV injection in a patient's home or residence.[408] This guidance established the payment rate for administering COVID–19 monoclonal antibody products through IV injection in a patient's home or residence as approximately $550.50. This rate reflects information about the costs involved in furnishing these unique injection products in a patient's home.

Comment: A few commenters asked that we confirm how payment will be made for monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID–19 after the end of the year in which the EUA declaration ends. The commenter envisioned this transition as moving from 95 percent of Average Wholesale Price (AWP) to Wholesale Acquisition Cost (WAC) + 3% in the quarter after the effective date of EUA declaration termination, and then to ASP+6% after a full quarter of data is collected.

Response: During the EUA declaration for drugs and biological products, Medicare will not pay for COVID–19 monoclonal antibody products that health care providers receive for free, which has been the case upon the product's initial availability in response to the COVID–19 PHE. Bebtelovimab is an example of an authorized product previously distributed to providers and suppliers by the U.S. Government and is now available on the commercial market. CMS sets the Medicare payment rate for the product based on 95 percent of the AWP for those settings that are

[408] *https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2022-02-18-mlnc-se.*

not paid under reasonable costs for vaccine products.

As stated above in section III.H.4.c., beginning January 1 of the year after the year in which the EUA declaration is terminated, CMS will pay providers and suppliers for covered COVID–19 monoclonal antibody products used for the treatment or for post-exposure prophylaxis of COVID–19 as biological products, for which payments are generally based on pricing methodologies for Medicare Part B drugs under section 1847A of the Act. We note depending on the setting, there are several different payment structures that could possibly apply to covered COVID–19 monoclonal antibody products when they are furnished. We believe the commenter is reflecting on how Medicare Part B pays for drugs and biological products under section 1847A of the Act, as it relates to products furnished incident to a physician's service. As we describe in section III.A.1 of this final rule, the payment limit amounts for most drugs and biologicals separately payable under Medicare Part B are based on the average sales price (ASP), plus a statutorily mandated 6 percent add-on. The add-on percentage for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent.[409]

Comment: Commenters overwhelmingly supported our proposal to continue paying for monoclonal antibody products used as pre-exposure prophylaxis for the prevention of COVID–19 under the Part B preventive vaccine benefit on a permanent basis. Several commenters suggested that continuing the policy to pay for these monoclonal antibody products under the preventive vaccine benefit will greatly benefit those who are immunocompromised, such as cancer patients or those with rare diseases, and those with severe adverse reactions to COVID–19 vaccines or their components, and will therefore increase health equity and health care access.

Some commenters recommended that we continue to distinguish between preventive monoclonal antibody products used as pre-exposure prophylaxis targeting infectious diseases and monoclonal antibody products used for treatment or post-exposure prophylaxis in other therapeutic areas, in order to continue to recognize the needs of patient populations like the immunocompromised. One commenter specifically requested that we cover and pay for other monoclonal antibodies used for pre-exposure prophylaxis for infectious diseases other than COVID–19 under the Part B preventive vaccine benefit.

Response: We appreciate the overall positive response to this proposal and we thank commenters for their insights. Regarding coverage and payment of monoclonal antibody products used for pre-exposure prophylaxis for infectious diseases other than COVID–19, we did not discuss or include proposals for these products in the CY 2023 PFS proposed rule. As such, these comments are outside the scope of this rulemaking.

After consideration of public comments, we are finalizing the proposed policy. That is, to ensure the aforementioned beneficiaries have access to COVID–19 pre-exposure prophylactic products, we are finalizing our proposal to continue to pay for these products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we are finalizing the proposal to maintain the current payment amount without a specified update mechanism and adjust for geographic cost variations using the PFS GAF.

In summary, we are finalizing these policies as proposed. We direct readers to the following section and its accompanying Tables 85 and 86 for a summary of the final payment amounts for CY 2023.

f. Summary of Payment Amounts for CY 2023 With or Without a Continuing EUA Declaration for Drugs and Biologicals

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, we are including Tables 85 and 86 that summarize our final provisions in both scenarios.

BILLING CODE 4150–28–P

[409] *https://www.cms.gov/files/document/r11572CP.pdf.*

TABLE 85: CY 2023 Part B Payment for Preventive Vaccine Administration if EUA Declaration Continues into CY 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$31.14	MEI	GAF
COVID-19 Vaccine[2,4]	$41.52	MEI	GAF
In-Home Additional Payment for COVID-19 Vaccine Administration (M0201)	$36.85	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]			
Infusion: Health Care Setting	$450.00	N/A	GAF
Infusion: Home	$750.00	N/A	GAF
Intravenous Injection: Health Care Setting	$350.50	N/A	GAF
Intravenous Injection: Home	$550.50	N/A	GAF
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[3] https://www.cms.gov/monoclonal.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] As of the issuance of the CY2023 PFS final rule, this product is only available under EUA as injection.

TABLE 86: Part B Payment for Preventive Vaccine Administration Beginning January 1, 2023, if EUA Declaration Ends on or Before December 31, 2022

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1,4]	$31.14	MEI	GAF
COVID-19[2,4]	$31.14	MEI	GAF
In-Home Additional Payment for COVID-19 Vaccine Administration (M0201)	$36.85	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	$150.50/$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered and beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] There are no monoclonal antibody products for pre-exposure prophylaxis of COVID-19 that have marketing authorization at this time.

5. Regulatory Updates and Conforming Changes

As discussed in the CY 2023 PFS proposed rule (87 FR 46228), in the November 2020 IFC, we published several changes to the regulations governing Part B preventive vaccines and their administration, in order to include the COVID–19 vaccine and its administration (85 FR 71147). We explained that since Section 3713 of the CARES Act added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration, the COVID–19 vaccine

was similarly added in several regulations regarding the influenza, pneumococcal, and hepatitis B virus (HBV) vaccinations. We stated our intention to finalize the following regulatory changes, which were adopted in the November 2020 IFC:

- § 410.152(l)(1), which includes the COVID–19 vaccine to the list of vaccines for which Medicare Part B pays 100 percent of the Medicare payment amount.
- § 410.160(b)(2), which includes the COVID–19 vaccine in the list of vaccines that are not subject to the Part B annual deductible and do not count toward meeting that deductible.
- § 411.15(e)(5), which adds an exception for COVID–19 vaccinations to the general exclusion of coverage for immunizations.
- § 414.701, which includes the COVID–19 vaccine in the list of statutorily covered drugs.
- § 414.707(a)(2)(iii), which includes the COVID–19 vaccine in the list of vaccines with a payment limit calculated using 95 percent of the AWP.
- § 414.900(b)(3), which includes the COVID–19 vaccine in the list of statutorily covered drugs.
- § 414.904(e)(1), which includes the COVID–19 vaccine in the list of vaccines with payment limits calculated using 95 percent of the AWP.

We noted that in the course of developing the proposed changes to § 410.152 described in section III.H.2.c. of the proposed rule, we came across several outdated and incomplete regulations regarding Part B preventive vaccines and vaccine administration. Therefore, we proposed updates and corrections to the following regulations:

- At § 410.10, Medical and other health services: Included services, we proposed to amend paragraph (l) to list pneumococcal, influenza, and COVID–19 vaccines and their administration.
- At § 410.10, Medical and other health services: Included services, we proposed to amend paragraph (p) to list both Hepatitis B vaccine and its administration, as defined in § 410.63(a).
- At § 410.57, we proposed to amend the section title to read ''Preventive Vaccinations,'' to amend paragraph (a) to state only that Medicare Part B pays for pneumococcal vaccine and its administration, to remove the remainder of the outdated language, and to add paragraph (d) to state that Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).
- At § 410.63, Hepatitis B vaccine and blood clotting factors: Conditions, we proposed to amend the introductory paragraph to replace the outdated reference to § 405.310 with an updated reference to § 411.15.
- At § 414.707, Basis of Payment, we proposed to amend paragraph (a)(2)(iii) to replace the phrase in parentheses with ''as defined in § 410.63(a) of this subchapter.''
- At § 414.904, Average sales price as the basis for payment, we proposed to amend paragraph (e)(1) to replace the parentheses with ''as defined in § 410.63(a) of this subchapter.''

Comment: We received one comment in support of these changes.

Response: We thank the commenter for their support and are finalizing these regulatory revisions as proposed.

I. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

1. Background—Nonemergency, Scheduled, Repetitive Ambulance Service

a. General Discussion

Section 1861(s)(7) of the Act states that, for the purposes of Medicare, the term ''medical and other health services'' includes ambulance services, but only ''where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations.'' Regulations at § 410.40 govern Medicare coverage of ambulance services. Under § 410.40(e), Medicare Part B covers ground (land and water) and air (fixed-wing and rotary-wing) ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.

Section 410.40(e) provides that nonemergency transportation by ambulance is appropriate if either the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. For a beneficiary to be considered bed-confined, § 410.40(e) states that *all* of the following criteria must be met: (1) the beneficiary is unable to get up from bed without assistance; (2) the beneficiary is unable to ambulate; and (3) the beneficiary is unable to sit in a chair or wheelchair. Section 410.40(e) further provides that bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation, but is one factor that is considered in medical necessity determinations. In all cases, a beneficiary's condition must be documented appropriately for coverage of services.

In the ''Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements'' final rule with comment period [410] (64 FR 3637, January 25, 1999) (hereinafter referred to as the ''January 25, 1999 final rule''), we finalized language at § 410.40(d)(3) to require ambulance providers or suppliers, in the case of nonemergency, unscheduled, ambulance services to obtain a physician certification statement (PCS). There, we explained that: (1) nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible, and, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS would help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3648).

We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries. However, in the January 25, 1999 final rule we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician and agreed with interested parties that while it is reasonable to expect that an ambulance provider or supplier could obtain a pre-transport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance providers and suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we finalized a requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the ''Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services''

[410] *https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1547.pdf.*

final rule with comment period [411] (67 FR 9100) (hereinafter referred to as the ''February 27, 2002 final rule''), in response to interested parties response, we modified our documentation regulations, noting that we had been made aware of instances in which ambulance providers and suppliers, despite having provided ambulance transports, were experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe through no fault of their own. We stated that the 48-hour period remained the appropriate period of time, but, with respect to unscheduled, or scheduled but non-repetitive nonemergency ambulance transports, created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(e)(3)(iii) where ambulance providers and suppliers unable to obtain a PCS from the attending physician could obtain a signed certification (*not* a physician certification statement) from certain other staff. At that time, we identified, at § 410.40(a)(iii), several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints were: (1) that the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

Since being finalized in the February 27, 2002 final rule, § 410.40(e)(2) has stated that Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (e)(1) of this section are met (67 FR 9132).

In the November 16, 2012 final rule with comment period [412] (77 FR 68892), we finalized provisions currently at § 410.40(e)(2), incorporating nearly the same provision found at § 410.40(e)(3)(v) to clarify that a PCS does not, in and of itself, demonstrate that a nonemergency, scheduled, repetitive ambulance service is medically necessary for Medicare coverage. As we note above, the 1861(s)(7) definition of ''ambulance service'' in the context of Medicare expresses the clinical medical necessity requirement that the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations.

In the November 15, 2019 final rule [413] (84 FR 62568), in response to interested parties' requests, we clarified the requirements for certification statements based on potential confusion surrounding the format, content, and use of both PCS and non-physician certification statements. Further, we added licensed practical nurses (LPNs), social workers and case managers as individuals listed at § 410.40(a)(iii) who may sign the non-physician certification statement if the ambulance provider or supplier is unable to obtain the attending physician's signature within 48 hours of the transport.

Other factors have significantly altered the Medicare ambulance benefit, notably section 637 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted January 2, 2013) (ATRA), which required a 10-percent reduction in fee schedule payments for nonemergency (BLS transports of beneficiaries with ESRD) to and from both hospital-based and freestanding renal dialysis treatment facilities, for non-emergent dialysis services. Section 53108 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) increased the payment reduction of fee schedule payments for BLS transports to and from renal dialysis treatments, from ATRA's 10 percent to 23 percent.

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) has published numerous reports about Medicare's ambulance benefit and has concluded that this benefit is highly vulnerable to abuse. In September 2015, in a report titled, ''Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports,'' [414] the OIG reported that approximately one in five ambulance suppliers had questionable billing, and that suppliers that had questionable billing provided nonemergency basic life support transports more often than other suppliers.

In addition, in June 2013, MedPAC published a report that included an analysis of nonemergent ambulance transports to dialysis facilities. The report showed that transports to and from dialysis facilities continue to grow and represent a large share of non-emergent ambulance claims. In the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined. In 2011, ambulance transports to and from dialysis facilities accounted for nearly $700 million in Medicare spending, or approximately 13 percent of Medicare expenditures on ambulance services. The report further found that certain States had dramatically higher spending on ambulance transportation for dialysis treatment than other States. We believe that the provisions that we proposed are consistent with MedPAC's recommendations that the agency promulgate national guidelines to more precisely define medical necessity requirements. This will ensure consistent application of the benefit across beneficiary populations, regardless of geographic location.

Under section 1115A of the Act, CMS initiated the testing of the Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Model, which tested whether prior authorization helped to reduce expenditures while maintaining or improving quality of care. Beneficiaries who qualify for these services are typically transported to receive either cancer treatment or dialysis, although there are other services for which this type of transportation is needed. Section 515 of the Medicare Access and CHIP Reauthorization Act (Pub. L. 114–10, enacted April 16, 2015) (MACRA), required this model to be expanded to

[411] *https://www.govinfo.gov/content/pkg/FR-2002-02-27/pdf/02-4548.pdf.*

[412] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of NonRandom Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; *https://www.govinfo.gov/content/pkg/FR-2012-11-16/pdf/2012-26900.pdf.*

[413] Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule; *https://www.govinfo.gov/content/pkg/FR-2019-11-15/pdf/2019-24086.pdf.*

[414] Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports (OEI–09–12–00351; 09/15) (*hhs.gov*).

include eight States and the District of Columbia, not later than January 1, 2016. Also in section 515 of MACRA, Congress amended section 1834(l) of the Act to require the model be expanded to all States, beginning January 1, 2017, to the extent that the expansion that Congress required above satisfied certain criteria specified at 1115A(c) of the Act.

We released two Interim Evaluation Reports [415] and a Final Evaluation Report [416] on the model. The Final Evaluation Report, similar to the two Interim Evaluation Reports, found that the model was successful in reducing nonemergency, scheduled, repetitive ambulance transport spending and total Medicare spending while maintaining the overall quality of and access to care. In comparison to groups of similar States, the model reduced nonemergency, scheduled, repetitive ambulance transport use by 72 percent and expenditures by 76 percent, for Medicare beneficiaries with end-stage renal disease (ESRD) and/or severe pressure ulcers in the model States, resulting in a reduction of approximately $750 million in expenditures. This decrease in nonemergency, scheduled, repetitive ambulance transport expenditures contributed to a 2.4 percent ($1 billion over the first 5 years of the model) decrease in total Medicare fee-for-service (FFS) expenditures among beneficiaries with ESRD and/or pressure ulcers relative to the comparison groups. Overall, the findings suggested that the model had few to no adverse effects on quality of, or access to, care.

On March 28, 2018, CMS' Chief Actuary certified that expansion of the model would reduce program spending under the Medicare program, thereby satisfying the requirements of section 1115A(c)(2) of the Act for expansion of the model. Based on the CMS Chief Actuary certification and the first Interim Evaluation Report, the HHS Secretary determined that the model met the statutory criteria for expansion under sections 1115A(c)(1) and (c)(3) of the Act. Therefore, on September 22, 2020, CMS announced that it would expand the model nationwide under section 1834(l)(16) of the Act.[417] The 8 participating States and the District of Columbia were transitioned to the national model on December 2, 2020. After a delay due to the COVID–19 public health emergency, HHS began expanding the model nationwide through multiple phases starting on December 1, 2021. As of August 1, 2022, the model is fully operational nationwide.

Inconsistent application of payments for medically necessary, nonemergent, repetitive, scheduled ambulance services has the potential to disproportionately and substantially impact communities of color, underserved communities (including rural communities), and modest-income beneficiaries. Further, these communities may disproportionately suffer from conditions for which nonemergent, repetitive, scheduled ambulance services are necessary, creating access to care issues with corresponding clinical complications. We believe that improving clarity in our regulatory provisions will have positive impacts on the health and well-being of beneficiaries. Therefore, we proposed and requested public comment on policy clarifications to ensure beneficiaries receive the care they need.

b. Legal Authorities

The legal authority for this provision is section 1861(s)(7) of the Act, which provides general authority for the ambulance benefit and grants the Secretary authority to prescribe regulations for the administration of the benefit.

2. Revision to § 410.40

We sought public comment on proposed language that clarifies documentation and medical necessity requirements for nonemergency, scheduled, repetitive ambulance services, by modifying § 410.40(e)(2)(ii).

Section 410.40 describes the Medicare Part B ambulance benefit, generally. Because medical necessity is a requirement of the statutory requirement at section 1861(s)(7) of the Act, the requirements for coverage are more fully explained in paragraph (e) of § 410.40, starting with general rules covering all Part B ambulance services, and the special rules that only apply to nonemergency, scheduled, repetitive ambulance services are situated in paragraph (e)(2). For the reasons discussed above, we proposed to modify existing language in § 410.40(e)(2)(ii) and add additional language to provide needed clarity and ensure consistent application of the nonemergency, scheduled, repetitive ambulance service benefit. We solicited comments on the proposal.

We proposed at § 410.40(e)(2)(ii) to retain the existing language stating that, in all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS (OMB control number 0938–0969). We proposed to maintain the language that states that the ambulance service must meet all program coverage criteria including vehicle and staffing requirements. We also proposed to maintain the language that states that a signed PCS does not alone demonstrate that transportation by ground ambulance was medically necessary. We proposed to clarify that the PCS, and additional documentation from the beneficiary's medical record, may be used to support a claim that transportation by ground ambulance is medically necessary. Further, we proposed to clarify that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a). Finally, we proposed to clarify that coverage includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

We received few comments on the proposed clarifications. Commenters were overwhelmingly supportive of the clarification proposed; however, commenters had some questions and suggestions. The following is a summary of the public comments received on the revisions to § 410.40 and our responses:

Comment: One commenter stated that the clarifications were critical for dialysis transport; however, they were concerned, stating that they did not want to be penalized for using forms with check boxes.

Response: We appreciate the commenters support. We did not propose and have not established new documentation requirements pertaining to forms and are only clarifying existing policies.

Comment: One commenter supported the clarifications; however, the commenter requested that we clarify that these changes only pertain the RSNAT prior authorization program. Further, the commenter wanted us to clarify what the ''additional medical record'' or the ''additional documentation'' should be and the specific data elements that prescribers should include.

Response: We decline to confine this regulatory clarification to the RSNAT prior authorization program, as there may be non-emergent, scheduled, repetitive ambulance transport services outside of that program that would be affected. To address the second point on

[415] *https://innovation.cms.gov/files/reports/rsnat-firstintevalrpt.pdf* and *https://innovation.cms.gov/data-andreports/2020/rsnat-secondintevalrpt.*

[416] *https://innovation.cms.gov/data-and-reports/2021/rsnat-finalevalrpt.*

[417] *https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide.*

clarification of terms, we did not propose to use the term ''additional medical record'' in the regulatory text. We did use the term ''additional documentation'' but did not propose a definition for that term. The data elements needed will vary depending upon the beneficiary's specific conditions and needs.

Comment: One commenter expressed concern about the clarifying language used in the proposal that states that the PCS does not, alone, demonstrate the medical necessity of transportation by ground ambulance. The commenter stated that this language seems to extend beyond the proposal addressing repetitive, scheduled, nonemergency ambulance transportation.

Response: We point out that the language cited is not new language and is contained in existing § 410.40(e)(2)(ii). When we proposed our clarifications to this section, we combined (i) and (ii). We did not change the substance of the language, simply the sentence order, and added the clarification cited in the proposal.

Comment: Another commenter questioned the PCS and additional documentation that must be provided to explain the beneficiary's need for transport by an ambulance. The commenter requested clarification regarding the use of the words ''may'' and ''must,'' stating their interpretation of the proposal is that the PCS and any additional documentation from the medical record is not required to be submitted, but can be included if the provider believes it could offer support of meeting medical necessity criteria. In addition, they interpret that ''the PCS and additional documentation *must* provide detailed explanations. . .'' to mean if or when a provider submits a PCS and any supporting documentation, that this is the specific information that Medicare Administrative Contractor (MAC) claim adjudicators will look for in verifying medical necessity criteria. Further, based on their understanding of the proposal as written, every claim submitted for reimbursement of nonemergency, scheduled, repetitive ambulance services will not require a PCS and additional documentation. The commenter stated if these were requirements, that this would be a burdensome task requiring operational changes, which they would not support.

Response: This proposal does not establish new obligations for documentation; rather, it merely clarifies existing requirements. We believe the commenter raises two distinct, but important questions: (1) whether the PCS and additional documentation must be prepared and retained for every non-emergency repetitive, scheduled ambulance service; and (2) whether such information needs to be *submitted with* every claim. Regarding whether the PCS and additional documentation must be prepared and retained, we refer the reader to § 410.40(e)(2)(i), where we state that Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if [emphasis added] the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished. In addition, our pre-proposal language and proposed regulatory language both reflect that the presence of a PCS *alone* is not sufficient to demonstrate medical necessity, and, therefore, must be supported by medical documentation.

We agree with the commenter's statement that the PCS and any additional documentation from the medical record is not required to be *submitted with* every claim, but must be provided upon request to support medical necessity and payment. In the commenters submission, they stated that they interpret that ''the PCS and additional documentation *must* provide detailed explanations. . .'' to mean if or when a provider submits a PCS and any supporting documentation, that this is the specific information Medicare Administrative Contractor (MAC) claim adjudicators will look for in verifying medical necessity criteria. We agree that, if requested, the MACs will review this information in determining medical necessity.

To address the commenter's understanding of the proposal, the commenter stated that they believe that every *claim submitted* for reimbursement of nonemergency, scheduled, repetitive ambulance services will not require a PCS and additional documentation. We agree that this information does not need to be *submitted* with every claim, but clarify that it must be retained, and submitted upon request. These requirements are consistent with current policy and operational practices, so they do not impose additional burdens on providers. We appreciate the commenter's questions and opportunity to clarify.

Comment: A commenter acknowledged support for our efforts to reduce policy inconsistencies and stated that much of the work to fulfill these requirements will not be performed by the ambulance suppliers, but, instead, will fall to the practitioner who orders the service. They urged CMS to be cognizant of the additional burden of these proposals and consider other ways that it can achieve these goals.

Response: As the commenter cited no specifics, we are not clear what additional burden the commenter believes would be imposed by virtue of this proposal. To clarify, we have not proposed to add any additional requirements and have only proposed to clarify existing requirements. There are no additional burdens associated with this policy clarification.

Comment: Two commenters supported the proposal, but asked CMS to amend § 410.40 to also authorize other practitioners, specifically nurse practitioners and physicians' assistants, to certify a patient's need for nonemergency, scheduled, repetitive ambulance services or transfers under EMTALA without physician consultation and cosignature.

Response: We appreciate the support of the proposal; however, the request to extend authorization to nurse practitioners and physicians' assistants is outside of the scope of this rule.

Comment: One commenter stated that Medicare needs to address the lack of coverage for an alternative, lower level of non-emergency transport and that CMS should ensure access to Medicaid NEMT for full and partial dual eligible beneficiaries.

Response: We appreciate these suggestions; however, these concerns are outside the scope of this rule, as the rule is focused on medical necessity requirements for nonemergency, scheduled, repetitive ambulance services.

Comment: One commenter expressed support for the RSNAT prior authorization model and this clarification to existing regulations; however, the commenter noted that CMS should reinvest these savings into EMS medicine by reimbursing physician oversight of EMS services.

Response: We thank the commenter for the suggestion; however, this is outside the scope of the rule, as the rule is focused on medical necessity requirements for nonemergency, scheduled, repetitive ambulance services.

Comment: Another commenter expressed support and urged CMS to work with the kidney care community to align on policy that can expand beneficiary access to non-emergency medical assistance benefits, including transportation options beyond ground ambulance services to dialysis facilities.

Response: We thank the commenter for the suggestion; however, this is outside the scope of the rule, as the rule is focused on medical necessity

requirements for nonemergency, scheduled, repetitive ambulance services.

As a result of, and in consideration of, the public comments, we are finalizing the revisions to § 410.40 as proposed.

J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment

1. Enrollment Process

a. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discussed in section III.J. of the proposed rule, we proposed several changes to our existing Medicare provider enrollment regulations. (We note that section III.K of the proposed rule addressed a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for the Medicare provider enrollment provisions we proposed:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

With respect to our Medicaid proposal in section III.K. of the proposed rule:

- Section 1902(kk)(3) of the Act,[418] as amended by section 6401(b) of the Affordable Care Act, which mandates that States require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.[419]
- Section 2107(e)(1) of the Act, as amended by section 6401(c) of the Affordable Care Act, which makes the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

[418] Because section 6401(b) of the Affordable Care Act erroneously added a duplicate section 1902(ii) of the Act, the Congress enacted a technical correction in the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) to redesignate section 1902(ii) of the Act as section 1902(kk) of the Act, a designation we will use in this final rule with comment period.

[419] Section 1304 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) added a new paragraph (j)(4) to section 1866 of the Act, thus re-designating the subsequent paragraphs. Accordingly, we are interpreting the reference in section 1902(kk)(3) of the Act to ''disclosure requirements established by the Secretary under section 1866(j)(4)'' of the Act to mean the disclosure requirements described in section 1866(j)(5) of the Act.

2. Medicare Enrollment Provisions

a. Expansion of Authority to Deny or Revoke Based on OIG Exclusion or Felony Conviction and Associated Definitions

i. OIG Exclusions

Under §§ 424.530(a)(2) and 424.535(a)(2), respectively, CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is excluded by the OIG. We proposed several changes related to these authorities.

First, we proposed to expand the categories of parties listed within these denial and revocation provisions to include: (1) managing organizations; and (2) officers and directors of the provider or supplier if the provider or supplier is a corporation. Consistent with sections 1124 and 1124A of the Act (and depending upon the specific enrollment transaction and provider type involved), these parties must be reported on the provider's or supplier's Form CMS–855 or, for Medicare diabetes prevention program (MDPP) suppliers, the Form CMS–20134. Although they are not explicitly listed in §§ 424.530(a)(2) and 424.535(a)(2), we have generally considered these individuals and entities to be parties that exercise managing control over the provider or supplier in a vein similar to managing employees. Accordingly, and to help prevent excluded managing organizations, officers, and directors from posing a program integrity threat to Medicare, we proposed to incorporate these persons and organizations within the two aforementioned regulatory paragraphs.

Second, we proposed to add new paragraphs to §§ 424.530(a)(2) and 424.535(a)(2) to clarify that the persons and entities listed in those two regulatory provisions include, but are not limited to, W–2 employees and contracted parties of the provider or supplier. We have traditionally applied §§ 424.530(a)(2) and 424.535(a)(2) to the individuals listed therein (such as supervising physicians) regardless of their W–2 status; this is consistent with the definition of ''managing employee'' in § 424.502, which does not exclude contracted personnel from its purview.

Pursuant to this change regarding contracted parties, we also proposed to:

- Redesignate the introductory paragraph of existing § 424.530(a)(2) as § 424.530(a)(2)(i).
- Redesignate current §§ 424.530(a)(2)(i) and (ii) as § 424.530(a)(2)(i)(A) and (B), respectively. The new paragraph concerning contracted personnel would be new § 424.530(a)(2)(ii).
- Make similar structural revisions to § 424.535(a)(2).

ii. Felony Convictions

Under §§ 424.530(a)(3) and 424.535(a)(3), respectively, CMS may deny or revoke enrollment if the provider or supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. We proposed to expand these two regulatory provisions to include therein managing organizations, officers, and directors. As previously explained, we are obligated to protect the Medicare program, the Trust Funds, and beneficiaries. As with exclusions, we are concerned that persons and entities that have engaged in felonious behavior could, through their association with the provider or supplier, present program integrity risks. Consequently, we believe that an expansion of §§ 424.530(a)(3) and 424.535(a)(3) is warranted.

We also proposed to add new paragraphs at §§ 424.530(a)(3)(iii) and 424.535(a)(3)(iv) clarifying that these two provisions apply to contracted parties, as well.

iii. Definitions

In light of our additions of ''managing organization,'' ''officer'', and ''director'' to the aforementioned denial and revocation provisions, we proposed to define these terms in § 424.502.

''Managing organization'' would mean an entity that exercises operational or managerial control over, or that directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement. We proposed to define ''officer'' as an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity. Since section 1124(a) of the Act requires the disclosure of officers if the entity is a corporation, we included the same reference to corporations in our proposed definition. In a similar context, we proposed to define ''director'' as a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. To further clarify this definition, however, we proposed that ''director'' includes any member of the corporation's governing body irrespective of the precise title of either the board or the member. This body could be a board of directors, board of trustees, or similar body, while a director can be merely a volunteer or ceremonial board member.

iv. Comments Received

The following is a summary of the public comments received on the foregoing proposals:

Comment: Several commenters supported our proposals to expand our denial and revocation authorities and to add definitions of ''managing organization,'' ''officer,'' and ''director''.

Response: We appreciate the commenters' support.

Comment: Regarding our proposal that the term ''director'' would include board members of non-profit corporations (NPCs), a commenter expressed concern about our longstanding requirement that volunteer board members of NPCs (including community-based NPCs) disclose their social security numbers (SSNs) on CMS enrollment applications.

Response: As we indicated in the proposed rule, we have long taken the position that sections 1124(a) and 1124A(a) of the Act require all directors (if the provider or supplier is a corporation) and their SSNs to be reported as part of the enrollment process. Given that sections 1124(a) and 1124A(a) of the Act make no distinction between for-profit and non-profit entities or between paid and voluntary board members, we believe that the SSNs of NPC board members must be disclosed.

Comment: Concerning our proposed changes to §§ 424.530(a)(2) and 424.535(a)(2), a commenter stated that the OIG does not always accurately identify fraud and that CMS should target actual, demonstrated fraud.

Response: We agree that targeting fraud is of utmost importance, but we emphasize that fraud is not the only activity that can threaten the Medicare program and its beneficiaries. To illustrate, section 1128 of the Act identifies numerous bases for OIG exclusions that do not necessarily involve health care fraud, such as a criminal conviction for the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. CMS also has more than 20 grounds for revocation of enrollment under § 424.535, many of which do not directly or necessarily pertain to fraudulent activity. Regardless, and given CMS' confidence in the thoroughness of the OIG's exclusion assessments, we believe that an OIG exclusion reflects conduct of sufficient severity that the application of §§ 424.530(a)(2) or 424.535(a)(2) in such cases is justified. We note further that an excluded party may appeal the exclusion pursuant to 42 CFR 402.214.

Comment: A commenter stated that in determining whether to deny or revoke enrollment based on a director's actions, CMS should consider whether the conduct occurred while the individual was serving as a director of the provider or supplier.

Response: Our central concern in the situation to which the commenter refers is the director's inappropriate conduct itself—and what it suggests about the director's and the associated provider or supplier's trustworthiness to interact with the Medicare program and its beneficiaries—rather than the specific forum in which it happened. For example, and as previously mentioned, §§ 424.530(a)(3) and 424.535(a)(3) apply to felony convictions occurring within the previous 10 years. In our experience in reviewing potential §§ 424.530(a)(3) and 424.535(a)(3) cases, many felonies involved activity that took place before the individual become a director or that was otherwise unrelated to his or her role as such. In this example, it is the felony itself, irrespective of the forum involved, that potentially threatens the integrity of the Medicare program.

As a result of the public comments, we are finalizing the revisions described in section III.J.2. of this final rule as proposed.

b. Reversal of Revocation or Denial

Sections 424.535(e) and 424.530(c) state that if a revocation or denial, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification. To maintain consistency with our aforementioned changes to §§ 424.530(a) and 424.535(a), we proposed to add managing organizations, officers, and directors to §§ 424.535(e) and 424.530(c).

The following is a summary of the public comments received on this proposal:

Comment: Several commenters expressed support for our proposed changes to §§ 424.535(e) and 424.530(c).

Response: We appreciate the commenters' support.

Comment: A commenter questioned whether the word ''terminates'' in §§ 424.535(e) and 424.530(c) means a termination of enrollment or a termination of the individual's or entity's relationship with the provider or supplier.

Response: It means a termination of the individual's or entity's business relationship with the provider or supplier.

As a result of the public comments, we are finalizing the revisions discussed in section III.J.2.b. of this final rule as proposed.

c. Medicare Revocation Based on Other Program Termination

Section 424.535(a)(12)(i) states, in part, that CMS can revoke enrollment if the provider or supplier is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any Federal health care program. However, under § 424.535(a)(12)(ii) revocation cannot occur unless and until the provider or supplier has exhausted all applicable appeal rights. Our position has always been that revocation under § 424.535(a)(12)(i) can ensue once the initial period to file an appeal has ended; that is, CMS need not wait until the expiration of every subsequent appellate period that would have applied had the provider or supplier appealed. To clarify this via rulemaking, we proposed to add the language ''or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal'' to the end of § 424.535(a)(12)(ii).

The following is a summary of the public comments received on this proposal:

Comment: Several commenters expressed support for our proposed change to § 424.535(a)(12)(ii).

Response: We appreciate the commenters' support.

Comment: A commenter expressed concern that the addition of our proposed language would shorten the period in which a provider or supplier can appeal a revocation of enrollment.

Response: Our proposed addition would not reduce the timeframe for filing an appeal of a revocation or otherwise affect appeal rights in any way. It merely clarifies that if no appeal is filed within the prescribed timeframe, the revocation becomes effective.

As a result of the public comments, we are finalizing the revisions discussed in section III.J.2.c as proposed.

d. Categorical Risk Designation—Ownership Changes and Adverse Actions

i. Background

Under the authority granted to us by section 6401(a) of the Affordable Care Act (which amended section 1866(j) to the Act), we established § 424.518 in a final rule with comment period entitled ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,'' which was published in the **Federal Register** on February 2, 2011 (76 FR 5862). Section 424.518 outlines levels of screening by which CMS and its MACs review initial applications, revalidation applications, and applications to add a practice location. These screening categories and requirements are based on a CMS assessment of the risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the risk that a certain provider or supplier type poses, the greater the scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three levels of screening in § 424.518: high, moderate, and limited. Irrespective of which level a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new location:

- Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
- Conducts State license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Furthermore, for those at the high screening level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals with a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all persons with a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are meant to correspond to the heightened risk involved.

There currently are only four provider or supplier types within the high categorical risk level under § 424.518(c)(1): newly/initially enrolling home health agencies (HHAs); newly/initially enrolling DMEPOS suppliers; newly/initially enrolling MDPP suppliers; and newly/initially enrolling opioid treatment programs (OTPs).

ii. Current Grounds for Risk Level Increase (or ''Bump Up'')

Under § 424.518(c)(3)(i) and (ii), CMS adjusts a particular provider's or supplier's screening level from ''limited'' or ''moderate'' to ''high'' if the provider or supplier:

- Has had a payment suspension within the previous 10 years;
- Has been excluded by the OIG;
- Has had its Medicare billing privileges revoked within the previous 10 years and is attempting to establish additional Medicare billing privileges by (i) enrolling as a new provider or supplier or (ii) adding a new practice location;
- Has been terminated or is otherwise precluded from billing Medicaid;
- Has been excluded from any Federal health care program; or
- Has been subject to any final adverse action (as defined at § 424.502) within the previous 10 years.

The general purpose of § 424.518(c)(3) is to ensure that providers and suppliers that have had certain adverse actions imposed against them are reviewed with a concomitant level of scrutiny.

iii. Analysis

As previously mentioned in this final rule, § 424.518 outlines screening requirements for initial enrollment applications, revalidation applications, and practice location additions. Yet it does not specifically address:

- Change of ownership (CHOW) applications under 42 CFR 489.18; or
- The reporting of a new owner when a formal § 489.18 CHOW is not involved (such as disclosing a new 10 percent owner per § 424.516(e)(1)).

Section 424.518's dearth of explicit applicability to these two situations effectively means that a high-risk level provider or supplier can have a new owner without the latter having to undergo the important scrutiny that fingerprint-based criminal background

checks furnish. In promulgating § 424.518 in 2011, we recognized the uniquely critical role that owners often play in the provider's or supplier's operations by restricting our fingerprinting requirement to such persons. To mandate the fingerprinting of owners with initial applications, revalidations, and new practice locations but not with the aforementioned two transactions that specifically focus on the disclosure of new owners would be both an inconsistency and a program integrity risk.

Concerning the risk-level elevation criteria in § 424.518(c)(3), there are numerous health care entities that have multiple enrollments under their organizational umbrella. Situations can arise where an organization with multiple enrollments has had an action described in § 424.518(c)(3) imposed against it or against one of its enrollments. Consider the following examples:

- Example 1—Entity Y has three separately enrolled physician groups (A, B, and C), each at the limited-risk level of categorical screening. Group C has just been revoked under § 424.535(a)(1) for non-compliance with enrollment requirements.
- Example 2—Organization Z has within its structure an enrolled HHA, an enrolled nurse practitioner group, and an enrolled independent diagnostic testing facility (IDTF). The organization itself has recently been convicted of a felony (which is identified as a final adverse action under § 424.502). All three of its enrollments are accordingly revoked.

The adverse actions described in these two examples fall within the scope of events that would trigger an increase in risk level under § 424.518 to ''high.'' There has been uncertainty among interested parties, particularly provider organizations with multiple enrollments, as to the extent of the risk-level elevation in these cases. That is, the issue is whether an adverse action imposed with respect to a particular enrollment applies strictly to said enrollment or also applies to all of the provider's or supplier's other enrollments, meaning that the screening level for these additional enrollments would, too, be raised to ''high.'' Under this latter approach, which has generally been our policy, the following would occur under aforementioned Examples 1 and 2:

- Example 1—All initial enrollment applications, revalidations, and additions of practice locations involving Group Practice A, B, or C (for instance, Group C sought to re-enroll in Medicare after the expiration of its reenrollment bar under § 424.535(c)) would be processed at the ''high'' level of categorical screening. In addition, if Entity Y sought to enroll new Group Practice D, the latter's initial application would be subject to the ''high'' screening category.
- Example 2—As with Example 1, all of Organization Z's enrollments would be elevated to ''high'' under § 424.518(c)(3). If any of the revoked providers and suppliers sought to reenroll in Medicare after their reenrollment bars expire, their enrollments would be processed at the high-risk level.

As discussed in the proposed rule, we believe the foregoing approach is warranted because we have historically viewed § 424.518(c)(3) as applying to the controlling provider or supplier at large and not necessarily being confined to one of its enrollments. The core consideration, in our view, is the risk that the behavior at issue poses to the Trust Funds and to beneficiary safety. Even if, for instance, a Medicaid termination occurred with only one of the entity's enrollments, this raises serious questions about the organization's oversight of the enrolled providers and suppliers under its control. We also noted in the proposed rule our belief that the overriding need to protect the Medicare program justifies heightened examination of the other enrollments within the organization's domain.

iv. Regulatory Revisions

Given the prior discussion and for reasons already outlined, we proposed the following changes to § 424.518.

First, the introductory paragraph of § 424.518 references initial applications, revalidation applications, and practice location additions as falling within § 424.518's purview. We proposed to add to this paragraph the following transactions: (1) change of ownership applications under § 489.18; and (2) the reporting of any new owner (regardless of ownership percentage) via a change of information or other enrollment transaction (such as a full or partial certified supplier ownership change) under Title 42.

Second, we proposed to clarify in § 424.518(c) that the provider and supplier types included therein—once enrolled—are subject to high-risk screening if they are submitting a § 489.18 change of ownership application or an application to report a new owner (as described in the previous paragraph). As a technical elucidation, we also proposed to change the language in paragraph (c)(1) that reads, ''CMS has designated the following home health agencies and suppliers of DMEPOS as ''high'' categorical risk'' to ''CMS has designated the following provider and supplier types as ''high'' categorical risk.'' This would merely clarify that certain providers and suppliers other than HHAs and DMEPOS suppliers (such as OTPs) fall within paragraph (c)(1).

Third, the introductory language at § 424.518(c)(3) states that CMS adjusts the screening level from limited or moderate to high if any of the previously cited adverse actions against the provider or supplier occur. To explain the extent of such adjustments, we proposed to add a new paragraph (c)(4). We proposed to state therein that any adjustment under paragraph (c)(3) would also apply to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the risk level under paragraph (c)(3) was originally raised.

The following is a summary of the public comments received on the foregoing proposals:

Comment: Several commenters questioned how our proposals concerning fingerprinting would impact providers and suppliers that are owned and operated by non-profit entities or by hedge funds. One commenter stated that if CMS intends to apply the fingerprinting requirement to non-profit providers and suppliers, CMS should undertake separate notice-and-comment rulemaking to explain how this process would work.

Response: We note two things. First, the fingerprinting requirement only applies to the fairly small number of providers and suppliers falling within the ''high'' screening level under § 424.518(c). It does not apply to all Medicare providers and suppliers. Second, and as has always been the case, only individuals who own a 5 percent or greater direct or indirect ownership interest in the provider or supplier need be fingerprinted; an entity itself cannot be fingerprinted. Accordingly, if a provider or supplier has no persons who fall within this category (for instance, all of its direct and indirect owners are organizations), fingerprinting is unnecessary. This same principle applies with respect to non-profit entities. Five percent or greater direct or indirect individual owners of all provider and supplier organizations, whether for-profit or non-profit, that fall within § 424.518(c) are subject to fingerprinting. There are no exceptions in § 424.518(c) for certain types of entities. However, § 424.518(c)'s

fingerprinting requirement does not apply if the organization has no individual owners. Accordingly, those non-profit entities that do not have such owners (and most non-profit entities do not) would not need to submit fingerprints under § 424.518(c).

Comment: A commenter requested that we revise proposed § 424.518(c)(4) to give MACs the discretion to make individual determinations as to whether a particular provider or supplier with the same LBN and TIN as the originally bumped-up provider or supplier should also be bumped-up.

Response: We respectfully disagree. As we explained in the proposed rule, we believe that the very close organizational nexus between these providers and suppliers requires a simultaneous increase in their risk levels.

Comment: A commenter opposed our proposed addition of ownership changes to the scope of § 424.518. The commenter focused on our aforementioned proposed introductory language regarding the reporting of a new owner ''regardless of the ownership percentage involved.'' The commenter appeared to interpret this to mean that providers and suppliers must now report to Medicare all ownership changes no matter how small the percentage.

Response: We respectfully believe that the commenter is misinterpreting our proposal. The term ''owner'' is defined in § 424.502 as any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier. This definition aligns with the reporting requirements for owners described in sections 1124 and 1124A of the Act. We did not propose to change these thresholds for disclosing new owners, and we do not believe the wording of our proposed change to § 424.518's introductory language indicates such an intent. The sole purpose of the caveat regarding ownership percentage is to clarify that the ownership change need not be, for instance, greater than 50 percent but can be as small as the minimum thresholds described in § 424.502's definition of owner.

Comment: Several commenters cautioned CMS against implementing proposed § 424.518(c)(4), as well as our expansion of § 424.518 to include ownership changes, until these provisions' potential impacts and burdens on providers, the MACs, and beneficiary access to care are assessed. They expressed particular concern about the burden on owners of multiple providers and suppliers. One commenter stated that because physician practices are often affiliated with health systems and other medical groups, proposed § 424.518(c)(4) could lead to unnecessarily enhanced screening of practices and their physicians, none of whom violated any laws; this, in turn, could delay care for beneficiaries. Considering the possible effects of this provision and the importance of alerting providers and suppliers thereof, this commenter recommended that CMS: (1) delay § 424.518(c)(4)'s implementation until July 1, 2023 at the earliest; and (2) monitor the provision's impact on the provider community and beneficiaries.

Response: We appreciate the commenters' concerns and emphasize that we carefully considered the possible impacts of these proposals. We estimated in the regulatory impact analysis of the proposed rule that less than 3,000 providers and suppliers per year would be affected by any of our proposed changes to § 424.518; we believe this number is extremely small when compared to the universe of over 2 million current Medicare providers and suppliers. Given this, the overall impact of these changes should be minimal, and we do not believe they will result in delays in enrollment application processing. We note that the fingerprinting requirement has existed for a decade, and CMS has not seen during this period any problems stemming therefrom regarding, for instance, patient access to care or application processing delays. Nonetheless, we will monitor the implementation of this provision for any potential, significant undue burdens.

Comment: A commenter expressed concern that our proposals would require the annual fingerprinting of owners of providers and suppliers in the high screening category.

Response: In terms of timing, fingerprinting of such owners is only required upon initial enrollment, revalidation, the addition of a practice location, and, as proposed, an ownership change as described in the introduction to § 424.518. Nothing in § 424.518 requires the annual submission of fingerprints.

As a result of the public comments, we are finalizing the revisions discussed in section III.J.2.d. of this final rule as proposed.

e. Categorical Risk Designation—Skilled Nursing Facilities (SNFs)

SNFs are currently in the limited-risk screening category under § 424.518. However, CMS in recent years has become increasingly concerned about certain problems within the SNF community, particularly potential and actual criminal behavior. Indeed, a specific concern raised in several government reports involves patient abuse. For instance, the United States Government Accountability Office (GAO) published an analysis on January 14, 2022 titled ''Health Care Capsule: Improving Nursing Home Quality and Information'' (GAO–22–105422). In this report, the GAO identified gaps in CMS' prior oversight of nursing homes that make it more difficult to prevent patient abuse. Another GAO report, titled ''Nursing Homes: Better Oversight Needed to Protect Residents from Abuse'' (GAO–19–433), was published in June 2019.[420] The study aimed to: (1) determine the trends and types of nursing home patient abuse in recent years; and (2) evaluate CMS' oversight that is intended to ensure residents are free from abuse. The report concluded, among other things, that patient abuse deficiencies found on State surveys more than doubled between 2013 and 2017.[421] It also noted inconsistencies as to when State survey abuse findings or allegations of abuse are referred to law enforcement.[422] The subject of background checks was also addressed. The GAO interviewed various interested parties and determined that nursing homes without adequate staff screening mechanisms (such as background checks) could result in hiring staff with histories of abuse.[423] It added that because ''staff screening through background checks and the nurse aide registry is not coordinated across the country, there are gaps that could enable individuals who committed crimes in one state to obtain employment at a nursing home in another state . . . . Staff from a nursing home we visited said the prevention of abuse 'starts with hiring the right staff' and noted the importance of conducting background checks and checking references for prospective employees.'' [424]

The OIG, too, has opined on this matter. In a September 2020 report titled, ''National Background Check Program for Long-Term Care Providers: Assessment of State Programs Concluded in 2019'' (OEI–07–20–00180), the OIG noted that patient abuse, patient neglect, and misappropriation of property have been detected as problems harmful to beneficiaries receiving long-term care. Somewhat akin to the previously mentioned June 2019 GAO report, the

[420] *https://www.gao.gov/assets/gao-19-433.pdf.*
[421] Ibid.
[422] Ibid., 42.
[423] Ibid., 29.
[424] Ibid., 31–32.

OIG stated that, per various studies, some nurse aides who were convicted of abuse, neglect, or theft had previous criminal convictions that could have been found through background checks of prospective employees.[425] The OIG added that such employee background checks can help protect long-term care beneficiaries.[426]

Our aforementioned concerns regarding problematic activity in the nursing home arena are not limited to patient abuse. We outlined in the proposed rule numerous recent cases that highlight issues regarding fraud or improper billing among nursing home owners or operators. The cases were as follows:

- In April 2019, a jury found an owner of nursing homes and assisted living facilities in Florida guilty of 20 charges related to health care fraud. The United States Department of Justice (DOJ) noted that the owner's actions were part of the largest health care fraud scheme ever charged by the DOJ. It involved over $1.3 billion in fraudulent claims to Medicare and Medicaid for services that were not provided, were not medically necessary, or were procured through the payment of kickbacks.[427]
- In July 2021, a Virginia nursing home operator was sentenced to 2 years in prison for defrauding Medicaid after submitting more than $188,000 in false claims.[428]
- In March 2022, the DOJ settled a False Claims Act case with a Georgia nursing home for $400,000. The matter involved allegations that the nursing home deliberately billed Medicare for services that were not reasonable, necessary, or skilled.[429]
- A nursing home entity based in Georgia (which operates nursing homes across the country) agreed in May 2021 to pay $11.2 million to resolve allegations that it: (1) violated the False Claims Act by causing its nursing homes to bill the Medicare program for rehabilitation therapy services that were not reasonable, necessary or skilled; and (2) billed Medicare and Medicaid for substandard skilled nursing services.[430]
- In January 2020, a New York man pled guilty in federal court to embezzlement and tax offenses related to his operation of nursing homes in Connecticut.[431]
- Also in 2020, a Pennsylvania nursing home chain and its related companies agreed to pay more than $15 million to settle claims that the chain provided medically unnecessary rehabilitation therapy to residents in order to meet revenue goals, instead of clinical needs.[432]
- A California corporation and 27 affiliated nursing homes in the State agreed in July 2020 to resolve allegations that they violated the False Claims Act by submitting false claims to Medicare for rehabilitation therapy services that were not reasonable or necessary.[433]
- In June 2019, four Illinois nursing facilities and a physical therapy center agreed to pay $9.7 million to resolve civil allegations that they violated the False Claims Act by providing unnecessary services to increase Medicare payments.[434]
- A Tennessee-based nursing home chain agreed in February 2018 to pay more than $18 million in allowed claims to resolve a lawsuit brought against them by the DOJ and the State of Tennessee for billing the Medicare and Medicaid programs for substandard nursing home services.[435]

As we explained in the proposed rule and reiterate here, the disconcerting number of recent cases involving fraud and improper billing by nursing home owners and operators, as well as the OIG and GAO reports concerning patient abuse at the nursing homes these individuals oversee, requires, in our view, strengthened protections of the Medicare program and its nursing home beneficiaries. CMS has an obligation to safeguard the integrity of both the Trust Funds and the services that nursing home patients receive. Financial malfeasance and beneficiary abuse are unacceptable, and we believe that more closely scrutinizing the owners of nursing homes through our existing criminal background checks under § 424.518 can help detect potential criminal or abusive behavior at the nursing home before it begins. We cited the following illustrations in the proposed rule:

- If a SNF owner is found through a fingerprint-based background review to have been convicted of battery, sexual assault, or other serious crime, this could raise significant concerns as to whether this conduct will be repeated during the owner's oversight or management of the facility.
- A SNF owner with an embezzlement conviction might be more inclined to divert the SNF's funds to his personal use (and away from monies otherwise intended for beneficiary care) than a different owner; he or she might also be more willing to tolerate malfeasance in the nursing home or to hire persons with criminal records.

As two of the aforementioned OIG and GAO reports indicated regarding nursing home employees, background reviews can prove helpful in screening individuals for possible problematic behavior. We, too, have found our fingerprint-based criminal background checks of great assistance in detecting felonious behavior by the owners of high-risk providers and suppliers.

Given the prevalence of recent unacceptable behavior by nursing home overseers and the OIG and GAO-documented instances of nursing home beneficiary abuse, we proposed to revise § 424.518 to move initially enrolling SNFs into the high-level of categorical screening; revalidating SNFs would be subject to moderate risk-level screening. This would help us detect parties potentially posing a risk of fraud, waste, or abuse and, with this, the threat of patient abuse. In addition, we stated in the proposed rule that our proposal would assist in protecting Medicare Trust Fund dollars and beneficiaries and aligns with the Biden-Harris Administration's initiative to improve nursing home accountability.[436]

The following is a summary of the public comments received on this proposal:

Comment: Several commenters expressed support for our proposal. They concurred with our concerns about patient abuse by nursing home staff as well as fraud and improper billing by nursing home owners and

[425] OEI–07–20–00180, p. 1. Such employee background checks are conducted pursuant to the National Background Check Program, enacted by legislation in 2010. This is a voluntary grant program for States to develop systems to conduct Federal and State background checks. See *https://www.bgcheckinfo.org/*.

[426] Ibid.

[427] *https://www.justice.gov/opa/pr/south-florida-health-care-facility-owner-convicted-role-largest-health-care-fraud-scheme-ever*.

[428] *https://www.justice.gov/usao-edva/pr/operator-residential-nursing-facility-sentenced-health-care-fraud*.

[429] *https://www.justice.gov/usao-ndga/pr/england-associates-lp-dba-new-london-health-center-pays-40000000-resolve-false-claims#:*.

[430] *https://www.justice.gov/opa/pr/savaseniorcare-llc-agrees-pay-112-million-resolve-false-claims-act-allegations*.

[431] *https://www.justice.gov/usao-ct/pr/nursing-home-operator-pleads-guilty-embezzlement-and-tax-offenses*.

[432] *https://www.justice.gov/usao-edpa/pr/pennsylvania-nursing-home-chain-pay-155-million-settle-false-claims-act-allegations*.

[433] *https://www.justice.gov/usao-cdca/pr/27-skilled-nursing-facilities-controlled-longwood-management-corp-pay-167-million*.

[434] *https://www.justice.gov/usao-ndil/pr/chicago-area-physical-therapy-center-and-4-nursing-facilities-pay-97-million-resolve*.

[435] *https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability*.

[436] See *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/*.

operators. One commenter stated that the multiple cases of patient abuse and financial fraud we cited in the proposed rule justified our proposed change.

Response: We appreciate the commenters' support.

Comment: A commenter expressed concern about our statement in the proposed rule regarding felonious activity by nursing home owners, in which we emphasized that §§ 424.530(a)(3) and 424.535(a)(3) are discretionary provisions that we are not required to apply in every case. The commenter contended that this is a loophole that could endanger Medicare beneficiaries and the Trust Funds and recommended that CMS remove the discretionary aspect of §§ 424.530(a)(3) and 424.535(a)(3).

Response: We appreciate this concern, but respectfully disagree with the commenter's suggestion. Every potential §§ 424.530(a)(3) and 424.535(a)(3) situation is different and, to ensure a careful review of the matter, we must consider all of the facts and circumstances involved.

Comment: Several commenters urged CMS to: (1) more closely examine the accuracy of information that SNFs furnish on their enrollment applications; and (2) deny or revoke their Medicare enrollment under, §§ 424.530(a)(4)) or 424.535(a)(4)), respectively, if they provide false or misleading information on their application. Citing various media reports, a commenter stated that nursing home owners: (1) often create new companies when they seek to purchase a SNF so that there is no ''record'' for the State to review; and (2) use multiple names in order to conceal their actual ownership of nursing facilities. Another commenter (also citing news reports) stated that actions such as creating new companies and using multiple names can decrease the transparency of SNF owners and shield them from accountability for wrongdoing.

Response: As the commenters noted, we can deny or revoke enrollment under §§ 424.530(a)(4)) or 424.535(a)(4), respectively, if a provider or supplier submits false or misleading data on its enrollment application. We take very seriously the importance of attempting to ensure the accuracy of submitted enrollment data. We will continue to do so and, as circumstances warrant, take action under §§ 424.530(a)(4)) or 424.535(a)(4).

Comment: A commenter recommended that, pursuant to § 424.535(a)(8)(ii), CMS revoke the enrollments of SNFs that engage in a pattern or practice of submitting claims that fail to meet Medicare requirements.

Response: We appreciate the commenter's concern. As with the submission of accurate enrollment information, providers and suppliers (including SNFs) have an obligation to submit claims that comply with Medicare requirements. Should circumstances warrant, we will exercise our revocation authority under § 424.535(a)(8)(ii).

Comment: A commenter stated that SNFs that have settled False Claims Act cases with the United States for fraudulently billing the Medicare program should be revoked from Medicare, even if the SNF did not formally admit responsibility for the fraudulent billing.

Response: We appreciate the commenter's concern and agree that it is important to undertake program integrity measures, consistent with our statutory and regulatory authority, with respect to providers and suppliers that engage or could engage in improper conduct.

Comment: A commenter contended that CMS lacks the statutory authority for its proposal to move SNFs to the high screening category. Citing language that CMS used in the previously mentioned February 2, 2011 final rule as support for its contention, the commenter stated that: (1) CMS' statutory authority under section 1866(j)(1)(A) of the Act regarding provider enrollment screening is restricted to matters involving fiscal program integrity and does not extend to the monitoring of provider and supplier conditions of participation (CoPs) (such as the SNF CoPs in 42 CFR part 483); and (2) quality of care is unrelated to the establishment of screening levels for providers and suppliers.

Response: Our proposal was not intended to use the increase in the screening level of SNFs to detect compliance with the SNF CoPs under 42 CFR part 483. Rather, it was to more closely monitor SNFs for having engaged in criminal activity that threatens Medicare beneficiaries and the Trust Funds. For instance, the OIG and GAO reports we cited discussed the abuse of patients at nursing homes, which can certainly involve potential criminal behavior; indeed, section 1128(a)(2) of the Act requires the Secretary to exclude from participation in any federal health care program an individual or entity that has been convicted of a criminal offense relating to the neglect or abuse of patients in connection with the delivery of a health care item or service. We also cited numerous instances of improper conduct, such as fraudulent billing, by nursing home owners. Moreover, we noted in the introductory paragraph of this rule's preamble discussion our concerns about potential and actual criminal conduct in nursing homes; no mention was made therein of quality of care. Although we referenced later in the proposed rule the Biden-Harris Administration's initiative regarding SNF quality of care and our proposal's role in it, this did not negate the proposal's fundamental emphasis on program integrity, a matter directly related to preventing parties that have engaged in criminal activity from entering the Medicare program. We believe such prevention falls squarely within the authority granted to the Secretary under section 1866(j)(1)(A) of the Act.

Comment: A commenter contended that sections 1102, 1871, 1902(kk)(3), and 2107(e)(1) of the Act, which we cited as authorities for our provider enrollment provisions, constitute insufficient legal bases for our SNF proposal or for taking measures to halt patient abuse by SNF employees. The commenter stated that: (1) sections 1102 and 1871 of the Act address general requirements for the Secretary to provide impact analyses and regulation promulgation requirements for the Medicare program; and (2) sections 1902(kk)(3) and 2107(e)(1) of the Act are merely conforming provisions designed to align the Medicaid and CHIP provider enrollment screening processes with the section 1866(j)(1)(A) Medicare screening provisions. The commenter stated that if CMS wishes to propose regulations addressing patient harm, it should use a different statutory authority.

Response: We would like to note that, we did not rely upon any of these four statutory provisions as authority for our SNF proposal; these were used as authorities for some of our other proposals. We instead relied upon section 1866(j) of the Act. Our references to patient abuse in the proposed rule were merely examples of potential criminal conduct that have come to our attention. We cited other types of improper behavior, too, such as fraudulent billing. We reiterate that the SNF proposal's focus went well beyond patient abuse to include any form of criminal activity that can jeopardize Medicare beneficiaries and the Trust Funds. Congress explicitly authorized the Secretary in section 1866(j)(2)(B)(ii) of the Act to use fingerprinting and criminal background checks as part of the screening process. We believe this underscores the fact that section 1866(j) of the Act permits us to screen for prior criminal activity regardless of whether it

involved patient abuse, fraudulent billing, or other nefarious conduct.

Comment: A commenter stated that none of the OIG or GAO reports CMS mentioned in the proposed rule recommended that CMS increase the risk level of SNFs under § 424.518 to address, for example, patient abuse; nor, the commenter added, has the DOJ urged CMS to do so. The commenter cited this as evidence that our proposal is unnecessary.

Response: We respectfully disagree with the commenter. We have undertaken many program integrity initiatives over the years on our own volition without prior prompting from the OIG, GAO, or the DOJ, and we previously outlined evidence (including OIG and GAO findings) in support of our proposal and explained why we believe it is necessary. Indeed, we must be able to rapidly respond to payment safeguard challenges as they arise and cannot wait (and are not required by law to wait) until a law enforcement or other government body recommends that we do so.

Comment: A commenter stated that our proposal is unnecessary because SNFs already undergo very extensive vetting before being able to participate in Medicare. This includes, but is not limited to: (1) furnishing detailed information on the enrollment application regarding the SNF's owners and managing employees and any final adverse actions (as that term is defined in § 424.502); and (2) undergoing the survey and certification process. The commenter added that CMS currently has measures in place to detect fraudulent behavior, such as improved data analytics and CMS' Targeted Probe and Educate Program, which addresses claim submission error rates. Using these and similar mechanisms, CMS should narrow its program integrity focus towards specific areas of vulnerability involving all provider and supplier types rather than apply an across-the-board fingerprinting requirement to SNFs. The commenter believes this would be a better use of CMS' resources.

Response: We sincerely appreciate the commenter's concern. However, we note that certain other provider and supplier types also undergo considerable vetting but are still subject to the enhanced scrutiny of the high screening category. To illustrate, HHAs must report the same information as SNFs on the enrollment application, undergo a survey, and meet capitalization requirements under § 489.28 with which no other provider or supplier type must comply. Although organizational DMEPOS suppliers do not undergo a survey, they must (unless exempted) be accredited under § 424.58, have a surety bond under § 424.57(d), and meet 30 different provider enrollment supplier standards in § 424.57(c). In addition, OTPs must be certified (and are subject to strict oversight) by HHS' Federal Substance Abuse and Mental Health Services Administration. All of these provider and supplier types also receive site visits under § 424.518, to which SNFs are not presently subject. The purpose of the high screening category is to review certain provider and supplier types presenting a heightened risk of fraud, waste, abuse above and beyond the normal screening that other provider and supplier types receive. In our view, merely because a provider or supplier already receives stringent review as part of the enrollment and/or certification processes does not mean that additional screening is never needed.

Comment: A commenter cited language in the aforementioned February 2, 2011 final rule whereby CMS states that fingerprinting will assist CMS ''in determining whether individuals submitted a complete and truthful Medicare enrollment application and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges.'' The commenter seemingly interpreted this to mean that the principal purpose of fingerprinting is to verify whether the provider or supplier was truthful on its application regarding its adverse legal history. The commenter stated that none of the criminal or civil cases CMS mentioned in the proposed rule indicated that the nursing facility misrepresented ownership or final adverse action information on any Medicare enrollment application. The commenter contended that because CMS presented no evidence that SNFs are historically untruthful on their applications, there is no basis to subject their owners to fingerprinting.

Response: We respectfully disagree with the commenter's apparent interpretation. The main purpose of fingerprinting has always been to check the provider's or supplier's criminal background with the FBI aside from whatever data the provider or supplier furnished on the application. Put more simply, the core objective is to assess whether a criminal history exists and not whether the provider or supplier accurately disclosed this data on the application. We note that the last clause of the above-quoted language states, ''and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges.'' This clause does not pertain to information accuracy but stresses the importance of fingerprinting in assessing enrollment eligibility as a whole. Moreover, we did not cite potential untruthfulness on the application as a factor when we included OTPs and MDPPs in the high screening category and hence required their owners to be fingerprinted; this is because our concerns focused on verifying possible criminal conduct by the owners of these two provider and supplier types irrespective of the data furnished on the application.

Comment: A commenter stated that CMS, in citing various criminal and civil cases against SNF owners and operators in the proposal rule, failed to note that the majority of these cases involved: (1) allegations related to a prior (and, the commenter stated, problematic) SNF payment model that has not existed since September 2019; and (2) settlements without any admission of guilt. Furthermore, the commenter stated that none of the cases demonstrate Medicare vulnerabilities under the current SNF payment model and that basing an increase in the SNF screening level on a defunct model would depart from CMS' previous rulemaking efforts regarding screening level classification.

Response: We believe that the payment model under which improper conduct occurs is far less important than the conduct itself. Providers and suppliers are obligated to abide by Medicare requirements regardless of the mechanism by which they are paid. We cannot disregard improper activity merely because it happened under a former payment system. In addition, to the extent the settlements in question did not (as part of the agreement) include an official admission of wrongdoing, the DOJ in the associated press releases nonetheless outlined the improper activities that were involved, conduct that we found extremely concerning. In our view, we would be derelict in our duty to protect the Medicare program from fraud, waste, and abuse if we simply ignored them.

Comment: A commenter noted that CMS cited two examples in the proposed rule of where prior criminal activity by SNF owners and operators could later result in patient abuse or other criminal conduct. The commenter stated that CMS identified no instances where this has actually happened. In addition, the commenter stated that CMS did not explain how fingerprinting would have prevented: (1) the patient abuse referenced in the aforementioned June 2019 OIG report and the September 2020 GAO report; or (2) any of the conduct outlined in the previously

mentioned DOJ criminal and civil cases or have detected any prior criminal convictions, since there was no indication that the involved parties had any. The commenter maintained that the cited DOJ cases, either individually or taken as a whole, do not justify moving SNFs to the high screening level, with the commenter adding that two of the cases did not even involve improper billing at all but rather: (1) the forging of the signature of a nurse whom the nursing home no longer employed; and (2) falsification of employee records.

Response: The two examples the commenter references were merely intended to help interested parties understand how certain criminal conduct could conceivably result in future improper activity. They were for illustrative purposes only.

As for the aforementioned OIG and GAO reports, these were cited to underscore the prevalence of patient abuse in nursing homes and the benefits of criminal background checks in potentially preventing it. Although the reports focused on patient harm by SNF staff, we believe their conclusion that background checks can help detect prior criminal activity can be equally applied to SNF owners and, by extension, our proposal. Simply because SNF owners were not specifically referenced in these reports does not negate the importance of the OIG's and GAO's findings regarding the general value of criminal background reviews in stemming patient abuse.

Concerning the above-referenced DOJ criminal cases, we emphasize that fingerprinting is not principally intended to actively prevent an individual from committing a felony. Instead, the aim is to keep persons who have already committed one from entering the Medicare program as an owner so as to eliminate the potential risk to Medicare and its beneficiaries that their criminal background might pose. If an individual who was convicted in one of these two criminal cases later attempted to become an owner of a Medicare-enrolling or enrolled SNF, fingerprinting would detect his or her criminal background.

Regarding the DOJ civil cases we cited, we reiterate that our primary concern from a program integrity perspective is the improper conduct itself rather than the specific means by which the DOJ sought to address it (that is, via a criminal case or a civil action). Depending on the precise circumstances of the case and the statutory provisions potentially implicated, fraudulent or otherwise improper billing can indeed involve criminal activity. We cannot ignore the risk that such behavior poses to the Medicare program, and it is important to have the ability via fingerprinting to discover it (to the extent it resulted in a criminal conviction).

Finally, with respect to the two cases involving forged signatures and falsified employee records, we again mention our authority under §§ 424.530(a)(3)) and 424.535(a)(3) to deny or revoke enrollment for any felony conviction within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. The conviction need not be for fraudulent billing or activity related to Medicare but can involve, for example, a crime against an individual (such as rape or assault) or a financial crime like embezzlement, income tax evasion, or insurance fraud. Felonies of any type are of concern to us, and, as already discussed, fingerprinting has proven useful in preventing owners with such backgrounds from entering the Medicare program.

Comment: A commenter stated that requiring site visits for initially enrolling and revalidating SNFs would be redundant and unnecessary for several reasons. First, SNFs are already subject to a survey as part of the certification process. Second, site visits are more appropriate for provider and supplier types that can quickly shift their practice locations and places of business than for the fixed, brick-and-mortar locations that SNFs generally have and which tend to be subject to stricter Federal and State scrutiny. In support of this statement, the commenter cited CMS statements in the February 2, 2011 final rule that the commenter believes is evidence that detecting such ''fly-by-night'' operations was and remains CMS' main motivation for site visits. Third, the commenter stated that SNF site visits would be an undue expenditure of time and resources given, again, the survey process and other stringent requirements to which SNFs must adhere. Fourth, in lieu of performing SNF site visits in the instances described in § 424.518, CMS should use its authority under § 424.517 to conduct them merely on an as-needed basis.

Response: We mentioned in the February 2, 2011 final rule that site visits were designed to ascertain whether the provider and supplier was: (1) located where it reported itself to be; and (2) a legitimate business. We noted our belief that site visits would be particularly useful for HHAs and DMEPOS suppliers given their history of heightened Medicare program risk and, as the commenter noted, their ability to switch locations more expeditiously than certain other provider and supplier types. Nonetheless, we assigned some of these other provider and supplier types to the moderate screening category, which, as already mentioned, requires a site visit. These included brick-and-mortar providers such as hospices, comprehensive outpatient rehabilitation facilities, and community mental health centers, each of which, like SNFs (and, for that matter, HHAs), undergo a survey; too, although OTPs are not surveyed, they have fixed locations, sometimes in affiliation with (or even as part of) a hospital. The above-referenced statements in the February 2, 2011 final rule were never intended to restrict CMS' authority to conduct site visits upon initial enrollment, revalidation, etc., to providers and suppliers capable of rapidly shifting locations and/or that do not undergo surveys. In a similar vein, and with respect to providers and suppliers in the moderate and high screening categories, § 424.517 was never meant to serve as a substitute for the site visits required under these categories but to supplement them. To illustrate, suppose CMS receives information 1 year after a provider revalidated its enrollment but well before its next revalidation due date that it has relocated without notifying CMS. The flexibility afforded by § 424.517 would enable CMS to perform a site visit even though none of the enrollment transactions discussed in § 424.518 (such as revalidation or, as we proposed, an ownership change) are involved.

We have not found site visits, including those of fixed locations that receive surveys, to be an unwarranted expenditure of resources. To the contrary, we deem them a crucial means of verifying a provider's or supplier's location (and that, among other things, the location is or remains operational) that is less intrusive than a comprehensive survey that ascertains compliance with Medicare CoPs or conditions of coverage. Even if a survey has very recently been performed, a follow-up site visit helps confirm that the provider did not move after the survey; this is an important consideration given the need to ensure the continued accuracy of the provider's enrollment information so that Medicare payments are made correctly.

As a result of the public comments, we are finalizing the revisions discussed in section III.J.2.e. of this final rule as proposed.

f. DMEPOS Payment Denial Based on Lack of Required Licensure

In comparison to many other provider and supplier types, DMEPOS suppliers have long presented to the Medicare program an elevated risk of fraud, waste, and abuse. Recognizing this, CMS over the years has established particularly stringent requirements with which DMEPOS suppliers must comply to enroll and maintain enrollment in Medicare, some of which we previously mentioned in this section III.J (for instance, the need to obtain and maintain a surety bond). To illustrate, § 424.57(b) contains five conditions of payment that DMEPOS suppliers must meet to receive payment. These include, for example: (1) submission of a completed application to enroll in Medicare; and (2) furnishing a DMEPOS item only on or after the date CMS issued the supplier a billing number. Noncompliance with any DMEPOS condition of payment in § 424.57(b) can result in a revocation under § 424.57(e)(1). In addition, § 424.57(c) lists 30 enrollment standards to which DMEPOS suppliers must adhere at all times. Should the supplier fail to meet any of them, revocation under § 424.57(e)(1) is warranted.

One such enrollment standard, codified in § 424.57(c)(1)(ii)(A), provides that if the State requires licensure to furnish certain items or services, the DMEPOS supplier must be licensed to provide the item or service. We have encountered situations where an unlicensed DMEPOS supplier furnishes items for an extended period. The supplier then terminates its enrollment or CMS revokes the supplier's enrollment under § 424.57(e)(1) effective 30 days after the DMEPOS supplier is sent notice of the revocation per § 405.874. Tens of thousands of Medicare dollars were placed at great risk because the supplier was furnishing items and services while unlicensed up to the point of its termination of enrollment. To address this vulnerability, we proposed an additional condition of payment in new paragraph (b)(6) of § 424.57. This condition would state that to receive payment for a furnished DMEPOS item or service, the supplier must have been in compliance with all conditions of payment in § 424.57(b) as well as with § 424.57(c)(1)(ii)(A) at the time the item or service was provided. We cited section 1834(j)(1)(B)(ii)(I) of the Act as authority for our proposal.

The following is a summary of the public comments received on this proposal:

Comment: Several commenters expressed support for our proposal.

Response: We appreciate the commenters' support.

Comment: Although supportive of our proposal, one commenter stated that beneficiaries must be protected against any responsibility for payment if the DMEPOS supplier's claim is denied due to a lack of licensure.

Response: As stated in § 424.555(b), no payment may be made for otherwise Medicare-covered items or services furnished to a Medicare beneficiary by a provider or supplier if the provider's or supplier's billing privileges are deactivated, denied, or revoked; moreover, the beneficiary under § 424.555(b) has no financial liability or responsibility for expenses in such cases. Since a DMEPOS supplier that does not meet licensure requirements is revoked from Medicare, the beneficiary protections described in § 424.555(b) would apply in the situation the commenter describes.

As a result of the public comments, we are finalizing the revision discussed in section III.J.2.f. of this final rule as proposed.

K. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

On September 10, 2019, we published a final rule with comment period in the **Federal Register** titled ''Program Integrity Enhancements to the Provider Enrollment Process'' (84 FR 47794). Several provisions therein implemented section 1866(j)(5) of the Act. Section 1866(j)(5)(A) of the Act requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose any current or previous direct or indirect affiliation with a provider or supplier that—(1) has uncollected debt; (2) has been or is subject to a payment suspension under a Federal health care program; (3) has been or is excluded by the OIG from Medicare, Medicaid, and CHIP; or (4) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked. Under section 1866(j)(5)(B) of the Act, the Secretary may deny enrollment based on such an affiliation if the Secretary determines that the affiliation poses an undue risk of fraud, waste, or abuse.

The above-mentioned statutory requirements were implemented in §§ 424.502 and 424.519 with respect to Medicare enrollment and 42 CFR 455.101 and 455.107 for Medicaid and CHIP enrollment. The general purpose of the affiliation disclosure requirement is to help combat fraud, waste, and abuse by enabling CMS and the States to: (1) better track certain current and past relationships between and among different providers and suppliers; and (2) identify and take action on affiliations among providers and suppliers that pose an undue risk to Medicare, Medicaid, or CHIP.

In terms of the scope and timing of the disclosure requirement, section 1866(j)(5)(A) of the Act states that providers and suppliers submitting an application for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP must make the disclosures in a form and manner and at such time as determined by the Secretary. Based in part on concerns about the potential burden on the provider community in disclosing affiliations on every initial and revalidation application (and pursuant to the aforementioned statutory authorization regarding the form, manner, and timing for submitting disclosures), current regulations outline a ''phased in'' approach to implementing the disclosure requirements, pending further rulemaking. For Medicare enrollment, § 424.519(b) states that providers and suppliers must submit affiliation disclosures upon a CMS request. CMS will make these requests when it determines that an initially enrolling or revalidating provider or supplier may have at least one affiliation meeting certain criteria specified in the regulation. For Medicaid and CHIP enrollments, § 455.107(b) requires each State, in consultation with CMS, to select one of the following two options for implementing the disclosure requirement:

- Under Option #1, all providers that are not enrolled in Medicare but are initially enrolling in Medicaid or CHIP or revalidating their Medicaid or CHIP enrollment information must disclose their affiliations.
- Under Option #2, providers that are not enrolled in Medicare but are initially enrolling in Medicaid or CHIP or revalidating their Medicaid or CHIP enrollment information must disclose their affiliations only upon request from the State. (The State will make the request when, in consultation with CMS, it has determined that the initially enrolling or revalidating provider may have at least one affiliation meeting certain criteria specified in the regulation.)

Existing § 455.107(b)(1)(ii) holds that the State cannot change options once its selection has been made. Our concern at the time of issuing § 455.107(b) was that switching options after one of them is implemented could lead to logistical and administrative complications and,

perhaps, confusion in the provider community as to what the State requires. Yet after consultations with the States and after analyzing data regarding the submission of affiliation disclosures to date, we do not believe § 455.107(b)(1)(ii) need be so restrictive. A number of States are seeking greater discretion in their operationalization of § 455.107(b), and we concur (as explained in the proposed rule) that increased flexibility is warranted. Accordingly, we proposed to revise § 455.107(b)(1)(ii) such that a State may, in consultation with CMS, change its selection under § 455.107(b) (after it has been made) from § 455.107(b)(2)(ii) to § 455.107(b)(2)(i). However, we noted that we would not permit a change from § 455.107(b)(2)(i) to § 455.107(b)(2)(ii). This is because the former option more thoroughly implements section 1866(j)(5)(A) and thus furnishes greater program integrity protections by requiring all enrolling or revalidating providers to disclose affiliations; section § 455.107(b)(2)(ii) requires disclosure in more limited circumstances.

The following is a summary of the public comments received on our proposal:

Comment: Several commenters expressed support for our proposal.

Response: We appreciate the commenters' support.

As a result of the public comments, we are finalizing our revision as proposed.

L. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

In the CY 2021 PFS final rule and CY 2022 PFS final rule, we finalized policies for the EPCS requirement specified in section 2003 of the SUPPORT Act (Pub. L. 115–271, enacted October 24, 2018). We refer readers to 86 FR 65361 through 65370 for the complete details of the statutory requirements and those finalized policies. Specifically, in the CY 2022 PFS final rule, we finalized multiple proposals related to EPCS. First, we finalized our proposal to extend the date of compliance actions to no earlier than January 1, 2023, and for prescribers writing Part D controlled substances prescriptions for beneficiaries in long-term care (LTC) facilities, we extended the date on or after which we will pursue compliance actions from January 1, 2022 to January 1, 2025 (86 FR 65364 and 65365). Second, we finalized our proposal to require prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366). Third, we finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369): (1) we amended § 423.160(a)(5) by adding paragraph (a)(5)(i), which is the exception listed in section 1860D–4(e)(7)(B)(i) of the Act, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity; (2) we amended § 423.160(a)(5) by adding paragraph (a)(5)(ii), which created an exception for prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using prescription drug event (PDE) claims data as of December 31st of the preceding year; (3) we amended § 423.160(a)(5) by adding paragraph (a)(5)(iii) to create an exception for prescribers located in the geographic area of an emergency or disaster declared by a Federal, State or local government entity; and (4) we amended § 423.160(a)(5) by adding paragraph (a)(5)(iv) to create an exception for prescribers who have received a CMS-approved waiver because the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control, respectively. We did not adopt exemptions for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits, or for prescribers issuing prescriptions for individuals enrolled in hospice. Finally, we finalized our proposal to limit compliance actions with respect to compliance from January 1, 2023, through December 31, 2023, to a non-compliance letter (now referred to as non-compliance notice) sent to prescribers that we believe are violating the EPCS requirement (86 FR 65370). Moving forward, we will refer to the letters CMS sends as the only non-compliance action as non-compliance ''notices'' to clarify that the compliance notification will not always be sent via a physical letter and can be sent via email, as discussed in the Timing for Issuing Non-compliance Notices section.

2. Evaluation of Compliance

In the CY 2022 PFS final rule, we discussed the EPCS policy, exceptions, and a compliance threshold. Specifically, we stated that starting in CY 2023, we would begin initial EPCS compliance actions (86 FR 65363). We noted that we believe it is important to provide a general timeline that describes the general process by which prescriber compliance will be evaluated. Previously, we stated that some exceptions would be evaluated on the basis of Prescription Drug Event (PDE) data from the preceding year as opposed to the evaluated year. We recognize that prescriber practices may change from year to year and believe it is inconsistent to evaluate exceptions and compliance on the basis of PDE data from the preceding year as opposed to the year under evaluation. To that end, we aimed to use PDE data from the evaluated year (that is, the current year) as soon as it becomes available to ensure that the data is relevant to the prescriber's practices in the evaluated year. For example, evaluation of CY 2023 prescriber practices will be based on CY 2023 PDE data, though the evaluation will not begin until late CY 2024 and will be based on the PDE data used in the Part D Payment Reconciliation for CY 2023. Following the PDE availability and our evaluation for exceptions and compliance, CMS will begin addressing prescriber non-compliance by issuing non-compliance notices as previously described in the CY 2022 PFS final rule (86 FR 65370).

Additionally, in the CY 2023 PFS proposed rule (87 FR 46240), we proposed to extend the existing non-compliance action of sending notices to non-compliant prescribers for the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the following year (January 1, 2024 through December 31, 2024). We also proposed a change to the data source used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 46239 through 46240). As also discussed in the CY 2023 PFS proposed rule, starting for the CY 2025 EPCS program implementation year, we are planning to propose alternative, more burdensome penalties that would apply to non-compliant prescribers rather than issuance of non-compliance notices. Therefore, we sought further public comment on potential penalties for non-compliant prescribers (87 FR 46240 through 46241).

3. Changes to Exceptions

a. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

In the CY 2022 PFS final rule, we finalized our proposal to amend § 423.160(a)(5) by adding § 423.160(a)(5)(ii), which created an exception for prescribers who issue 100 or fewer controlled substance

prescriptions for Part D drugs per calendar year as determined using PDE claims data as of December 31st of the preceding year, so that these prescribers are not required to meet the EPCS requirement. We referred to this exception as one for small prescribers. For a complete discussion of this topic please see the CY 2022 PFS final rule (86 FR 65366 and 65367). We noted that we intended to implement the proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within this exception. We stated CMS will use the previous year's data to determine whether the prescriber falls under this exception for the year-in-question.

In the CY 2023 PFS proposed rule (87 FR 46238 through 46239), we proposed to modify the exception to better align the timeframes of data used to evaluate each exception. We also noted that, other than the small prescriber exception, every exception described in the CY 2022 PFS final rule is evaluated based on data from the same year to which the exception is applied. For instance, in the case of a recognized emergency, an exception would be granted during the period of time in the year in which the emergency took place, and the emergency would not be considered for an exception in the following year's compliance evaluation, except to the extent that the emergency continued into the following year. Similarly, for purposes of § 423.160(a)(5)(ii), we noted that we believe that it is consistent to consider the prescriptions issued during the evaluated period, rather than the previous year, in case there are year-over-year changes. In this manner, we explained that we believe the proposal is a more consistent approach than the existing requirement to utilize claims data from the prior year to assess whether a prescriber issues 100 or fewer Part D controlled substance prescriptions.

Therefore, we proposed to change the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualifies for an exception based on the number of Part D controlled substance claims. To effect this change, we proposed to modify the exception at § 423.160(a)(5)(ii), which states, ''Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data as of December 31st of the *preceding* year,'' by changing ''CMS claims data as of December 31st of the preceding year'' to ''CMS claims data with dates of service as of December 31st of the current year.'' We noted that if finalized, the provision would become effective for CY 2023 and for subsequent years. Thus, for CY 2023 EPCS compliance, the small prescriber exception would be assessed using CY 2023 PDE data based on our proposed change. Additionally, a prescriber's compliance status would be evaluated based on PDE data reflecting PDEs with a 'Date of Service' within the evaluated calendar year, which Part D sponsors must submit by mid-way through the following year.

The following is the example we provided of how we expect this to work in practice:

Prescriber A had fewer than 100 Medicare Part D controlled substances prescriptions in CY 2022, and therefore, was excepted from EPCS compliance for CY 2022. During the first quarter of CY 2023, she issues 85 Part D controlled substance prescriptions. After Prescriber A crosses the threshold of more than 100 Part D controlled substance prescriptions, she must reach the compliance threshold of electronically prescribing at least 70 percent of all her prescribed Part D Schedule II, III, IV, and V controlled substances in CY 2023. If she does not utilize EPCS for at least 70 percent of Part D controlled substance prescriptions in CY 2023, including those prescribed prior to reaching the 100 Part D controlled substance prescriptions threshold, she would be subject to a compliance action based on failing to meet the requirement at § 423.160(a)(5), unless another exception applied. PDEs with a Date of Service between January 1, 2023 to December 31, 2023, with a submission date on or before the PDE submission deadline for 2023 (that is, June 28, 2024) would be included in the compliance analysis.

Again, we noted in the CY 2023 PFS proposed rule (87 FR 46239) that if the proposal were finalized, neither CMS nor an individual prescriber will be able to determine until after the evaluated year whether or not the individual prescriber qualifies as a ''small prescriber'' for purposes of § 423.160(a)(5)(ii), unless the prescriber tracks the number of Medicare Part D controlled substance prescriptions the prescriber issues during the evaluated year. This is in comparison to our existing policy, where CMS would not determine if prescribers qualified as a ''small prescriber'' until the middle of the evaluated year when the PDE data from the prior year becomes available. Despite the delay in identifying which prescribers qualify for the small prescriber exception, we explained that we believe the proposal would better identify small prescribers for purposes of EPCS compliance and simplify the program by aligning the time periods of the exceptions. We also noted that we believe that prescribers will be able to understand their Medicare Part D controlled substance prescribing patterns more clearly throughout the first 2 years of the EPCS program, where the only action for non-compliance is a notice.

We sought comment on the proposal to modify the exception at § 423.160(a)(5)(ii) and on the possibility that prescribers would avoid prescribing controlled substances to Medicare beneficiaries, particularly where they are approaching the 100 Part D controlled substance prescriptions threshold late in a calendar year, in order to remain a small prescriber.

Additionally, recognizing some prescribers are expecting CMS to use the CY 2022 PDE data to assess whether the exception at § 423.160(a)(5)(ii) applies for purposes of CY 2023 EPCS compliance, we sought comment on an alternative for the CY 2023 year only. In the alternative, we noted that we would recognize a prescriber as a small prescriber for purposes of the exception at § 423.160(a)(5)(ii) if the prescriber had fewer than 100 Part D controlled substance prescriptions in CY 2022 or fewer than 100 Part D controlled substance prescriptions in CY 2023. We discussed that we did not propose this option because we thought it would be simpler to have a single set of exceptions for the program versus different rules for different years. Additionally, we noted that we believed the risk to prescribers who may change their small prescriber status would be low as the sole consequence for non-compliance for CY 2023 is a notice.

The following is a summary of the public comments received on the Cases where Prescribers Issue Only a Small Number of Part D Prescriptions provision and our responses:

Comment: A few commenters supported our proposal to use prescriptions issued during the evaluated period, rather than the previous year, to calculate the small prescriber exception. Commenters noted this would be a more accurate accounting of prescribing levels and would align the timelines. One commenter supported the proposal but disagreed with the concern referenced in the proposal that questioned whether prescribers would avoid prescribing controlled substances in order to retain small prescriber status.

Response: We agree that this change would improve accuracy, as well as align timelines and appreciate the belief that prescribers would not avoid

prescribing controlled substance prescriptions for Part D drugs, where appropriate, to retain the small prescriber status.

Comment: A few commenters did not support our proposal to use prescriptions issued during the evaluated period, rather than the previous year, to determine whether the small prescriber exception applies to a particular prescriber. Commenters expressed concern that the proposal will be overly confusing for prescribers in small practices and hard for prescribers to track. One commenter noted that prescribers may be unduly subject to a compliance action because they may not be aware of the number of Part D controlled substance prescriptions they have written. Another commenter stated their belief that the proposal would have unintended consequences for patients' access to controlled substances, especially in medically underserved areas, if prescribers are reluctant to write controlled substance prescriptions for Part D drugs.

Response: We acknowledged the commenters' concerns. To address potential confusion about the small prescriber status and to improve transparency, we intend to provide feedback to prescribers via an online dashboard that will contain a variety of EPCS elements (EPCS dashboard) and will be developed as soon as technically feasible. At a minimum, the initial dashboard will include whether or not a prescriber was determined to be compliant (at this point, those who are exempt from the requirements are considered compliant) or non-compliant. We anticipate adding information that defines the type of exceptions and provides more detail about prescribers' EPCS status so that they can see the number of prescriptions for Medicare Part D controlled substances they issued in the measurement period (evaluated year). Due to the lag in claims data, this information would not be available until after the PDE submission deadline, which is generally 6 months after the end of the calendar year being evaluated. For example, for the CY 2023 evaluated year, the information on small prescriber exceptions, based on PDE claims data from CY 2023, will be available in the second half of 2024 because PDE data for the 2023 evaluated year is not due to CMS until the end of June 2024. Additionally, through the CY 2024 EPCS compliance year and based on a proposal we finalize below, the only consequence of non-compliance is a notice informing the prescriber of the prescriber's non-compliance. Therefore, CMS will provide prescribers who do not meet the small prescriber exception with at least two separate notices that they do not meet the exception, with information included about how they can come into compliance with the requirement at § 423.160(a)(5), before a compliance action other than a notice would be imposed. We believe this will also help educate prescribers who do not qualify as a small prescriber.

We agree that changes to the program should not contribute to a negative impact on patients' access to prescriptions for controlled substances that are Part D drugs. We do not believe that the specific policy of changing the year from which PDE data is used to determine the small prescriber status will impact patient access because as we mention above, if we used the prior year, prescribers would not know until late in the evaluated year whether or not they met that exception. We do intend to monitor for potential other factors that could affect access, by monitoring the number of providers prescribing Medicare Part D controlled substances and the number of prescribed Medicare Part D controlled substances, and to consider stakeholder feedback to address potential issues through future rulemaking. Additionally, we note that prescribers who are concerned about EPCS and patient access, and who are unable to conduct EPCS due to circumstances beyond their control, may apply for a waiver from EPCS program requirements of up to one year.

Comment: A few commenters noted that CMS should notify small prescribers when they are approaching the 100-prescription threshold. One commenter noted that CMS should include specific instructions on compliance in situations where the prescriber no longer meets the small prescriber exception along with appropriate time to comply. One commenter requested clarification that prescribers are not required to track the number of Medicare Part D controlled substance prescriptions to qualify as a small prescriber, and that non-compliance notices will not be issued before CMS determines a prescriber's small prescriber status.

Response: We appreciate the commenters' recommendations, but we do not believe it is operationally feasible to notify prescribers as they are approaching the 100-prescription threshold. Our analysis for the small prescriber exception relies on the controlled substance PDEs found in Medicare Part D claims data based on the prescriber NPI, which can take an estimated 6 months to sufficiently capture those prescriptions.

We clarify that prescribers are not required to track the number of controlled substance prescriptions for Part D drugs they issue. Prescribers, however, will not be able to determine until after the evaluated year whether or not they qualify as ''small prescribers'' for purposes of § 423.160(a)(5)(ii) unless they track the number of controlled substance prescriptions for Part D drugs they issue during the evaluated year. We will calculate this information after the calendar year being evaluated, integrate the information into our compliance calculations, and for the CY 2023 and CY 2024 EPCS program implementation years, will send a notice for all prescribers who are non-compliant. Additionally, all prescribers will at a minimum be able to find their compliance status in an EPCS dashboard and, as soon as feasible, will be able to view data about their EPCS exceptions status and their compliance rate in the EPCS dashboard. Non-compliance notices, as the only non-compliance action at this time, will not be sent until after all EPCS calculations, including determining the applicability of the small prescriber exception, are completed.

Comment: A few commenters recommended alternatives to our proposals. One commenter recommended that if a prescriber was a small prescriber in the prior year, they should not be penalized in the current year but rather offered a warning. Another commenter recommended that the 70 percent compliance calculation should begin after a notification is sent and should not apply to the first 100 prescriptions for controlled substances that are Part D drugs. A few commenters recommended that CMS allow appropriate exceptions to the EPCS requirement for certain written prescriptions, such as buprenorphine. One commenter noted that titrations for some EPCS drugs such as buprenorphine often have complicated directions for use that sometimes result in errors when electronically prescribed. One commenter requested the exception be expanded to small practices as well.

Response: We thank the commenters for their suggested alternatives. In future rulemaking, we may consider the recommendation that if a prescriber was a small prescriber in the prior year, they should not be penalized in the current year but rather offered a warning, as we assess potential future non-compliance actions. We do not believe this modification is necessary when the only action for non-compliance is a notice. We believe prescribers will have adequate time to assess whether or not they are a small prescriber before

different, potentially more burdensome non-compliance actions would be imposed. Additionally, we do not believe it is feasible to start the 70 percent compliance calculation after sending a notification that the first 100 prescriptions for controlled substances that are Part D drugs have been issued. As discussed in the prior response, due to data lag, we will not have immediate access to information allowing us to know when a prescriber has exceeded 100 prescriptions for controlled substances that are Part D drugs. Prescribers, however, would have the option to track the number of prescriptions for controlled substances that are Part D drugs they issue during an evaluated year.

In the 2022 PFS final rule (86 FR 65368), we noted that buprenorphine prescriptions make up less than 2 percent of all Part D Schedule II, III, IV, and V prescriptions. It is for this reason that we believe prescribers who experience difficulties electronically prescribing buprenorphine should still be able to meet the compliance threshold that allows prescribers to fully comply with the EPCS requirement in § 423.160(a)(5) if they electronically prescribe 70 percent or more of their Part D controlled substance prescriptions. As a result, we do not believe that an exception for this purpose is necessary. Additionally, should a prescriber find that the requirements related to prescribing buprenorphine prevent the prescriber from utilizing EPCS, we encourage the prescriber to request a waiver documenting the circumstances beyond the prescriber's control, which we will consider. In addition, we will continue to monitor PDE data for trends, including whether certain prescriptions are more frequently prescribed using paper prescriptions. If CMS finds that this is the case, we could consider taking future actions, such as proposing additional exceptions to the requirement at § 423.160(a)(5), to help ensure that EPCS is not becoming overly burdensome for these prescriptions.

We do not believe it is appropriate to expand the exception in § 423.160(a)(5)(ii) to small practices at this time. It is our intention to exempt prescribers who prescribe fewer than 100 Part D controlled substance prescriptions. As discussed in the CY 2022 PFS final rule (86 FR 65366), based on our conversations with stakeholders, we believe the cost of EPCS transactions is less than the cost of transmitting certain transactions manually, and we believe that the initial investment to install EPCS equipment and software is likely justified once prescribers transmit more than 100 Part D controlled substance prescriptions per year. We solicited comment on this assumption and the cost of third-party applications required to conduct EPCS. We noted in the CY 2022 PFS final rule that we did not receive any comments on these assumptions (86 FR 65366). We do not believe it necessary to expand the exception to small practices because prescribers in small practices could prescribe many more controlled substance prescriptions for Part D drugs than would be required to justify the initial investment, depending on the number of prescribers in a given small practice and the type of practice. Therefore, we believe it most appropriate to consider the number of controlled substance prescriptions for Part D drugs each prescriber issues for purposes of this exception.

Comment: One commenter supported the alternative outlined for the CY 2023 year only, in which CMS would recognize a prescriber as a small prescriber for purposes of the exception if the prescriber had fewer than 100 Part D controlled substance prescriptions in 2022 or fewer than 100 Part D controlled substance prescriptions in 2023. The commenter stated their belief that the alternative is accommodating to small practices, considering some prescribers are expecting CMS to use the CY 2022 PDE data to assess whether the exception applies for purposes of CY 2023 EPCS compliance as finalized in the CY 2022 PFS final rule.

Response: We believe that the benefit of the alternative to prescribers in small practices is limited because they would not know until the middle of the evaluated year whether or not they qualified for the small prescriber exception. For example, if we used the controlled substance prescriptions for Part D drugs prescribed in CY 2022 to determine the small prescriber exception for the CY 2023 evaluated year, then prescribers would not know that information until the second half of CY 2023, which would limit their ability to modify their practices. We believe the benefits of having a single set of rules across program years will ultimately be less confusing to prescribers. We are therefore declining to adopt this alternative.

Comment: One commenter did not believe that low volume of opioid prescriptions should be a reason to exempt a prescriber from the EPCS requirement. The commenter expressed concern that there is no requirement that ''cash pay'' prescriptions be submitted by the pharmacy to the PDP or Medicare Advantage Prescription Drug plans (MAPD), meaning that CMS cannot use this method to monitor for fraud, waste, and abuse. The commenter suggested CMS to reconsider any volume-based exceptions as creating a dangerous loophole contrary to Congress's intent for EPCS and against the public interest.

Response: We appreciate the commenter's feedback, but in our proposal, we did not reconsider the need for a small prescriber exception, we only proposed to modify the date range used to calculate the exception.

After consideration of the public comments, we are finalizing without modification our proposal to change the exception at § 423.160(a)(5)(ii), to state ''Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.''

b. Cases of Recognized Emergencies

In the CY 2022 PFS final rule (86 FR 65367 and 65368), we finalized our proposal to adopt an exception at § 423.160(a)(5)(iii) for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. We stated that to qualify for this exception, this circumstance will have to arise from an emergency or disaster declared by a Federal, State, or local government entity. We finalized our proposal to determine whether a prescriber qualifies for this exception based on whether the prescriber's National Council for Prescription Drug Programs (NCPDP) Pharmacy Database address is located in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity, which is reflected in the text of § 423.160(a)(5)(iii). Since, as stated in the CY 2022 PFS proposed and final rules, we intend this exception to avoid unduly burdening prescribers during difficult situations, we would like to again clarify that this exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring.

We have determined that the NCPDP Pharmacy Database contains pharmacy addresses as opposed to prescriber addresses. Because it is likely that the address of a prescriber differs from that of the pharmacy where a prescription is filled, and the prescriber might be located at an address within an emergency or disaster area when the pharmacy is not, we believe the NCPDP database may not always be an appropriate data source to inform the

exception based on emergencies such as natural disasters, pandemics, or similar situations where there is an environmental hazard. It is our intention that the EPCS exception apply based on where the prescriber is located, not where the pharmacy is located, to the extent that the locations differ. We believe the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) would have the most current address information for prescribers who are enrolled in Medicare. Additionally, this is the data source that the Quality Payment Program's Merit-based Incentive Payment System (MIPS) uses to determine if a MIPS eligible clinician is located in an area that has been affected by extreme and uncontrollable circumstances (82 FR 53895 through 53900). Therefore, for prescribers who have an address in PECOS, we proposed to use the PECOS address instead of the of the NCPDP Pharmacy Database address to determine whether the exception at § 423.160(a)(5)(iii) is applicable. We noted that we have concerns that not all prescribers would be enrolled in Medicare, and therefore, their addresses would not be in PECOS. In situations where prescribers do not have a PECOS address, we proposed to use the prescriber address in the National Plan and Provider Enumeration System (NPPES) data. We proposed to revise the text of § 423.160(a)(5)(iii) accordingly. Additionally, we sought public comment on whether using NPPES, NCPDP, or some other database is appropriate when there is no prescriber address in PECOS.

We also sought comment on an alternative of using NPPES as the source of addresses for all prescribers. We noted that we believe this data may have information for all prescribers, but that providers may not update their address in NPPES as often as they do in PECOS. Finally, we sought comment on other potential data sources that could be used to verify a prescriber's address for purposes of § 423.160(a)(5)(iii).

The following is a summary of the public comments received on Cases of Recognized Emergencies and our responses:

Comment: A few commenters supported the proposal to use PECOS as the source of data to identify a prescriber's location for purposes of § 423.160(a)(5)(iii). The commenters noted that the change from NCPDP to PECOS would result in more accurate information and help to relieve administrative burden on providers.

Response: We agree that using PECOS would provide the most current address information for prescribers who are enrolled in Medicare.

After consideration of public comments, we are finalizing without modification our proposal to change the exception at § 423.160(a)(5)(iii), to state ''(iii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.''

4. Penalties

Section 1860D–4(e)(7)(D) of the Act gives the Secretary the authority through rulemaking to enforce and specify appropriate penalties for non-compliance with the EPCS requirement. In the CY 2022 PFS proposed and final rules, we sought feedback from interested parties on whether CMS should impose penalties for non-compliance with the EPCS requirement and if so, what penalties should be imposed. We are continuing to examine State EPCS requirements and their accompanying penalties. However, because these requirements have only been recently implemented and most States do not have penalties for failing to adopt EPCS, we have not been able to evaluate what type of penalties have been effective to enforce State mandates.

In our ongoing implementation of the EPCS requirement, we continue to seek input to ensure that we do not place too much of a burden on prescribers, as we do not want this requirement to have an unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries, where appropriate, should they not have EPCS set-up. We continue to believe additional time is needed to gather more feedback from interested parties on the most effective and most appropriate type of penalties. In the CY 2022 PFS final rule, we finalized our proposal to limit CY 2023 compliance actions to a non-compliance notice sent to prescribers that are violating the EPCS requirement.

a. Timing for Issuing Non-Compliance Notices

In the CY 2023 PFS proposed rule, we proposed to adjust the period of time during which CMS will issue non-compliance notices as the sole non-compliance action. For the period of time during which CMS non-compliance actions will consist of sending notices to prescribers that we believe are violating EPCS requirements, we proposed to extend the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 implementation year (January 1, 2024 through December 31, 2024). We discussed in the CY 2023 PFS proposed rule that, if adopted, CMS compliance actions will consist of CMS sending notices to prescribers who we believe are violating the EPCS requirement between January 1, 2023 and December 31, 2024. The content of the notices would remain unchanged. These notices, as the sole non-compliance action at this time, will consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the EPCS dashboard to request a waiver. We sought public comment on the proposal.

The following is a summary of the public comments received on the Timing for Issuing Non-compliance Notices and our responses:

Comment: Many commenters supported our proposal to extend the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 EPCS program implementation year through the CY 2024 EPCS program implementation year. They noted our proposal will provide non-compliant prescribers additional time to achieve compliance, recognizes the unique situation practices, prescribers, and patients face during the COVID–19 pandemic while promoting the value and convenience of EPCS, and prioritizes access to appropriate care for patients. A few commenters noted that continued education and assistance to gain compliance with EPCS through the non-compliance notices would be more effective than punitive measures, especially as there are still broadband internet access problems in some remote communities. A few commenters noted extending the existing compliance action of sending notices to non-compliant prescribers for CY 2024 gives vendors and practices time to implement EPCS and adjust products and technology to align with Drug Enforcement Administration (DEA) EPCS requirements and regulations.

Response: We agree that sending notices as the only non-compliance action to prescribers, rather than imposing alternative non-compliance actions, may avoid overly burdening prescribers who are unable to meet the

EPCS mandate in CY 2024 while providing non-compliant prescribers additional time to achieve compliance and promoting the value and convenience of EPCS through the non-compliance notices. We would like to clarify that these notices would be sent by email when possible to all available email addresses in PECOS and NPPES and by regular mail if there is no email address in PECOS or and no email address in NPPES. These notices will consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, and an information solicitation as to why they are not conducting EPCS. If there is an email address in either PECOS or NPPES, then the only notice the prescriber receives will be via email. Prescribers must exercise diligence to ensure that the email address is accurate and up to date (that is, accessible to and monitored by the prescriber).

Comment: A few commenters did not support our proposal to extend the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 EPCS program implementation year to the CY 2024 year because they stated timely enforcement of the Federal EPCS mandate is essential to supporting the nation's ongoing fight against drug abuse and diversion, especially now when these problems have been exacerbated by the PHE for COVID–19, and the continued enforcement delay of the of the Medicare Part D EPCS requirements undermines the requirements of the program. One commenter noted that all parties have had more than adequate time to prepare for implementation of these requirements and stated that the needed infrastructure is in place, the updated transmission standard has been finalized, and the technology is updated, so now the policy should follow suit, in the commenter's view. One commenter stated that since the first year of enforcement includes the non-compliance notice and that there would be no immediate fines or other actions against non-compliant prescribers, the initial enforcement action would serve as a prompt for non-compliant prescribers to come into compliance with the EPCS requirements for CY 2023. The commenter noted that with the delay, and without the promise of imminent enforcement, some prescribers who could otherwise make the necessary system updates may delay doing so because the deadline is no longer looming. The commenter also noted that the availability of the waiver process for prescribers in temporary situations accommodates prescribers unable to conduct EPCS due to circumstances beyond the prescriber's control.

Response: We agree that the timely enforcement of the Federal EPCS mandate is essential to supporting the nation's ongoing fight against drug abuse and diversion. At this time, we want to continue to ensure that our actions do not have unintended consequences for prescribers who still require additional time to implement EPCS, while also recognizing the benefits of EPCS. It is for this reason that we encourage prescribers to conduct EPCS as soon as possible.

Our proposal to send non-compliance notices as the sole non-compliance action through the CY 2024 EPCS program implementation year would consist of sending notices to prescribers that we believe are violating the EPCS requirement during that period of time. We are still considering adopting penalties in future rulemaking and plan to use information gathered in the Request for Information Relating to Potential Future EPCS Penalties (87 FR 46240 and 46241) to inform future compliance action decisions. We agree that the initial enforcement action of sending non-compliance notices for CY 2023 and CY 2024 EPCS program implementation years will serve as a prompt for non-compliant prescribers to come into compliance with the EPCS requirements. We appreciate that the commenter is concerned that by extending the period of time during which CMS will send non-compliance notices as the sole non-compliance action prescribers might delay EPCS adoption, but we do note that from 2020 to 2021, we saw an increase, from 62.3 percent in 2020 to 79.6 percent in 2021, in prescribers who electronically prescribed 70 percent or more of their Medicare Part D controlled substances. Through the information provided in our non-compliance notices, we anticipate this number to continue to grow.

Comment: One commenter stated that we should not delay the commencement of enforcement actions, as it sends the wrong message to prescribers about the need to comply. The commenter noted we should continue to move forward with sending compliance enforcement notices in CY 2023 to improve EPCS adherence knowing there is a compliance threshold of 70 percent and exceptions in place for prescribers who face extraordinary circumstances. The commenter noted that EPCS represents progress in the movement toward the use of interoperable technology, supports inclusion of a verifiable and traceable history, prevents drug abuse, and reduces burden. The commenter also noted that experience at the State level demonstrates the importance of enforcement mechanisms, as States with enforcement mechanisms have faster EPCS adoption rates than States without enforcement mechanisms. The commenter noted that EPCS saves money and lives and urged us to send non-compliance notices in CY 2023 to improve EPCS adherence.

Response: We proposed to extend the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023), with non-compliance notices sent out in 2024, to the CY 2024 EPCS program implementation year (January 1, 2024 through December 31, 2024), with non-compliance notices sent out in 2025. Our proposal maintains the compliance action of sending notices to non-compliant prescribers based on the CY 2023 EPCS program implementation year and extends the sending of notices to non-compliant prescribers as the compliance action for the CY 2024 EPCS program year, as well. We disagree with the commenter that we are delaying the commencement of enforcement actions, as sending non-compliance notices is an enforcement and compliance action. We agree with the commenter that EPCS encourages the use of interoperable technology, produces a verifiable and traceable history, prevents fraud and abuse, and reduces burden. We also believe we should continue to move forward with sending compliance enforcement notices to improve EPCS adherence and encourage faster EPCS adoption rates.

After consideration of public comments, we are finalizing our proposal without modification to extend the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024, through December 31, 2024).

b. Request for Information Relating to Potential Future EPCS Penalties

Consistent with the CY 2022 PFS final rule, we continue to be interested in identifying additional meaningful penalties to enforce the EPCS requirement. Therefore, we sought public comment on additional penalties that CMS may impose to enforce the EPCS requirement through a Request for Information in the CY 2023 PFS

proposed rule (87 FR 46240 through 46241). We noted that any penalties would go into effect no sooner than January 1, 2025. We are exploring a range of options, and we explained that feedback from interested parties would help us to develop meaningful and appropriate penalties in the future.

While we will not be responding to specific comments submitted in response to this Request for Information, we will actively consider all input as we develop future regulatory proposals. Any updates to specific requirements related to potential EPCS penalties or actions may be addressed through separate and future notice-and-comment rulemaking, as necessary.

M. Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services is made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and 42 CFR 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments at § 414.610(c)(5)(i) are: (1) a 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments at sections 1834(l)(12)(A) and (13)(A) of the Act and § 414.610 are: (1) a 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Section 50203(a)(1) and (2) of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018) includes an extension of the temporary add-on payments through December 31, 2022.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirements for the Ground Ambulance Providers and Suppliers To Submit Cost and Other Information Background

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers (ground ambulance organizations) to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Section 1834(l)(17)(B)(i) of the Act required the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act required that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Section 311 of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103) amended section 1834(l)(17)(F)(i) of the Act to delay the deadline for MedPAC to submit its report to Congress on the ground ambulance data collection system study until the second June 15th following the date the Secretary transmits data for the first representative sample of ground ambulance organizations. Section 1834(l)(17)(I) of the Act states that the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) does not apply to the collection of information required under section 1834(l)(17) of the Act.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance organizations at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. In the CY 2020 PFS final rule (84 FR 62863 through 629897), we finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. This instrument includes the specific questions that will be asked of ground ambulance organizations about the total service volume, costs, and revenue associated with a provider or supplier's entire ground ambulance organization in such a way that MedPAC could use to calculate an average cost per ground ambulance transport. We refer the reader to our CY 2020 PFS final rule (84 FR 62863 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

In the CY 2022 PFS final rule (86 FR 65306 through 65317), we finalized a number of updates to the Medicare Ground Ambulance Data Collection System, including: (1) a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in year 3; (2) aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and the data collected will be publicly available beginning in 2024; and (3) revisions to the Medicare Ground Ambulance Data Collection Instrument that include better accounting for labor hours across different categories of personnel and better distinguishing between accrual and cost basis accounting methodologies. We refer the reader to our CY 2022 PFS final rule (86 FR 65306–65317) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

3. Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2020 PFS final rule (84 FR 62867), the Medicare Ground Ambulance Data Collection Instrument uses screening questions and skip patterns so that it is applicable to all ground ambulance organizations regardless of their size, scope of operations and services offered, and structure. We stated that we believe this approach is easier to navigate and less time consuming to complete than a cost report template or instrument and that it minimizes respondent burden by directing ground ambulance organizations to only view and respond to questions that apply to their specific type of organization, all while still collecting the information required in section 1834(l)(17)(A) of the Act.

The CY 2020 PFS final rule provided a detailed overview of the elements of the data collection instrument, including questions to collect information on costs, revenues, utilization (which CMS defines for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations. Table 87 includes a high-level summary of the 13 sections of the Medicare Ground Ambulance Data Collection Instrument.

TABLE 87: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
General Survey Instructions (1)	Information on background and motivation for data collection, instructions for navigating the instrument, and links for questions and other resources.
Ground Ambulance Organization Characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground Ambulance Service Volume (5) and Service Mix (6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Hours and costs associated with emergency medical technicians (EMTs), administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; annual cost of ownership, insurance, maintenance, and utilities.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual cost of ownership; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

As described in the CY 2022 PFS final rule (86 FR 65307), we made several changes to the instrument instructions and questions to improve clarity and reduce burden for respondents. A printable version of the current instrument instructions and questions is available in English and Spanish on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*.

In the CY 2023 PFS proposed rule (87 FR 46243), we stated that we have continued to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via four primary channels. First, we receive email and other written communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers to commonly asked questions. This document is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*. Through review of questions and feedback, we have identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document. Second, we answer questions live from interested parties during

webinars, dedicated question and answer sessions, and other educational sessions. As with the emailed questions described above, live question and answer exchanges sometimes identify opportunities for clarifying instrument language. Third, we conducted cognitive testing and user acceptance testing of the GADCS. Feedback from this preliminary testing effort was helpful to identify some additional opportunities for clarification. Fourth, we continue to identify opportunities to clarify instructions and correct a small number of typos as we work to develop the web-based, programmed version of the Medicare Ground Ambulance Data Collection Instrument.

Based on information that we received via the four sources described above, we proposed in the CY 2023 PFS proposed rule (87 FR 46243) the following further changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The proposed changes and clarifications aimed to reduce burden on respondents, improve data quality, or both. We grouped our proposed changes and clarifications into four broad categories:

- Editorial changes for clarity and consistency.
- Updates to reflect the web-based system.
- Clarifications responding to feedback from questions from interested parties and testing.
- Typos and Technical Corrections.

A draft of the updated instrument that includes all of the CY 2023 proposed changes is posted on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*.

a. Editorial Changes for Clarity and Consistency

In the CY 2023 PFS proposed rule (87 FR 46244), we proposed 14 editorial changes to improve the clarity of instrument instructions and questions. We stated that we do not believe these changes substantively affect the meaning of any instruction or question.

The first three proposed changes would apply throughout the entire Medicare Ground Ambulance Data Collection Instrument. Specifically, we proposed to:

- Use the past tense to refer to data collected during selected ground ambulance organizations' continuous 12-month data collection periods throughout the instrument. All organizations are currently required to complete their data collection prior to reporting the data. Using the present tense may be confusion by implying organizations should report data beyond their 12-month data collection period.
- Consistently refer to ''ground ambulance'' rather than only ''ambulance'' throughout the instrument to clarify that the scope of the Medicare Ground Ambulance Data Collection System (GADCS) is limited to ground ambulance operations and not air ambulance operations.
- Edit sentences written in the passive voice to the active voice for editorial consistency.

The fourth and fifth proposed changes in the CY 2023 PFS proposed rule (87 FR 46244) focused on Section 1 (General Survey Instructions) in the instrument as we proposed to:

- Refer to organizations' ''continuous 12-month data collection period'' rather than just ''12-month data collection period'' throughout the instrument. We believe this will help remind organizations that their data collection period must cover a continuous, 12-month period.
- Align the description of how organizations must provide their data collection start date prior to data reporting in Section 1 (General Survey Instructions) with the process codified at § 414.626(b)(1).

The remainder of the proposed changes in this category in the CY 2023 PFS proposed rule (87 FR 46244) focused on editorial changes to specific instrument questions or instructions in Sections 2 (Organizational Characteristics) through Section 6 (Service Mix). Specifically, we proposed to:

- Edit response Option d in Section 2, Question 9 from ''Another health care organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services),'' to ''Other health care delivery operations such as a clinic or urgent care center (excluding hospitals, skilled nursing facilities, or other Medicare provider of services in Option c).'' In a previous clarification, we reworded Section 2, Question 9 from ''Does your ground ambulance operation share any operational costs, such as building space or personnel, with one of the following?'' to ''Does your organization provide any of the following services or operations (select all that apply)?'' Given the change in the structure of the question asking about types of services/operations as opposed to types of organizations, we proposed to reword one answer option to better reflect the question.
- Clarify Section 4 (Emergency Response Time), Question 4b, which asks whether the organization is penalized if it exceeds response time targets, to focus specifically on monetary penalties. We are concerned that the current phrasing is too subjective and will be difficult for respondents to answer.
- Clarify that the definition of ''total response'' in the Section 5 (Ground Ambulance Service Volume) instructions and Section 5, Question 1 applies to ''emergency responses'' rather than ''EMS responses.'' In some organizations, the initial responders to a call for service may not be EMS responders.
- Clarify that estimates of the share of responses that are joint with another organization are acceptable in Section 5, Question 3c, to better align with Section 5, Question 3a where estimates are explicitly permitted.
- Specify in Sections 5 and 6 (Service Mix) and elsewhere in the Medicare Ground Ambulance Data Collection Instrument when questions ask for information on ''ground ambulance transports'' rather than just ''transports'' to avoid confusion with services that may colloquially be referred to as transports but that do not meet the definition of a ''ground ambulance transport'' in the instrument, which is defined as ''the use of a fully staffed and equipped ground ambulance responding to a request for service to provide a medically necessary transport (based on the rules relevant to the applicable payer).''

The 11th and 12th proposed changes in the CY 2023 proposed rule (87 FR 46244) applied to Section 7 (Labor Costs) where we proposed to:

- Standardize the example staff categories listed under ''other medical staff'' across all Section 7 tables. Currently, the first table in Section 7 lists ''respiratory therapist'' among example staff categories while none of the subsequent tables do. We proposed to remove ''respiratory therapist'' as an example from the first table in Section 7 for consistency and brevity. However, respiratory therapists should continue to be included in this category, along with all other medical staff, even if they are not specifically cited as an example.
- Add a reminder (''do not include medical directors'') in Section 7.3 (Volunteer Labor), Question 3 on administrative/facility volunteer hours to ensure respondents do not include medical directors in this category (medical director hours are reported separately).

The 13th proposed change in the CY 2023 PFS proposed rule (87 FR 46244) applied to Section 9 (Vehicle Costs) as we proposed to:

- Define ''Quick Response Vehicle'' alongside the acronym (QRV)

throughout the instrument and particular in Section 9 (Vehicle Costs). The current Section 9 instructions sometimes refer to ''QRV'' without elaboration. We believed this may be confusing to some ground ambulance organizations.

The 14th and final proposed change in this category in the CY 2023 PFS proposed rule (87 FR 46244) related to Section 13 (Revenue). Specifically, we proposed to:

• Edit the warning that applies to organizations operating both ground and air ambulances in Section 13 to clarify that air ambulance revenue should not be included in Section 13 except in the organization's response to Section 13, Question 1. This question explicitly asks organizations to report on revenue across their entire organization, including revenue related to services other than ground ambulance services, and so the current warning may seem to be contradictory.

We invited comments on the 14 proposed editorial changes for clarity and consistency, which we summarize and respond to below.

Comment: One commenter expressed support for our proposal to clarify the difference between ''EMS response'' and ''emergency response'' in Section 5, Question 1. The commenter stated that situations arise where a supervisor (who may or may not be an EMT) arrives on the scene first and subsequently cancels the call for a broader EMS or ambulance response. The commenter noted that the proposed language helps to clarify the language and will more effectively capture the data sought in this section.

Response: We appreciate the commenter's support of this proposal. We agree this clarification will be helpful.

Comment: One commenter generally supported our proposal to allow respondents to provide an estimate in response to Section 5, Question 3c, which asks for the share of responses that are joint with another organization. The commenter further stated that while the example in the question of an ambulance organization responding alongside a local fire department clearly qualifies as a joint response for the purposes of this question, other situations such as advanced life support EMS programs intercepting basic life support ambulances are more ambiguous. As such, the commenter requested that CMS further clarifies this question, particularly in terms of the specific scenarios that should be considered as respondents answer this question.

Response: We agree with the commenter that additional clarification in Section 5, Question 3c will be helpful to improve the accuracy of the responses. The intent of Section 5, Question 3c was to include all joint responses with another organization, such as a separate fire department (as noted in the current question text) or another public safety organization or ground ambulance organization. After considering this comment, we are clarifying Section 5, Question 3c to read as follows: Does your organization respond to calls with another non-transporting agency such as a local fire department that is not part of your organization? After the question, the following instructions will be provided: This includes joint responses with other ground ambulance organizations, as well as cases where a fire, police, or other public safety department responses to calls for service with your organization. Only consider cases where your ground ambulance does or would have transported the patient, if necessary.

Comment: One commenter supported the refinements outlined in the proposed rule and appreciated the efforts to provide additional clarity in the Medicare Ground Ambulance Data Collection System without referring to specific proposals.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our 14 editorial changes for clarity and consistency proposals as proposed with one additional editorial change. As a result of the comment on Section 5, Question 3c, we are clarifying Section 5, Question 3c to read as follows: Does your organization respond to calls with another non-transporting agency such as a local fire department that is not part of your organization? After the question, the following instructions will be provided: This includes joint responses with other ground ambulance organizations as well as cases where a fire, police, or other public safety department responses to calls for service with your organization. Only consider cases where your ground ambulance does or would have transported the patient, if necessary.

b. Updates To Reflect the Web-Based System

As we discussed in the CY 2023 proposed rule (87 FR 46244), we are in the process of developing the web-based GADCS portal and programmed instrument that ground ambulance organizations will use to report data. The printable instrument noted several cases where the ultimate instrument functionality and wording hinges on the specifications and implementation of the GADCS portal and programmed instrument, for example around account creation, programmed skip logic, and pop-up warnings.

In the CY 2023 PFS proposed rule (87 FR 46244), we proposed 13 changes to the printable instrument so that it better matches our current plans and expectations for the programmed instrument. We discussed that we believe these changes will help ground ambulance organizations referencing the printable instrument understand how the data they have collected should be entered in the programmed instrument on the GADCS portal. We proposed to:

• Update the brief description of the programmed instrument's functionality in Section 1. We proposed the specific text: ''Your organization must report the required information prior to [INSERT DATE], which is 5 months after the end of its data collection period. You can enter the required information over multiple sittings. The system will save your responses after every screen, or whenever you hit the ''Save'' button at the bottom of your screen. When you log in again later, you can pick up where you left off. After you enter all required information, a Certifier at your organization will review the entire response and either request changes or certify the information. [Note: This instruction will be updated to reflect the capabilities of the programmed instrument.]'' This description provides readers of the printable instrument a clearer sense of the functionality they should expect from the programmed instrument.

• Add specific pop-up window text from Section 2, Question 1 in the programmed instrument to the printable instrument. Section 2, Question 1 confirms that the ground ambulance organization billed Medicare for ground ambulance services during its continuous, 12-month data collection period. A response of ''no'' effectively ends the organization's reporting requirement under GADCS. As a result, the programmed instrument includes pop-up warnings asking the respondent to confirm that they did not bill Medicare for ground ambulance services. We noted that we believe describing the pop-up boxes as programming notes in the printable instrument will help organizations no longer providing ground ambulance organizations understand how they will progress through the GADCS.

• Edit the printable instrument to refer to ''your organization's data collection period'' rather than ''calendar year 202X [or fill fiscal year as appropriate]'' throughout the document.

Given CMS' approach to collecting data collection period start dates and contact information from organizations within 30 days of notification, we expect to know the data collection period start date ahead of the organization entering the web-based GADCS. We noted that we believe it will be clearer for organizations if the question text refers consistently to the organization's data collection period.

- Move Section 7.2, Question 4 (''Does your organization contract with a medical director, rather than employing them directly?'') to earlier in Section 7, immediately following Section 7, Question 1, to become Section 7, Question 2. The existing Section 7, Question 2 item (asking about staff categories not used by the organization) would be renumbered as Section 7, Question 3. With the current flow of Section 7 in the printable instrument, organizations contracting with a medical director must confusingly answer a question on why they do not employ a medical director *before* they report that they contract with one. Asking whether the organization contracts with a medical director earlier in Section 7 enables the programmed instrument to better adapt later questions in Section 7 related to medical directors. For example, organizations indicating earlier in Section 7 that they contract with a medical director will not need to be asked why they do not employ a medical director.
- Clarify the instructions for Section 8.1 (Facility Information) Question 1, Section 9.1 (Ground Ambulance Vehicle Costs), Questions 1 and 2, and Section 9.2 (Other Vehicle Costs (Non-Ambulance)), Questions 1 and 2 so that they note the number of facilities and vehicles that users report as answers to these questions will adjust the number of rows that they subsequently see in Section 8.2 (Annual Lease, Mortgage, and Other Costs of Ownership for Facilities), Section 9.1, and Section 9.2 tables, respectively. We noted that we believe this clarification would help users understand the linkages between these initial questions and the later tables that they need to fill out. This clarification may also help users appreciate that changing earlier answers to these initial questions will have ramifications for the tables that follow, including the potential addition or deletion of rows.
- Allow organizations to enter information by hand or via an uploaded file for the facility-level tables in Section 8.1 and for the vehicle-level tables in Section 9.1 and Section 9.2. These tables require organizations to report on the characteristics and expenses related to individual facilities and vehicles. Ground ambulance organizations with many facilities and/or vehicles may find it burdensome to enter information on each facility and vehicle individually in the web-based GADCS. Other organizations may find it easier or preferable to enter information by hand. Organizations choosing to import responses for these three tables would use Microsoft Excel templates with the same structure as the tables in the web-based instrument. Organizations would download these templates prior to or while reporting information to the GADCS, complete the template, and then import the completed template into the GADCS. The GADCS would validate completed templates and request modifications (if necessary) prior to accepting completed templates. Organizations importing responses for these tables would have an opportunity to review their responses before continuing to later Section 8 and/or Section 9 questions. We noted that the proposed change would require clarification in the Section 8 and Section 9 instructions to describe the two alternative data entry approaches. The revised instructions would stress that the use of the import templates is optional and that the exact same information is required regardless of whether information is entered by hand or via the template. We noted that we believe offering the option to import responses to these tables will substantially reduce response burden particularly for larger ground ambulance organizations with many facilities and/or vehicles.

The remaining proposed changes in this category (changes 6–12) in the CY 2023 PFS proposed rule (87 FR 46245) aimed to harmonize and clarify programming notes throughout the instrument related to ground ambulance organizations that also provide other services (for example, fire departments, or ''shared services'' as we describe them in the instrument). The programming notes in the printable instrument are meant to provide context to readers on the ultimate functionality of the programmed instrument within the constraints of a static document. Some of the programming notes were broadened and updated since the initial version of the printable instrument while others have not. We noted that we believe some ground ambulance organizations may want to respond to questions as if they were shared services, even if they do not meet the specific programming notes laid out in the printable instrument. Broadly, we proposed to expand or remove programming notes restricting certain responses for follow-up questions for shared services. We noted that we believe this will provide respondents with more flexibility to respond to questions in a way that best matches their characteristics, services, and organizational structure.

Specifically, for changes to programming notes, we proposed to:

- Edit the Section 2, Question 9 note to read: '[Note: For the remainder of the data collection instrument, instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that answer Section 2, Question 7 = ''a'' or ''b'' AND Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b. To streamline the skip logic, the answers to these questions are referred to as ''Public Safety = Yes'' for the remainder of the document.]'
- Clarify the definition of ''total responses'' in the Section 5 (Service Volume) instructions and Question 1 which currently reads: '[If Section 2, Question 7 is ''a'' also display] ''Include emergency responses that did not involve a ground ambulance, such as those involving only fire trucks and/or other fire/rescue vehicles;'' [if ''b''] ''Include emergency responses that did not involve a ground ambulance, such as those involving only police cars and/or other public safety vehicles.'' ' These instructions do not account for those who indicated public safety services in Section 2, Question 9. We proposed to use the new ''public safety'' definition and to decrease repetitiveness for those with both fire and other public safety services: ''[If Public Safety = Yes] Include emergency responses that did not involve a ground ambulance, such as those involving only fire trucks, other fire/rescue vehicles, police cars and/or other public safety vehicles.''
- Edit programming notes throughout Section 7 (Labor Costs) instructions to refer to ''If Public Safety = Yes'' rather than ''if appropriate for shared services.''
- Make the skip logic more precise and consistent throughout Section 7.1 by changing ''[Include only if relevant based on responses to Section 7, Question 1] Total hours worked annually related to fire, police, and/or other public safety operations'' and ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include if any paid EMT/response staff with fire, police, and/or other public safety role was indicated in Section 7, Question 1].''
- Change ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include

if any paid Administration/Facilities or medical director staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.2.

• Change ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include if any volunteer EMT/response staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.3, Question 2.

• Change ''[Include only if relevant based on responses to Section 7, Question 1 and populate with ''fire,'' ''police,'' and/or ''other public safety'' as appropriate]'' to ''[Include if any volunteer administrative/facilities staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.3, Question 4.

We invited comments on the proposals aiming to better align the printable instrument with the functionality of the programmed instrument and system, which we summarize and respond to below.

Comment: One commenter supported CMS' recognition of the importance of medical direction and oversight by including questions in Section 7 (Labor Costs) pertaining to whether the position is paid for or voluntary, the nature of the compensation arrangement, the amount of hours worked annually, and the amount of total compensation. The commenter noted that these data would demonstrate the unequivocal importance of EMS physician medical directors to patient safety and outcomes and would implore CMS to explore reimbursement for EMS clinical and quality outcomes, as well as the critically important role of an EMS physician medical director, which should be an industry standard.

Response: We appreciate the commenter's support for the proposal.

Comment: Three commenters made specific recommendations with respect to the usability and functionality of the Medicare Ground Ambulance Data Collection System. Two of these commenters recommended the inclusion of a ''save'' function as information is entered. Three commenters recommended programmed error and validation checks. Three commenters recommended that the GADCS should be a user-friendly experience and should be designed in a way that does not increase administrative burden or costs.

Response: As we described in the CY 2020 PFS final rule (84 FR 62868), we designed the Medicare Ground Ambulance Data Collection System to collect the information required in section 1834(l)(17)(A) of the Act while: (1) accommodating a wide range of ground ambulance organizations; and (2) minimizing respondent burden. Subsequent improvements in the Medicare Ground Ambulance Data Collection System in the CY 2022 PFS final rule (86 FR 65306), and those described in this final rule, aim to further streamline the Medicare Ground Ambulance Data Collection System and reduce burden.

Several of the features noted by commenters are already part of the web-based GADCS. The system already includes an ''autosave'' feature that saves responses as they are entered. This feature is always active. It allows the same user to enter information at different times, and/or multiple users to enter information at different times. The system also already includes many validation and error checking steps that are automatically applied as respondents enter information. The purpose of these checks is to prevent respondents from entering information that does not align with the instructions, or that does not make sense.

Comment: One commenter expressed general support for ground ambulance organizations to be able to import responses into the GADCS as a way to reduce human error. The commenter noted that it is not clear which sections and questions can be answered by uploading spreadsheets. The commenter suggested that the system allow organizations to report information via an application programming interface (API).

Response: We have recently updated the Medicare Ground Ambulance Data Collection System to give respondents an option to complete and import Microsoft Excel-based templates to respond to certain questions in Section 8 (Facilities Costs) and in Section 9 (Vehicle Costs). Please see our Ambulance Events website at *https://www.cms.gov/medicare/ambulance-fee-schedule-zip-code-files/ambulance-events* for further information. We do not have plans to implement additional import functionality prior to the launch of the system. CMS will continue to assess the benefits of an API in future years.

Comment: One commenter expressed concern regarding potential discrepancies between the printable version of the GADCS instrument and the web-based, programmed version of the instrument that some ground ambulance organizations have tested for CMS. The same commenter noted that it would be helpful for the web-based Medicare Ground Ambulance Data Collection System to include a print function.

Response: The version of the web-based system available for testing is not the final version that ground ambulance organizations will use to report data to CMS. Our main interest in testing the system is to identify opportunities to improve the clarity and functioning of the web-based system. The printable instrument will be updated with the most recent changes, such as those we are finalizing in this final rule, and will be the version that ground ambulance organizations use to report to the GADCS. The questions in the web-based, programmed system will be identical to the printable instrument that will be posted on CMS' Ambulances Services Center website when this final rule is published. We also note that the web-based Medicare Ground Ambulance Data Collection System will have a ''print'' function so that respondents can view and/or save an Adobe PDF or paper copy of their responses.

Comment: One commenter asked that CMS provide a timeline on when it plans to release the data from selected ground ambulance organizations in Year 1 and Year 2 that reported to the Medicare Ground Ambulance Data Collection System. The commenter stated that this information will help the community understand the timeline so that the ground ambulance industry can gather ''lessons learned'' to help address any issues that may arise for the next reporting period.

Response: As described in the CY 2020 PFS final rule (84 FR 62897), we plan to post a report on our website describing the data collected via the Medicare Ground Ambulance Data Collection System including information on summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable. We stated that these data will be made available to the public through posting on our website at least every 2 years and we will post summary results by the last quarter of 2022. However, in the CY 2022 PFS final rule (86 FR 65317), due to the COVID–19 delay, we revised § 414.626(f) to state that we will make the data collected under the GADCS publicly available beginning in 2024.

Comment: One commenter asked for confirmation that the same individual will be able to serve in the data entry submitter and data certifier roles for the purposes of reporting data to the web-based system. The commenter noted that smaller organizations may be more likely to have the same individual serving in both roles.

Response: We will not require a ground ambulance organization to fill the data entry submitter and data certifier roles with different individuals, even if the ground ambulance organization otherwise has different individuals serving in those roles.

After consideration of the public comments we received, we are finalizing our proposed updates to reflect the web-based system.

c. Clarifications Responding to Feedback From Interested Parties' Questions and Testing

In the CY 2023 PFS proposed rule (87 FR 46246), we proposed 12 instrument changes stemming from feedback we received from emailed questions, during live question and answer and other educational sessions, and via preliminary testing. Specifically, we proposed to:

- Clarify when and how to report expenses paid for by a local municipality in the Section 1 General Survey Instructions. Several organizations have asked CMS for guidance on how to collect and report data in this scenario. The GADCS FAQ includes several entries related to this question. In brief, whether or not municipal expenses for dispatch services, fuel, facility space, employee benefits, or in any other category must be reported under GADCS depends on the relationship between the ground ambulance organization and the municipality. If the ground ambulance organization is owned and operated by the same municipality paying for the expense, then the expense is in-scope and must be reported. If not, for example in cases where a municipality provides dispatch services to local ground ambulance organizations free of charge, then the expense should not be included. In many cases, ground ambulance organizations can report when a particular input or resource is donated, which likely applies in these cases. To help resolve any ambiguity, we proposed to replace the Section 1 text starting with ''If your organization is part of a local government . . .'' with the following text adapted from existing FAQ entries: ''If your organization was part of a municipal government or larger entity that paid for certain ground ambulance expenses (for example, if your municipality pays for rent, benefits, fuel, or dispatch), you must report information on these expenses. This applies only in cases where you are owned or operated by or have a partnership or joint venture with the entity that covers expenses for your ground ambulance operation. In other cases, do not estimate or report the value of donated vehicles, supplies, equipment, or other resources or labor used in your ground ambulance operation. For example, if your local hospital provided drugs at no cost, but you are not a hospital-based ground ambulance organization, then do not report the expense associated with the donated drugs.''
- Remove the text ''in your primary service area (the area in which you usually provide service and where the majority of your transport pickups occur)'' from Section 4 (Emergency Response Time), Question 1, which asks the organization to describe its approach to measuring response times. The intent is for this question to ask about how the organization measures response times across all responses, not just those in their primary service area. Some interested parties shared that they expected to see a corresponding question for their secondary service area. We believe this clarification should resolve any ambiguity.
- Add programming notes to the printable instrument noting that a response to Section 4 (Emergency Response Time) questions related to their primary and secondary service areas should be answered only when the organization provided emergency responses in such areas. For example, an organization with both primary and secondary service areas that provided emergency responses in their primary service area but not in their secondary service area should report response time information for their primary but not secondary area. Several organizations have asked how to report information in Section 4 in this case.
- Clarify that the scope of GADCS is limited to ground ambulance operations. For the many ground ambulance organizations that are fire department-based, a Medicare provider, or provide other services beyond ground ambulance services, only a portion of total expenses and revenue are associated with ground ambulance operations. As a result, with the exception of two specific questions (Section 12, Question 1, and Section 13, Question 1), information on expenses and revenue must be reported to GADCS in such a way that CMS can identify an amount associated with or allocated to ground ambulance operations.
- Add guidance throughout Sections 7 through 13 related to allocating a share of expenses and revenue attributable to ground ambulance operations versus other operations (for example, fire, police, or hospital operations). Several ground ambulance organizations and other interested parties have posed questions to CMS asking for clarification on the specific methods they should use to allocate certain amounts prior to reporting information to GADCS. Allocating expenses is crucial for ground ambulance organizations that also provide other services or functions. If amounts are not allocated appropriately, the expenses and revenue reported to GADCS may be higher or lower than the actual expenses and revenue related to organizations' ground ambulance operations. The current instrument instructions allow ground ambulance organizations to use their current allocation approach or any reasonable alternative. The additional guidance in the instrument would provide an example allocation approach relevant to each section. For example, in fire department-based organizations, respondents can allocate dispatch, fire truck, and firefighter/EMT labor expenses using the share of total responses that are medical calls for service and/or involve a fully staffed and equipped ambulance. As another example relevant to fire department-based organizations, Medicare providers, and some other organizations, respondents can allocate facility expenses based on the share of square footage used by ground ambulance operations. While organizations looking for guidance on an approach could adopt these allocation methods, all organizations would remain free to use alternative allocation methods.
- Add a new screening question asking whether the ground ambulance organization broadly contracts out their ground ambulance organization. We have heard that in some cases a Medicare provider or supplier billing for ground ambulance services and selected to participate in GADCS will pay another organization to provide the entirety of the selected organization's emergency medical services capability, including ambulances, facilities, and EMT/response staff. In other cases, a selected organization may provide ambulances and facilities while some or all EMT/response labor is contracted out to another company. The current instrument instructions ask respondents to report the expenses associated with these broad contracts in Section 11, Question 1. However, the instrument instructions in Sections 7 through 11 do not specify whether the sampled organization should report on staff, facilities, and vehicles that are not owned or leased by the organization itself but instead are provided by the organization with which the sample organization contracts to provide

ground ambulance services. If selected organizations that broadly contract out staffing or ground ambulance capabilities report the total contract expenses in Section 11 but do not report on the staff, facilities, and vehicles that their contractor used to provide services in Sections 7 through 9, then the selected organization's expenses will appear very high relative to the inputs they report as necessary to run their ground ambulance operation.

• Add a new screening question in Section 2 that will ask whether organizations contract out some or all of their labor, facilities, vehicles, or other key inputs used to furnish ground ambulance services. We proposed that organizations answering ''yes'' to this initial screening question will see new instructions in Sections 7 through 13 asking them to report only select information on inputs provided by their contractors, including staff hours in Section 7, the number of facilities in Section 8, and counts of vehicles in Section 9. Importantly, the additional instruction will stress that organizations should not report on expenses for these contracted inputs in these sections. Organizations should continue to report the total expense for the broadly contracted service in Section 11, Question 1, following the existing instrument instructions. We noted that we believe this change will allow those analyzing data collected via GADCS to better align expenses for organizations that broadly contract out their ground ambulance services with the inputs reported via GADCS.

• Clarify (in Chapter 7 (Labor Costs)) for interested parties how to report labor hours and costs for staff categories not explicitly listed in the instrument. The Section 7 instructions already include a note that respondents should include Advanced-EMTs in the EMT-Intermediate category. To more prominently note how to collect and report data on Advanced-EMTs, and to provide more general guidance for other EMT/response labor categories that are State or locality-specific, we proposed to add the following instruction in Section 7: ''If your State uses levels of certification and licensure that differ from these categories, use your best judgement to assign staff to the CMS categories available.''

• Revise Section 7 labor category definitions from ''. . . with Fire/Police/Public Safety role'' to read ''. . . with role supporting fire, police, and/or other public safety operations.'' The Section 7 instructions require that staff with fire, police, or other public safety roles be included in separate ''with Fire/Police/Public Safety roles'' categories, regardless of whether they respond to calls for service (for example, as firefighter/EMTs); have a fire, police, or other public safety administrative or management role; or a combination of response and administrative roles. We learned that some ground ambulance organizations interpreted ''with Fire/Police/Public Safety roles'' in Section 7 labor categories to refer only to public safety responses role (that is, responding to calls for service) and not to other fire, police, or other public safety roles (for example, administrative or management roles). We believe this should clarify that our intent is not to limit the question to just fire, police, and other public safety response roles.

The remaining proposed changes in this category in the CY 2023 PFS proposed rule (87 FR 46247) were related to clarifying skip logic and response categories. Specifically, we proposed to:

• Remove the shared service programming note from that question so that all organizations are able to provide a response. When speaking to ambulance organizations, we noted that some organizations that do not meet our definition of shared services (that is, share services with public safety, hospital, or other medical organization) may nonetheless have shared costs with other types of operations. For example, a government-based ground ambulance organization may have computers and printers which are shared by other municipal services. The shared service skip logic programming note was inadvertently included Section 9.2, Question 4. Even without the skip logic, respondents will still be able to report that 100 percent of expenses are related to their ground ambulance operation.

• Streamline the categories and examples presented in the Section 11, Question 3 question on ground ambulance expenses not otherwise reported. We received many questions on how to report certain specific expenses in the provided categories and whether it was appropriate to include a specific expense the ''Other'' category. Specifically, we proposed to:

++ Change the note in this question that reads ''(excluding labor for medical director if accounted for in Question 1 above or in the labor section)'' to read ''(excluding labor for medical director which must be included in Section 11 Question 1 or in the labor section)'' because expenses associated with Medical Directors may be reported either in Section 7 (Labor Costs) or in Section 11, Question 1.

++ Delete the cost category ''Overhead allocation from parent organization/central office'' as we already provide places to report these costs throughout relevant sections of the instrument.

++ Move the ''Miscellaneous administrative fees/costs . . .'' category to the end of the ''Administrative and General Expenses'' section to improve flow.

++ Clarify that fees for ''Licenses'' should ''(Include professional or any other license fees not reported elsewhere in the instrument. Do not include any vehicle license fees previously reported in the Vehicles Section.)''

We invited comments on the proposals focusing on clarifications in response to feedback from interested parties' questions and testing. We did not receive any comments on clarifications responding to feedback from questions from interested parties and testing, and therefore, we are finalizing as proposed.

In addition to finalizing our proposed changes, we are adding additional guidance related to allocation. The web-based GADCS instrument will present text from the Frequently Asked Question (FAQ) document related to allocation. The FAQ document is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Medicare-Ground-Ambulance-FAQs.pdf*.

In order to implement the addition of screening questions for broadly contracted services, we are adding a new question at the end of Section 2 (Organizational Characteristics) asking whether the organization contracted some or all of the following during its continuous, 12-month data collection period:

• EMT labor specifically (excluding medical direction).

• Broader ground ambulance services, for example specific response capabilities in terms of ambulance units or service hours.

Answering ''Yes'' to either of these response options presents the respondent with additional instructions on how to report labor, vehicles, and facilities expenses in Sections 7 (Labor Costs), 8 (Facilities Costs), and 9 (Vehicle Costs). These instructions are repeated at the start of the respective sections. The instructions will direct organizations answering ''Yes'' to either of these response options to: (1) report on the number and type of labor hours, facilities, and vehicles used by their contractor; (2) enter $0 as appropriate as the annual expense for staff, facilities, and vehicles in Sections 7 (Labor Costs), 8 (Facilities Costs), and 9 (Vehicle Costs); and (3) report the total contract expense in Section 11 (Other Costs),

Question 1. This approach will provide CMS with information on the type and number of labor hours, facilities, and vehicles without requiring organizations outsourcing core ground ambulance operations to request detailed allocated expenses from their contractors. We considered alternatives where respondents in this scenario would have to report separate expenses in Sections 7, 8, and 9, rather than in Section 11. However, these alternatives could involve substantial additional administrative effort for users and would have required more extensive changes to Section 11 questions to explicitly exclude costs for contracted services reported in sections prior to Section 11.

We did not receive any comments on clarifications responding to feedback from questions from interested parties and testing, and therefore, we are finalizing as proposed. We are also finalizing adding additional guidance related to allocation and adding a new question at the end of Section 2 (Organizational Characteristics) asking whether the organization contracted some or all of the following during its continuous, 12-month data collection period.

d. Typos and Technical Corrections

In the CY 2023 PFS proposed rule (87 FR 46248), the final category of our proposed changes to the instrument addressed technical corrections and typos. We proposed 10 corrections to the data collection instrument. Specifically, we proposed to:

- Clarify that Section 4, Question 3 refers to twice the average as intended and as respondents will infer given the flow of questions. The Section 4, Question 3, item refers to the ''90th percentile'' rather than ''twice the average.'' When we removed the question referring to the 90th percentile response time and replaced it with a question asking about the share of responses longer than twice the average response time, as finalized in the CY 2022 PFS final rule (86 FR 65310), we should have but did not also adjust the text in this question.
- Update the Section 7.2 definition to read ''total hours worked by paid administrative/facilities and medical director staff.'' The Section 7.2 instructions define total hours worked as ''total hours worked by paid administrative staff.'' While medical directors are also included in Section 7.2, the current definition inadvertently excludes medical directors.
- Address in the same instrument section, an inadvertent omission in Question 3. This question refers to ''administrative labor costs'' which excludes facility labor costs as is specified throughout the remainder of the section. We would correct this inadvertent omission by replacing ''administrative labor costs'' with ''administrative/facilities costs.''
- Implement a technical correction in Section 8.1, Question 3 which states ''for each of the following types of facilities'' when it should read ''for each of the following facilities.'' The question asks for information at the facility level (not by type of facilities).
- Insert ''rent,'' which was inadvertently omitted, into the Section 8.2, Question 3 text so that it reads ''Please report the allocated portion of rent, lease, or ownership facilities costs. . . .''.
- Remove the skip logic and programming note in Section 9.2, Question 4 which erroneously specifies that the total number of statute miles traveled by non-ambulance water vehicles only be asked of organizations that noted in Section 2 that they operated water ambulances. Because organizations may have water rescue vehicles, but no water ambulances, we believe this correction is warranted.
- Remove an extraneous ''ground ambulance'' term in the middle of Section 9.3, Question 4. As a result, the question would read ''What was the total maintenance cost of all vehicles (ground ambulance and non-ambulance) used to respond to ground ambulance calls or support ground ambulance operations during your organization's data collection period?''
- Revise the Section 11 instructions asking for information on allocated central office expenses. The revised question would read ''(Questions 2 and 5)'' instead of just ''(Question 2)'' to align with prior changes in the CY 2022 PFS final rule (86 FR 65313) to ensure respondents can report allocated central office costs throughout the instrument.
- Edit a comma splice in the first sentence of the Section 11 instructions so they begin ''This section asks about . . .''
- Remove the word ''approximate'' as it was erroneously included in Section 13, Question 2b and does not align with any of the other questions in this section.

We invited comments on these proposals to address typos and technical clarifications.

Comment: One commenter expressed general support for addressing typos and errors in the GADCS instrument but did not address any of the typo and technical correction proposals individually.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing our 10 corrections as proposed. In addition, upon further review of the GADCS instrument, we identified one additional typo which we believe is important to address. The table in Section 13, Question 5, which asks for information on other sources of revenue not previously reported, includes a row for revenue from standby events. In the printable GADCS instrument, this row includes a programming note indicating that the row should only appear if the respondent answered ''Yes'' to Section 5, Question 7. This programming note should instead reference Section 5, Question 8, which asks whether the organization provided standby services during its continuous, 12-month data collection period. For clarity, we corrected this additional typo and will include the correction in the next posted version of the GADCS instrument.

4. Automation Process for Submitting a Hardship Exemption Request and Informal Review Request

In the CY 2020 PFS final rule (84 FR 62895), we codified the hardship exemption requirement at § 414.626(d). We stated that a ground ambulance organization can apply for a hardship exemption request based on a significant hardship, such as a natural disaster, bankruptcy, or other similar situation, that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

Specifically, § 414.626(d)(1) states that to request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following: Ground ambulance organization name; NPI number; Ground ambulance organization address; Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable); Reason for requesting a

hardship exemption; Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.); Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section; and Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization. Section 414.626 (d)(2) states that CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

In the CY 2020 PFS final rule (84 FR 62896), we also codified the process to request an informal review process under which a sampled ground ambulance organization may seek an informal review of a determination that is subject to the 10 percent reduction in payment at § 414.626(e). Section 414.626(e) outlines the notification of non-compliance and informal review. First, for notification of non-compliance, a ground ambulance organization selected under § 414.626 (c) for a year that does not sufficiently report data under paragraph (b) of this section will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9). Second, with respect to informal review, a ground ambulance organization that receives a written notification under § 414.610 (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notification by submitting all of the following information: ground ambulance organization name; NPI number; chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization; ground ambulance organization's selected data collection period and data reporting period; and a statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

In the CY 2020 PFS final rule (84 FR 62897), we stated that the hardship exemption and informal review requests should be submitted to the Ambulance ODF mailbox (*AMBULANCEODF@cms.hhs.gov*). We have been looking for ways to streamline both the hardship exemption request and informal review request and have determined that the most efficient method would be to require that the ground ambulance organizations submit a web-based form via the Medicare Ground Ambulance Data Collection System instead of submitting the requests via our Ambulance ODF mailbox. This method would be simpler, less burdensome, and less prone to error to track and process all incoming hardship exemption requests and informal review requests. We intend to launch the web-based portal that ground ambulance organizations can use to submit their hardship exemption and informal review requests in late 2022. We will share more information about the web-based portal when available.

We proposed to update our regulations to give us the necessary flexibility to specify how ground ambulance organizations should submit these requests, including to our web-based portal once that portal is operational. Specifically, we proposed to revise § 414.626(d)(1) and (e)(2) to state that these requests must be submitted in the form and manner specified by CMS.

As we stated in the CY 2020 PFS final rule (84 FR 62895) and in § 414.626(d)(1), the hardship exemption request form may be accessed on the Ambulances Services Center website for reference.

We invited comments on this proposal, which we summarize and respond to below.

Comment: We received three comments on this proposal. One commenter supported the refinements outlined in the proposed rule. Another commenter applauded CMS and stated that the proposed method for submission is a significant improvement over the current process. The commenter further stated that while it is expected that hardship exemption requests would be rare, applying for such a request would indicate a significant event has occurred and that such event heavily impacted the ability of the ground ambulance organization to provide services. Therefore, this commenter stated that streamlining the process for requesting a hardship exemption under likely intense circumstances would be welcomed. The commenter further stated that CMS should continue to find ways to simplify and modernize processes across its programs generally. Another commenter encouraged CMS to implement this proposal in a way that does not increase administrative burden and in a way that is revenue neutral given the increase in expenses to provide care to patients.

Response: We appreciate the support of the commenters. We are finalizing changes now that we believe further streamline the Medicare Ground Ambulance Data Collection System and reduce burden.

After consideration of the public comments we received, we are finalizing our proposal to update our regulations to give us the necessary flexibility to specify how ground ambulance organizations should submit these requests, including to our web-based portal once that portal is operational. Specifically, we are revising § 414.626(d)(1) and (e)(2) to state that these requests must be submitted in the form and manner specified by CMS.

N. Proposed Revisions to the HCPCS Level II Coding Policies for Skin Substitutes [437]

1. Background

a. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures

Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under that part. To process claims and determine payment for items and services under Medicare, CMS needs a way to appropriately identify the items and services billed. CMS has established certain codes for providers and suppliers to use to identify items and services on claims. Medicare receives over 1 billion electronic claims per year.

The HCPCS is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The HCPCS Level I code set is comprised of Current Procedural Terminology (CPT®) codes [438] and the HCPCS Level II code set is used primarily to identify items, services,

[437] As discussed in section II.J. of this final rule, CMS is not finalizing the adoption of the term ''wound care management products'' in this final rule. Therefore, we will use the term ''skin substitutes'' in this section for purposes of consistency throughout the final rule.

[438] The CPT® is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Decisions regarding the addition, deletion, or revisions of the CPT® codes are made and published by the American Medical Association (AMA) through the CPT® Editorial Panel. More information on CPT® codes can be found at *www.ama-assn/about/cpt-editorial-panel/cpt-code-process.*

supplies, and equipment that are not identified by CPT® codes.

HCPCS Level II codes were originally created for use by government insurers including Medicare. On August 17, 2000, HHS published a final rule (65 FR 50312) in which it adopted HCPCS Level II codes as the standard code set to be used by all payers for, among other things, health care equipment and supplies not described by CPT® codes, for use in Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions (45 CFR 162.1002). The HCPCS Level II coding system was selected as the standard code set, in part, because of its wide acceptance among both public and private insurers. With few exceptions,[439] HCPCS Level II codes are maintained by CMS, which is responsible for making decisions about additions, revisions, and discontinuations of codes. CMS maintains the code set for Medicare, but because HCPCS Level II is a standard code set designated for use under HIPAA by all payers, CMS also considers the needs of other payers, including both government and private insurers, in establishing and maintaining codes.

HCPCS Level II codes are alpha-numeric codes that begin with an alphabetical letter followed by four numeric digits. Currently, there are almost 8,000 HCPCS Level II codes that represent categories of like items and services. Each code includes a text descriptor (code text) that identifies the category of items and services encompassed in the code. HCPCS Level II codes are generally organized into lettered categories that loosely describe the types of codes under that letter;[440] however, the lettered categories are not dispositive, meaning that they are not all inclusive of the types of items and services described in the heading for each lettered category.

Anyone may submit a request to CMS for modifying the HCPCS Level II code set. Three types of coding revisions to the HCPCS may be requested: (1) that a new code be added (this may include requests to split an existing code category into its components or into subcategories); (2) that the language used to describe an existing code be changed; or (3) that an existing code be discontinued. Applicants who choose to submit a HCPCS Level II code application must submit their application using the online application portal known as the Medicare Electronic Application Request Information System™ (MEARIS™).[441]

The procedures by which the public submits and CMS evaluates code applications to modify the HCPCS Level II code set have been primarily included in documents released on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo*. We update and release the HCPCS Level II dataset files to our contractors and the public via our website on a quarterly basis.

Prior to 2020, CMS received and reviewed HCPCS Level II code applications and typically made related coding changes annually, including releasing updated coding files. However, in November 2019, we announced updates to our HCPCS Level II coding procedures to enable shorter and more frequent HCPCS Level II code application cycles beginning in January 2020 as part of our initiative to facilitate launching new products into the marketplace for providers and patients. Specifically, we implemented a process under which HCPCS Level II code applications for drugs and biological products may be submitted and are reviewed quarterly, and HCPCS Level II code applications for non-drugs and non-biological products may be submitted and are reviewed biannually.

The current coding procedures provide an opportunity for applicants who are dissatisfied with our coding decisions in a quarterly or biannual cycle an opportunity to reapply in a subsequent quarterly or biannual cycle. We release decisions on coding actions on both a quarterly and biannual basis for the respective coding cycle in the same format we used prior to 2020 to announce annual decisions. Additional information pertaining to CMS' HCPCS Level II coding decisions and procedures is available on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo*.

b. Food and Drug Administration (FDA) Regulation of Skin Substitutes

The FDA regulates skin substitutes based on a variety of factors, including intended use. Certain skin substitutes are considered Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) that are regulated by the FDA solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271 (''361 HCT/Ps''). To be regulated as a 361 HCT/P, the product must meet the four criteria set forth in 21 CFR 1271.10(a):

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- Either, the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and: (1) Is for autologous use; (2) Is for allogeneic use in a first-degree or second-degree blood relative; or (3) Is for reproductive use.

For 361 HCT/Ps, establishments that perform one or more steps in the manufacture of the 361 HCT/Ps must register and list their 361 HCT/Ps annually in the FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval by FDA is not needed. FDA acceptance of an establishment registration and 361 HCT/P listing form does not constitute a determination that an establishment is compliant with applicable FDA rules and regulations or that the 361 HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

Other skin substitutes are regulated by the FDA as devices that may be subject to premarket review through a 510(k) premarket notification submission (''510(k)'') in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations in subpart E of 21 CFR part 807, through a premarket

[439] The Code on Dental Procedures and Nomenclature (CDT® code) represents a separate medical code set adopted under HIPAA. See 45 CFR 162.1002. Based on alpha-numeric format, they are considered HCPCS Level II series D-codes but are maintained, copyrighted, licensed and published separately by the American Dental Association. More information on CDT® codes can be found at *https://www.ada.org/en/publications/cdt*.

[440] A-codes: Transportation Services, Medical and Surgical Supplies, Miscellaneous; B-codes: Enteral and Parenteral Therapy; C-codes: Hospital Outpatient Prospective Payment System; D-codes: Dental Procedures; E-codes: Durable Medical Equipment; G-codes: Temporary Codes for Procedures and Professional Services; H-codes: Rehabilitative Services; J-codes: Drugs Administered Other Than Oral Method, Chemotherapy Drugs; K-codes: Medicare National Codes for DMEPOS; L-codes: Orthotics, and Prosthetics; M-codes: Medical Services; P-codes: Pathology and Laboratory Services; Q-codes: Medicare National Codes; R-codes: Diagnostic Radiology Services; S-codes: Non-Medicare National Codes; T-codes: State Medicaid Agency Codes; U-codes: Clinical Laboratory Tests; and V-codes: Vision and Hearing Services. 85 FR 70374.

[441] OMB control number 0938–1042. Expiration Date: 07/31/2023.

approval (PMA) application process under section 515 of the FD&C Act and regulations in 21 CFR part 814, or through a De Novo classification request (De Novo request) under section 513(f)(2) of the FD&C Act and regulations in subpart D of 21 CFR part 860, or that may be exempt from premarket notification requirements. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to PMA (section 510(k), 510(n), 513(f)(1), or 513(i) of the FD&C Act).[442] A PMA is the most stringent type of premarket device submission and is required for approval of class III medical devices.[443] A De Novo request provides a marketing pathway for novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification [510(k)] submissions, when applicable.[444]

2. Proposed Revisions to the HCPCS Level II Coding Policies for Skin Substitutes

As of July 2022, there are approximately 155 unique HCPCS Level II codes that describe skin substitutes. Of these products, 137 are currently assigned a Q code. We assigned a Q code to these products because, at the time we made the code assignment, Medicare considered these products to be biological products. When these products are used in the office setting, they are paid by Medicare using the methodology under section 1847A of the Act, which, in many cases, is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

In addition, as part of our requirements for HCPCS Level II applications, we have always required proof of how a product is regulated by the FDA to assist in verification that the product is medical and legally on the market. For example, we have required the 510(k) clearance letter or the PMA approval letter for skin substitutes that are regulated by the FDA as devices.[445] For products described in the application as 361 HCT/Ps, we have required proof that the manufacturer registered and listed their 361 HCT/P with the FDA pursuant to 21 CFR part 1271.

Beginning in 2020, in accordance with section 1833(e) of the Act, we concluded that each application requesting a HCPCS Level II code for a skin substitute described in the application as a 361 HCT/P must additionally include a letter from the FDA's Tissue Reference Group (TRG) recommending that the product appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. As we stated in the CY 2023 PFS proposed rule (87 FR 46251), this information is necessary for CMS to determine, for coding purposes, how the product should be classified. For example, such information may be necessary to determine whether the product should be coded as a different type of single source drug or biological product rather than as a 361 HCT/P.[446] We stated in the CY 2023 PFS proposed rule that the collection of this additional information was intended to assist us in appropriately classifying, for purposes of assigning a HCPCS Level II code, when these medical products are 361 HCT/Ps, biological products, drugs, or other.[447]

In the CY 2022 PFS final rule (86 FR 65121), we also finalized that ten specific 510(k)-cleared skin substitutes for which we had received a HCPCS Level II code application would be payable by Medicare in the physician office setting as contractor priced products that are billed separately from the procedure to apply them. In the latter part of 2021, we published final decisions that assigned an A code to each of these ten 510(k)-cleared skin substitutes, with an effective date of January 1, 2022. These final decisions are located on the CMS website at *https://www.cms.gov/files/document/2021-hcpcs-application-summary-supplemental-coding-cycle-updated-04062022.pdf*.

We subsequently discovered that we had inadvertently assigned an A code to one product (bio-ConneKt Wound Matrix) for which a Q code, Q4161, had already been assigned. As such, we updated the Supplemental Coding Cycle decision document in December 2021 to remove the A code assignment for bio-ConneKt Wound Matrix while retaining A code assignments for the other nine 510(k)-cleared skin substitutes. Following the Supplemental Coding Cycle, we assigned additional A codes for three 510(k)-cleared skin substitutes with an effective date of April 1, 2022, for which we received a first-time HCPCS Level II application in the Second Biannual, 2021 HCPCS Coding Cycle.[448] Since the publication of the CY 2023 PFS proposed rule, we have assigned A codes to an additional five 510(k)-cleared skin substitutes with an effective date of October 1, 2022, for which we received a first-time HCPCS Level II application in the First Biannual, 2022 HCPCS Coding Cycle.

a. Proposed Revisions to General Coding Policy for Skin Substitutes

In the CY 2023 PFS proposed rule (87 FR 46251), we proposed to uniformly classify skin substitutes (that are not regulated by the FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) consistently in the HCPCS Level II code set based on information presented to CMS as described in additional detail below, effective January 1, 2024. We proposed that the assignment of A codes to all skin substitutes would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for skin substitutes to which we previously assigned a Q code. See below for further details, as we also proposed that manufacturers of

[442] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#:~:text=A%20510(k)%20requires%20demonstration,and%20effective%20as%20the%20predicate.&text=the%20information%20submitted%20to%20FDA,as%20the%20legally%20marketed%20device.*

[443] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.*

[444] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request.*

[445] To date, CMS has not received a HCPCS Level II application for any skin substitutes regulated by the FDA as a device through a De Novo request, but a De Novo request approval letter would have been required as part of the application to assist in verification that the product was medical and legally on the market.

[446] Under a final rule promulgated by the FDA on August 31, 2016, manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, must register and list their HCT/Ps following the procedures in 21 CFR part 207 or 807, as applicable, rather than 21 CFR part 1271. FDA also maintains Frequently Asked Questions on this topic at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/questions-and-answers-regarding-end-compliance-and-enforcement-policy-certain-human-cells-tissues-or.*

[447] When a medical product is improperly grouped or described by CMS in the HCPCS Level II code set relative to our established conventions, payers may unintentionally apply inaccurate coverage and/or payment to the provider or supplier submitting a claim, and in that way, the beneficiary or enrollee may be subject to inaccurate cost-sharing. Each payer establishes its own methodology for coverage and payment but often rely on the HCPCS Level II groupings of similar types of medical products to accelerate the adoption process of new technologies.

[448] *https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2–2021-non-drug-and-non-biological-items-and-services.pdf.*

certain skin substitutes will need to submit additional information to CMS prior to the assignment of an A code. We stated in the CY 2023 PFS proposed rule that these proposals aligned with our proposal in section II.J. of that proposed rule that all skin substitutes would be eligible for coverage under section 1861(s)(2)(A) of the Act as incident to supplies that are commonly furnished in the physician office setting.

We stated in the CY 2023 PFS proposed rule (87 FR 46251) that HCPCS Level II Q codes are used to identify products separately payable as drugs and biologicals under Medicare Part B, and that such products are priced using the methodology in section 1847A of the Act which, in many cases, means that payment is based on the ASP plus a statutorily-mandated 6 percent add-on. We also stated that A codes are used to identify transportation services and medical and surgical supplies. We stated that we believed that the assignment of an A code to all skin substitutes that are not drugs or biological products [449] would better reflect what the product is for purposes of assigning a code because this proposed approach aligned with the payment proposal in section II.J. of the proposed rule that would establish a consistent pricing methodology by pricing all skin substitutes as incident to supplies. We also noted in the proposed rule that we believed the proposed policy would provide a more consistent and transparent approach to coding for skin substitutes.

b. Proposed Additional Requirements Specific to HCPCS Level II Coding for Skin Substitutes

With respect to 361 HCT/Ps, we proposed to no longer evaluate HCPCS Level II coding applications for such products on a quarterly basis beginning January 1, 2024,[450] and to instead evaluate them through our biannual coding cycles for non-drugs and non-biological products. We explained that our proposal to assign A codes to all skin substitutes that are not drugs or biological products and to review these products in the same biannual coding cycle would align with the payment proposal in section II.J. of the proposed rule, as CMS uses the biannual cycles to review code applications for non-drugs and non-biological products and section II.J proposed to price these products as incident to supplies. We noted that the biannual coding cycle includes preliminary coding determinations and an opportunity for written and public comment, which may assist manufacturers and CMS in reconciling any discrepancies with information submitted to us or addressing questions about a product that we may raise; we noted that we believed this dialogue would be productive for all involved.

We further proposed that manufacturers of products described as 361 HCT/Ps that have already been assigned a Q code must also provide documentation from the FDA (that is, the TRG recommendation letter) that indicates how the product appears to be regulated by the FDA.[451] This information would be part of a HCPCS Level II application submitted via MEARIS™ and would be part of a public meeting for consideration. We proposed to allow a 12-month period from the effective date of the CY 2023 PFS final rule (that is, January 1, 2024) to allow for application submissions. We explained that this deadline for application submission would provide sufficient time for applicants to communicate with the FDA in regard to the TRG recommendation letter, as applicable. We also encouraged manufacturers with an existing Q code for products described as 361 HCT/Ps who would need to re-apply for an A code to submit their request for a TRG recommendation to the FDA as soon as feasible to ensure that they receive the recommendation in time to include it with the re-application. After a public meeting and appropriate review by CMS, we proposed to discontinue all existing Q codes for skin substitutes and to establish new A codes for such products that have submitted the appropriate documentation. We proposed to make the effective date of the new A codes coincide with the discontinuation date of the corresponding Q codes such that there would be no gap between the effective dates of the discontinued codes and the newly established codes. Based on our biannual coding process for non-drugs and non-biological products, we noted that we anticipated the new A codes would take effect on October 1, 2024. If an application is *not* submitted, we proposed to discontinue the Q code in the quarterly update cycle following the proposed deadline for re-application submission (that is, January 1, 2024), which we anticipated would take effect on April 1, 2024.

We also proposed to collect additional information in support of HCPCS Level II code applications for these products. As proposed, all first-time applications for 361 HCT/Ps would need to continue to be supported, as we started in 2020, with documentation from the FDA (that is, the TRG recommendation letter) that indicates how the product appears to be regulated by the FDA. That is, for a product that is described by the applicant as a 361 HCT/P, we proposed that the application would need to provide a recommendation letter from the FDA's TRG which would aid in our determination of how the product should be classified for coding purposes. We stated that the FDA TRG recommendation letter assists us in recognizing whether a product is a skin substitute, separately payable drug or biological product, or otherwise and aids us in issuing an appropriate code consistent with our coding conventions.[452] We noted that a recommendation letter from FDA's TRG would also be necessary in other circumstances, such as when a product manufacturer seeks a change to a current code descriptor or presents other information to us in which a product's market status or other event has changed and the manufacturer believes a code should be revised.

We noted that we would notify the public of all future coding decisions for skin substitutes through our standard process of posting decisions for each coding cycle on the HCPCS web page on *CMS.gov* (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary*).

c. Summary of Proposals

In summary, we proposed: (1) that the assignment of A codes to all skin substitutes (that are not regulated by FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) would continue with respect to products for which a HCPCS Level II

[449] Drug and biological products would generally be coded as J or Q codes.

[450] Manufacturers of skin substitutes that received a 510(k) clearance, PMA approval, or a granted De Novo request are currently reviewed in the non-drugs and non-biologicals biannual coding cycle and will continue in that cycle.

[451] Manufacturers of skin substitutes that received a 510(k) clearance, PMA approval, or a granted De Novo request do not need to resubmit documentation. These products will be reclassified to an A code at the same time as the established 361 HCT/P products with Q codes are reclassified to an A code (that is, October 1, 2024).

[452] Based on prior experience, we noted that we may identify discrepancies between the FDA TRG recommendation letter and the application presented to CMS, particularly in regard to indications of use and clinical claims. In cases of discrepancies, we may ask for clarification, encourage the applicant to consult further with the FDA, consult further with the FDA ourselves, and/or engage with the applicant through the public meeting process. In doing so, we are working to ascertain that the product is a skin substitute rather than another product, which may be more appropriately classified elsewhere in the HCPCS Level II code set.

code is requested for the first time, as well as for skin substitutes to which we previously assigned a Q code; (2) to discontinue all existing Q codes for skin substitutes; (3) to require, prior to the assignment of an A code, products with an existing Q code that were described by the applicant as a 361 HCT/P to submit a HCPCS Level II application within 12 months of the effective date of the final rule (that is, January 1, 2024); (4) to require that a recommendation letter from the FDA's TRG be submitted as part of the HCPCS Level II application for all skin substitutes described by the applicant as a 361 HCT/P, regardless if it is a first-time application or an application for a product with an existing Q code; and (5) to evaluate HCPCS Level II coding applications for all 361 HCT/P skin substitutes through our biannual coding cycles for non-drugs and non-biological products, rather than on a quarterly basis, beginning January 1, 2024.

We sought comments on these proposals. We also sought comments on whether any codes were unintentionally omitted from the list of skin substitutes for which new code applications would need to be submitted or new A codes would be issued for devices that are 510(k)-cleared, PMA-approved, or classified into class I or class II through a De Novo request (Table 88) and should have similarly been subject to this proposal.

TABLE 88: Skin Substitutes for Which We Proposed to Issue New A-Codes for 510(k)-cleared/PMA/De Novo Skin Substitutes or for Which New Code Applications Would Need to Be Submitted Within 12 Months of the Effective Date of the CY 2023 PFS Final Rule

Code	Long Descriptor	Short Descriptor	Effective Date
Q4101	Apligraf, per square centimeter	Apligraf	1/1/2014
Q4102	Oasis wound matrix, per square centimeter	Oasis wound matrix	1/1/2014
Q4103	Oasis burn matrix, per square centimeter	Oasis burn matrix	1/1/2014
Q4104	Integra bilayer matrix wound dressing (bmwd), per square centimeter	Integra bmwd	1/1/2014
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter	Integra drt or omnigraft	1/1/2017
Q4106	Dermagraft, per square centimeter	Dermagraft	1/1/2014
Q4107	Graftjacket, per square centimeter	Graftjacket	1/1/2014
Q4108	Integra matrix, per square centimeter	Integra matrix	1/1/2014
Q4110	Primatrix, per square centimeter	Primatrix	1/1/2014
Q4111	Gammagraft, per square centimeter	Gammagraft	1/1/2014
Q4112	Cymetra, injectable, 1 cc	Cymetra injectable	1/1/2011
Q4113	Graftjacket xpress, injectable, 1 cc	Graftjacket xpress	1/1/2011
Q4114	Integra flowable wound matrix, injectable, 1 cc	Integra flowable wound matri	1/1/2014
Q4115	Alloskin, per square centimeter	Alloskin	1/1/2014
Q4116	Alloderm, per square centimeter	Alloderm	1/1/2014
Q4117	Hyalomatrix, per square centimeter	Hyalomatrix	1/1/2011
Q4118	Matristem micromatrix, 1 mg	Matristem micromatrix	1/1/2014
Q4121	Theraskin, per square centimeter	Theraskin	1/1/2018
Q4122	Dermacell, dermacell awm or dermacell awm porous, per square centimeter	Dermacell, awm, porous sq cm	10/1/2019
Q4123	Alloskin rt, per square centimeter	Alloskin	1/1/2012
Q4124	Oasis ultra tri-layer wound matrix, per square centimeter	Oasis tri-layer wound matrix	1/1/2014
Q4125	Arthroflex, per square centimeter	Arthroflex	1/1/2012
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter	Memoderm/derma/tranz/integup	1/1/2013
Q4127	Talymed, per square centimeter	Talymed	1/1/2016
Q4128	Flex hd, allopatch hd, or matrix hd, per square centimeter	Flexhd/allopatchhd/matrixhd	1/1/2013
Q4130	Strattice tm, per square centimeter	Strattice tm	1/1/2012
Q4132	Grafix core and grafixpl core, per square centimeter	Grafix core, grafixpl core	1/1/2018
Q4133	Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter	Grafix stravix prime pl sqcm	1/1/2019
Q4134	Hmatrix, per square centimeter	Hmatrix	1/1/2013
Q4135	Mediskin, per square centimeter	Mediskin	1/1/2013
Q4136	Ez-derm, per square centimeter	Ezderm	1/1/2013
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter	Amnioexcel biodexcel 1sq cm	1/1/2019
Q4138	Biodfence dryflex, per square centimeter	Biodfence dryflex, 1cm	1/1/2014
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc	Amnio or biodmatrix, inj 1cc	1/1/2014
Q4140	Biodfence, per square centimeter	Biodfence 1cm	1/1/2014
Q4141	Alloskin ac, per square centimeter	Alloskin ac, 1 cm	1/1/2014
Q4142	Xcm biologic tissue matrix, per square centimeter	Xcm biologic tiss matrix 1cm	1/1/2014
Q4143	Repriza, per square centimeter	Repriza, 1cm	1/1/2014
Q4145	Epifix, injectable, 1 mg	Epifix, inj, 1mg	1/1/2014
Q4146	Tensix, per square centimeter	Tensix, 1cm	1/1/2014
Q4147	Architect, architect px, or architect fx, extracellular matrix, per square centimeter	Architect ecm px fx 1 sq cm	1/1/2015
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter	Neox neox rt or clarix cord	1/1/2018
Q4149	Excellagen, 0.1 cc	Excellagen, 0.1 cc	1/1/2014
Q4150	Allowrap ds or dry, per square centimeter	Allowrap ds or dry 1 sq cm	1/1/2015

Code	Long Descriptor	Short Descriptor	Effective Date
Q4151	Amnioband or guardian, per square centimeter	Amnioband, guardian 1 sq cm	1/1/2015
Q4152	Dermapure, per square centimeter	Dermapure 1 square cm	1/1/2015
Q4153	Dermavest and plurivest, per square centimeter	Dermavest, plurivest sq cm	1/1/2016
Q4154	Biovance, per square centimeter	Biovance 1 square cm	1/1/2015
Q4155	Neoxflo or clarixflo, 1 mg	Neoxflo or clarixflo 1 mg	1/1/2015
Q4156	Neox 100 or clarix 100, per square centimeter	Neox 100 or clarix 100	1/1/2018
Q4157	Revitalon, per square centimeter	Revitalon 1 square cm	1/1/2015
Q4158	Kerecis omega3, per square centimeter	Kerecis omega3, per sq cm	1/1/2018
Q4159	Affinity, per square centimeter	Affinity1 square cm	1/1/2015
Q4160	Nushield, per square centimeter	Nushield 1 square cm	1/1/2015
Q4161	Bio-connekt wound matrix, per square centimeter	Bio-connekt per square cm	1/1/2016
Q4162	Woundex flow, bioskin flow, 0.5 cc	Wndex flw, bioskn flw, 0.5cc	1/1/2018
Q4163	Woundex, bioskin, per square centimeter	Woundex, bioskin, per sq cm	1/1/2018
Q4164	Helicoll, per square centimeter	Helicoll, per square cm	1/1/2016
Q4165	Keramatrix or kerasorb, per square centimeter	Keramatrix, kerasorb sq cm	10/1/2019
Q4166	Cytal, per square centimeter	Cytal, per square centimeter	1/1/2017
Q4167	Truskin, per square centimeter	Truskin, per sq centimeter	1/1/2017
Q4168	Amnioband, 1 mg	Amnioband, 1 mg	1/1/2017
Q4169	Artacent wound, per square centimeter	Artacent wound, per sq cm	1/1/2017
Q4170	Cygnus, per square centimeter	Cygnus, per sq cm	1/1/2017
Q4171	Interfyl, 1 mg	Interfyl, 1 mg	1/1/2017
Q4173	Palingen or palingen xplus, per square centimeter	Palingen or palingen xplus	1/1/2017
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc	Palingen or promatrx	1/1/2017
Q4175	Miroderm, per square centimeter	Miroderm	1/1/2017
Q4176	Neopatch or therion, per square centimeter	Neopatch or therion, 1 sq cm	7/1/2020
Q4177	Floweramnioflo, 0.1 cc	Floweramnioflo, 0.1 cc	1/1/2018
Q4178	Floweramniopatch, per square centimeter	Floweramniopatch, per sq cm	1/1/2018
Q4179	Flowerderm, per square centimeter	Flowerderm, per sq cm	1/1/2018
Q4180	Revita, per square centimeter	Revita, per sq cm	1/1/2018
Q4181	Amnio wound, per square centimeter	Amnio wound, per square cm	1/1/2018
Q4182	Transcyte, per square centimeter	Transcyte, per sq centimeter	1/1/2018
Q4183	Surgigraft, per square centimeter	Surgigraft, 1 sq cm	1/1/2019
Q4184	Cellesta or cellesta duo, per square centimeter	Cellesta or duo per sq cm	10/1/2019
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc	Cellesta flowab amnion 0.5cc	1/1/2019
Q4186	Epifix, per square centimeter	Epifix 1 sq cm	1/1/2019
Q4187	Epicord, per square centimeter	Epicord 1 sq cm	1/1/2019
Q4188	Amnioarmor, per square centimeter	Amnioarmor 1 sq cm	1/1/2019
Q4189	Artacent ac, 1 mg	Artacent ac, 1 mg	1/1/2019
Q4190	Artacent ac, per square centimeter	Artacent ac 1 sq cm	1/1/2019
Q4191	Restorigin, per square centimeter	Restorigin 1 sq cm	1/1/2019
Q4192	Restorigin, 1 cc	Restorigin, 1 cc	1/1/2019
Q4193	Coll-e-derm, per square centimeter	Coll-e-derm 1 sq cm	1/1/2019
Q4194	Novachor, per square centimeter	Novachor 1 sq cm	1/12019
Q4195	Puraply, per square centimeter	Puraply 1 sq cm	1/1/2019
Q4196	Puraply am, per square centimeter	Puraply am 1 sq cm	1/1/2019
Q4197	Puraply xt, per square centimeter	Puraply xt 1 sq cm	1/1/2019
Q4198	Genesis amniotic membrane, per square centimeter	Genesis amnio membrane 1sqcm	1/1/2019
Q4200	Skin te, per square centimeter	Skin te 1 sq cm	1/1/2019
Q4201	Matrion, per square centimeter	Matrion 1 sq cm	1/1/2019
Q4202	Keroxx (2.5g/cc), 1cc	Keroxx (2.5g/cc), 1cc	1/1/2019
Q4203	Derma-gide, per square centimeter	Derma-gide, 1 sq cm	1/1/2019
Q4204	Xwrap, per square centimeter	Xwrap 1 sq cm	1/1/2019
Q4205	Membrane graft or membrane wrap, per square centimeter	Membrane graft or wrap sq cm	10/1/2019
Q4206	Fluid flow or fluid gf, 1 cc	Fluid flow or fluid gf 1 cc	10/1/2019
Q4208	Novafix, per square cenitmeter	Novafix per sq cm	10/1/2019

Code	Long Descriptor	Short Descriptor	Effective Date
Q4209	Surgraft, per square centimeter	Surgraft per sq cm	10/1/2019
Q4210	Axolotl graft or axolotl dualgraft, per square centimeter	Axolotl graf dualgraf sq cm	10/1/2019
Q4211	Amnion bio or axobiomembrane, per square centimeter	Amnion bio or axobio sq cm	10/1/2019
Q4212	Allogen, per cc	Allogen, per cc	10/1/2019
Q4213	Ascent, 0.5 mg	Ascent, 0.5 mg	10/1/2019
Q4214	Cellesta cord, per square centimeter	Cellesta cord per sq cm	10/1/2019
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg	Axolotl ambient, cryo 0.1 mg	10/1/2019
Q4216	Artacent cord, per square centimeter	Artacent cord per sq cm	10/1/2019
Q4217	Woundfix, biowound, woundfix plus, biowound plus, woundfix xplus or biowound xplus, per square centimeter	Woundfix biowound plus xplus	10/1/2019
Q4218	Surgicord, per square centimeter	Surgicord per sq cm	10/1/2019
Q4219	Surgigraft-dual, per square centimeter	Surgigraft dual per sq cm	10/1/2019
Q4220	Bellacell hd or surederm, per square centimeter	Bellacell hd, surederm sq cm	10/1/2019
Q4221	Amniowrap2, per square centimeter	Amniowrap2 per sq cm	10/1/2019
Q4222	Progenamatrix, per square centimeter	Progenamatrix, per sq cm	10/1/2019
Q4226	Myown skin, includes harvesting and preparation procedures, per square centimeter	Myown harv prep proc sq cm	10/1/2019
Q4227	Amniocore, per square centimeter	Amniocore per sq cm	7/1/2020
Q4229	Cogenex amniotic membrane, per square centimeter	Cogenex amnio memb per sq cm	7/1/2020
Q4230	Cogenex flowable amnion, per 0.5 cc	Cogenex flow amnion 0.5 cc	7/1/2020
Q4231	Corplex p, per cc	Corplex p, per cc	7/1/2020
Q4232	Corplex, per square centimeter	Corplex, per sq cm	7/1/2020
Q4233	Surfactor or nudyn, per 0.5 cc	Surfactor /nudyn per 0.5 cc	7/1/2020
Q4234	Xcellerate, per square centimeter	Xcellerate, per sq cm	7/1/2020
Q4235	Amniorepair or altiply, per square centimeter	Amniorepair or altiply sq cm	7/1/2020
Q4237	Cryo-cord, per square centimeter	Cryo-cord, per sq cm	7/1/2020
Q4238	Derm-maxx, per square centimeter	Derm-maxx, per sq cm	7/1/2020
Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter	Amnio-maxx or lite per sq cm	7/1/2020
Q4240	Corecyte, for topical use only, per 0.5 cc	Corecyte topical only 0.5 cc	7/1/2020
Q4241	Polycyte, for topical use only, per 0.5 cc	Polycyte, topical only 0.5cc	7/1/2020
Q4242	Amniocyte plus, per 0.5 cc	Amniocyte plus, per 0.5 cc	7/1/2020
Q4244	Procenta, per 200 mg	Procenta, per 200 mg	7/1/2020
Q4245	Amniotext, per cc	Amniotext, per cc	7/1/2020
Q4246	Coretext or protext, per cc	Coretext or protext, per cc	7/1/2020
Q4247	Amniotext patch, per square centimeter	Amniotext patch, per sq cm	7/1/2020
Q4248	Dermacyte amniotic membrane allograft, per square centimeter	Dermacyte amn mem allo sq cm	7/1/2020
Q4249	Amniply, for topical use only, per square centimeter	Amniply, per sq cm	10/1/2020
Q4250	Amnioamp-mp, per square centimeter	Amnioamp-mp per sq cm	10/1/2020
Q4254	Novafix dl, per square centimeter	Novafix dl per sq cm	10/1/2020
Q4255	Reguard, for topical use only, per square centimeter	Reguard, topical use per sq	10/1/2020

For all 361 HCT/Ps for which CMS has issued a Q code with an effective date on or after October 1, 2021, as shown in Table 89, we proposed to discontinue the Q code and issue an A code, effective on the same date as the other products discussed in the proposal (that is, October 1, 2024). We did not propose to require resubmission of a HCPCS Level II coding application for these HCT/Ps because the applications already included a TRG recommendation letter from the FDA. We also proposed to take a similar approach for all new 361 HCT/Ps in which Q codes are issued before January 1, 2024.

TABLE 89: HCPCS Level II Q Codes for Skin Substitutes Effective on or after October 1, 2021

Code	Long Descriptor	Short Descriptor	Effective Date
Q4251	Vim, per square centimeter	Vim, per square centimeter	10/01/2021
Q4252	Vendaje, per square centimeter	Vendaje, per square centimet	10/01/2021
Q4253	Zenith amniotic membrane, per square centimeter	Zenith amniotic membrane psc	10/01/2021
Q4199	Cygnus matrix, per square centimeter	Cygnus matrix, per sq cm	01/01/2022
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter	Hhf10-p per sq cm	04/01/2022
Q4225	Amniobind, per square centimeter	Amniobind, per sq cm	04/01/2022
Q4256	Mlg-complete, per square centimeter	Mlg complete, per sq cm	04/01/2022
Q4257	Relese, per square centimeter	Relese, per sq cm	04/01/2022
Q4258	Enverse, per square centimeter	Enverse, per sq cm	04/01/2022
Q4259	Celera dual layer or celera dual membrane, per square centimeter	Celera per sq cm	07/01/2022
Q4260	Signature apatch, per square centimeter	Signature apatch, per sq cm	07/01/2022
Q4261	Tag, per square centimeter	Tag, per square centimeter	07/01/2022

d. Comments Received on the Proposed Coding Policies

We received public comments on the coding policies that we proposed. Some of the commenters expressed support for our proposed coding policies, while other commenters expressed concerns regarding our proposed coding policies. The coding proposals were one part of our overall proposed approach to refining how we treat skin substitutes furnished in the physician office setting for purposes of coding, coverage, and payment under Medicare. As described more fully in section II.J. of this final rule, we are not finalizing our coverage and payment proposals with respect to these products. Accordingly, we are also not finalizing any of the coding proposals at this time. We are also not summarizing the public comments we received at this time and point interested parties to *regulations.gov* if they would like to review those public comments. We intend to summarize the public comments we received, and respond to those comments, in future rulemaking.

IV. Updates to the Quality Payment Program

A. CY 2023 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule outlines changes to the Quality Payment Program starting January 1, 2023, except as otherwise noted for specific provisions. The CY 2023 performance period/2025 MIPS payment year continues to move the Quality Payment Program forward to focus more on our measurement efforts, refines how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and encourages participation in Advanced Alternative Payment Models (APMs).

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. The weights of those four performance categories are specified in statute. For CY 2023, those weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category. If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) status, they are excluded from the MIPS reporting requirements and payment adjustment. Those that are qualifying APM participants (QPs) for the year are eligible to receive a 5 percent lump sum incentive payment during the corresponding payment year through CY 2024, or a differential payment update under the PFS for payment years beginning in 2026.

Participation in the Quality Payment Program, defined as clinicians with a final score greater than 0, including both those who submitted data (engaged) and those who did not submit data, remained consistent at 100 percent in the fifth year (CY 2021 performance period). We saw 100 percent of MIPS eligible clinicians participate in MIPS in 2021 with 698,937 MIPS eligible clinicians participating and receiving a payment adjustment, which was similar to our 2020 participation rates with 933,545 MIPS eligible clinicians receiving a payment adjustment and 933,543 MIPS eligible participants. Therefore, participation rates in MIPS did not meaningfully change in 2021 as compared to 2020. We did see a decrease in the number of eligible clinicians receiving a payment adjustment with 698,937 MIPS eligible clinicians in 2021 compared to 933,545 in 2020. In addition, 86.03 percent of MIPS eligible clinicians received a positive payment adjustment for the 2023 MIPS payment year based on CY 2021 performance period data. We note that due to the Public Health Emergency (PHE) for COVID–19, 196,252 (or about 28 percent of 698,937) MIPS eligible clinicians received reweighting for the CY 2021 performance period/2023 MIPS payment year of one or more MIPS performance categories under the MIPS extreme and uncontrollable circumstances policy.

Please note that results for the CY 2021 performance period/2023 MIPS payment year are subject to change as a result of the targeted review process which began on August 22, 2022 and will conclude on October 21, 2022. For more information on the targeted review process for 2021 please see our targeted review guide at *https://qpp-cm-prod-*

content.s3.amazonaws.com/uploads/2038/2021%20Targeted%20Review%20Guide.pdf.

Regarding performance in Advanced APMs, for the 2021 QP Performance Period, 271,276 eligible clinicians earned Qualifying APM Participant (QP) status while another 3,378 eligible clinicians earned partial QP status. We plan to continue developing Quality Payment Program policies that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with MVPs to allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we make long-term improvements, continue evolving MIPS policies, and plan to begin implementing MVPs in 2023, we remain committed to our program goals. We are aligning with broader CMS initiatives, such as the CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy*), to unify strategic efforts to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures. The vision for the CMS National Quality Strategy is to shape a resilient, high-value American health care system to achieve high-quality, safe, equitable, and accessible care for all. This strategy aims to promote the highest quality outcomes and safest care for all individuals. It also focuses on a person-centric approach as individuals journey across the continuum of care and across payer type. The goals of the strategy incorporate lessons learned from the COVID–19 public health emergency (PHE) to inform both short and long-term direction for our health care system as well as support the creation of a more equitable, safe, and outcomes-based health care system for all individuals. The planned implementation of MVPs aligns with many of the objectives and goals the CMS National Quality Strategy will strive to achieve.

b. Summary of Major Provisions

(1) Major MIPS Provisions

MIPS aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care.

We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from interested parties that MIPS does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias. Interested parties have indicated that these issues detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that the MVP framework will connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients (86 FR 65391). We intend to focus the future of MIPS on MVP development and implementation.

Additionally, we have heard from patients, clinicians, and other interested parties that they would like more comprehensive and granular reporting from the MIPS program. To that end, in the CY 2022 PFS final rule (86 FR 65396 and 65397), we established voluntary subgroup reporting to help provide patients and clinicians information that is clinically meaningful at a more granular level.

(a) MIPS Value Pathways Development

As discussed in the CY 2023 PFS final rule (87 FR 46263), we intend to continue improving the MIPS program through MVPs, promote the use of connected measures and activities, reward clinicians for providing high value care, and help all clinicians improve care and engage patients. We also intend to gather information from interested parties to help guide efforts to advance health equity throughout CMS quality programs. We previously finalized an MVP development process involving the submission of MVPs by interested parties for our consideration (85 FR 84849 through 84850). We believe the MVP development process should also consider feedback from the general public outside of the notice and comment rulemaking process through which MVPs are adopted. Therefore, we are finalizing our proposal to modify the MVP development process such that were CMS to receive a new candidate MVP, evaluate it through the MVP development process and determine it ''ready'' for feedback, CMS would post a draft version of the MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback from interested parties as well as the general public for a 30-day period.

In addition, we previously established a process for soliciting interested party recommendations for potential updates to established MVPs. On an annual basis, beginning in January, interested parties may submit their recommendations for the revision of an established MVP, and that input is accepted on a rolling basis throughout the year. We believe the MVP maintenance process should also consider feedback from the general public outside of the notice and comment rulemaking process through which MVPs are revised. Therefore, we are finalizing our proposal that after we review the submitted recommendations to revise established MVPs, and identify any feasible and appropriate revisions to established MVPs, we would host an annual public facing webinar, open to interested parties and the general public through which they may offer their feedback on potential revisions to the MVPs.

In the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that will be available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year.

In the CY 2023 PFS proposed rule (87 FR 46266), we proposed revisions to these seven MVPs based on the proposed removals of certain activities from the improvement activities inventory and the addition of other relevant existing quality measures for MVP participants to select from. We are finalizing the revisions to these seven MVPs. In addition, through this rulemaking cycle, we are finalizing as proposed five additional new MVPs:

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

The MVP framework aims to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care. As discussed in the proposed rule (87 FR 46264), we are continuing to explore opportunities to advance health equity in accordance with the CMS Framework for Health

Equity 2022–2023,[453] across all CMS programs and policies, including the MVP framework. We are considering how MVPs should evolve to better promote higher value care and APM participation by both primary care and specialist clinicians. We sought public comment, through a request for information (see 87 FR 46264 through 46265), on ways to integrate MVPs into APP reporting and how to best facilitate specialty clinician reporting of quality performance measures (in addition to the APP) that reflect the specialty services provided.

(b) Subgroup Reporting

To support clinicians in their transition to subgroup reporting, subgroup reporting will be voluntary for the CY 2023, 2024, and 2025 performance periods/2025, 2026, and 2027 MIPS payment years. Multispecialty groups that choose to report through an MVP will be required to participate as subgroups beginning with CY 2026 performance period/2028 MIPS payment year. As discussed in section IV.A.4.e. of this final rule, we are finalizing the following policies for subgroups:

- *Subgroup description requirement:* A group must submit a description of each subgroup at the time of registration.
- *Limitation of one subgroup per TIN–NPI combination:* An individual eligible clinician, as represented by a TIN/NPI combination may register for no more than one subgroup within a group's TIN.
- *Subgroup determination period:* CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the first segment of the applicable MIPS determination period.
- *Subgroup scores for administrative claims measures and cost measures:* Subgroups are scored on each selected population health measure based on their affiliated group score, if available and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We are also finalizing that subgroups are scored on the cost measures included in the MVP that they select, based on their affiliated group score, if available. If the affiliated group score is not available, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).
- *Scoring for subgroups that register but do not report:* We will not assign a score for subgroups that register but do not submit data for an applicable performance period.

(c) Requests for Information (RFI)

The CY 2023 PFS proposed rule contained the following RFIs (87 FR 46256 through 46263):

- Request for Information Regarding QP Determination Calculations at the Individual Eligible Clinician Level
- Request for Information Regarding the Transition from APM Incentive Payments to the Enhanced PFS Conversion Factor Update for QPs
- Request for Information on Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs
- Request for Information on Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)
- Request for Information on Risk Indicators Within Complex Patient Bonus Formula to Continue to Align with CMS Approach to Operationalizing Health Equity

We thank commenters for their responses to these requests for information. We may consider this information to inform future rulemaking.

(2) Major APM Provisions

(a) APM Entity Level Reporting of Promoting Interoperability Performance Category

We are finalizing a policy to introduce a voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the CY 2023 performance period.

(b) Payment Based on Quality Measures

We are finalizing a policy to revise the regulations and to clarify that the criterion for Advanced APMs that payment must be based on quality measures can be met through the use of a single quality measure that meets the criteria specified at § 414.1415(b)(2) and (b)(3). We also proposed conforming changes in the Other Payer Advanced APM regulations.

(c) Medical Home Model 50 Eligible Clinician Limit

We are finalizing a policy to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity. We explained that we would identify the eligible clinicians in the APM Entity on each of the three QP determination dates (March 31, June 30, and August 31). This policy would become effective in Performance Year 2023. We also proposed conforming changes in the Other Payer Advanced APM regulations which will require that the eligible clinician pursuing the option provide the relevant information.

(3) Other MIPS and APM Policies

(a) Quality Performance Category

In the CY 2023 PFS proposed rule (87 FR 46276 through 46280), we proposed the following proposals: expand the definition of the term high priority measure to include health equity quality measures; change the CAHPS for MIPS case-mix adjustor for ''Asian language survey completion'' to use instead ''language other than English spoken at home,'' ''Spanish language spoken at home,'' and ''Asian language spoken at home'' variables; increase the data completeness criteria threshold from 70 percent to 75 percent for the CY 2024 and 2025 performance periods/2026 and 2027 MIPS payment years; and establish a set of 195 quality measures. In the CY 2023 PFS proposed rule (87 FR 46155 through 46157, 46277, and 46280 through 48283), we sought public comment regarding requests for information pertaining to each of the following topics: the addition of questions related to health disparities and price transparency to the CAHPS for MIPS Survey; the development and implementation of health equity quality measures; and the development and implementation of quality measures that address amputation avoidance in diabetic patients.

(b) Cost Performance Category

In section IV.A.6.c. of this final rule, we finalized as proposed to update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group.

(c) Improvement Activities Performance Category

We are finalizing as proposed to add four new, modify five existing, and remove six existing improvement activities from the Inventory. The new and modified activities help fill gaps we have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. All four of the new activities

[453] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032, Available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

being finalized relate to CMS Six Health Equity Priorities for Reducing Disparities in Health. We also recommended the removal of six activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the Inventory offers flexibility and choice without a potentially burdensome number of activities available.

(d) Promoting Interoperability Performance Category

We are finalizing several changes to the Promoting Interoperability performance category. Specifically, we are finalizing: (1) to require and modify the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure with added exclusions while maintaining the associated points at 10 points; (2) to expand the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III, and IV drugs; (3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective; (4) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective; (5) to limit a clinician's time at the first level of active engagement to one performance period but delaying the applicability date until performance periods in 2024; (6) to modify the scoring methodology for the Promoting Interoperability performance category; and (7) to continue to reweight the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians.

(e) Payment Adjustment

We are finalizing as proposed to use the CY 2019 MIPS payment year as the prior period and the rounded mean final score of 75 points from that prior period as the performance threshold for the CY 2025 MIPS payment year.

(f) Scoring

For scoring of the quality performance category, we are finalizing as proposed to score administrative claims measures using benchmarks calculate from data collected during the performance period and clarifying the topped-out measure lifecycle in instances where a measure is suppressed or otherwise has a benchmark removed. We also included a request for information on which additional risk indicators and data sources we should consider for the complex patient bonus to better assess the social and medical complexity for the patients of MIPS eligible clinicians. Lastly, we are finalizing as proposed to establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year.

(g) Third Party Intermediaries

We are finalizing our proposal to update the definition of third party intermediary consistent with existing policies and to make other minor technical edits to the regulation text governing third party intermediaries accordingly. We are also finalizing our proposal to revise QCDR measure self-nomination and measure approval requirements, including to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year. We are finalizing our proposal to continue delaying this requirement based on our recognition of the continuing impact of the COVID–19 public health emergency on the ability of QCDRs to test measures. We are finalizing our proposal to revise remedial action and termination policies.

(h) Public Reporting/Physician Compare

In an effort to expand the information available to patients and caregivers when choosing a doctor or clinician, we are finalizing as proposed to publicly report on individual clinician and group profile pages:

- A telehealth indicator, as applicable, and technically feasible, for those clinicians furnishing covered telehealth services.
- Utilization data related to applicable conditions treated and procedures performed by each clinician or group respectively.

Additionally, we sought feedback from interested parties through a request for information, on ways to incorporate health equity into public reporting on Care Compare.

2. Definitions

At § 414.1305, we are finalizing as proposed revisions to the definitions of the following terms:

- Multispecialty group;
- Single specialty group;
- Facility-based group;
- Facility-based MIPS eligible clinician
- High priority measure; and
- Third party intermediary.

These terms and definitions are discussed in detail in the relevant sections of the proposed rule.

7. Transforming MIPS: MVP Strategy

a. MVP Vision Overview

As discussed in the CY 2023 PFS proposed rule (87 FR 46263 and 46264), we are moving to MIPS Value Pathways (MVPs) to improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to participation in Alternative Payment Models (APMs). We intend to promote high value care by connecting performance on cost, quality, and patient experience of care to payment. We believe the MVP framework will move MIPS forward on the path to value by connecting the MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability. The MVP framework aims to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care. We intend for MVPs to drive value and help clinicians and practices prepare to take on and manage financial risk, for example, through Advanced APMs, as they build out their quality infrastructure components and gain experience with cost measurement. We envision that MVPs, in which there is aligned measurement of quality of care and cost, continuous improvement and innovation within the practice, and efficient management and transfers of information, will help clinicians deliver higher value care and remove barriers to APM participation. Combining linked performance measures and activities with more performance measurement standardization and focused reporting of meaningful measures in MVPs will, we believe, produce data that can better assist patients in comparing clinician performance and in selecting clinicians. Such data can also assist clinicians in making care improvements and making appropriate specialist referrals. As more clinicians have applicable MVPs available, the performance data available to patients will expand, and in the future, information on specialists in multispecialty groups will increase in our Compare Tools, enabling patients to make more informed choices for their care. MVPs will be available for voluntary reporting beginning with the CY 2023 MIPS performance period, and we intend for MVPs to become the only method to participate in MIPS in future

years, although we have not yet established the timing for the sunset of traditional MIPS.[454]

We continue to explore opportunities to advance health equity across all CMS programs and specifically the Quality Payment Program via MVPs and updated performance measures (see 87 FR 46264 in the CY 2023 PFS proposed rule). On April 22, 2022, the CMS Office of Minority Health released the *CMS Framework for Health Equity,*[455] which updates the CMS Equity Plan with an enhanced and more comprehensive 10-year approach to further embed health equity across all of CMS programs including Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces®. This *CMS Framework for Health Equity* outlines five priorities: (1) Expand the collection, reporting and analysis of standardized data; (2) Assess causes of disparities within CMS programs, and address inequities in policies and operations to close gaps; (3) Build capacity of health care organizations and the workforce to reduce health and health care disparities; (4) Advance language access, health literacy, and the provision of culturally tailored services; and (5) Increase all forms of accessibility to health care services and coverage.[456] We intend to use this health equity framework across CMS to design, implement, and operationalize policies to support health for all people served by our programs, eliminate avoidable differences in health outcomes experienced by people who are underserved, and provide the care and support that our enrollees need to thrive.

We continue to consider ways that we can advance health equity via the Quality Payment Program. As we implement MVPs, we are considering how best to further the five priorities of the CMS Framework for Health Equity. We intend for both MVPs and APMs to advance health equity and increase the value of health care for all as we leverage improvement activities, quality measure performance data, and public reporting. We anticipate that MVPs and APMs will have greater impact on health equity as participation grows.

In the CY 2023 PFS proposed rule we considered approaches for advancing health equity in MIPS and sought feedback (see 87 FR 46276 through 87 FR 46283). Specifically, see 87 FR 46280 through 46283 and 87 FR 46331 respectively for our request for comment on developing health equity measures in MIPS and MIPS Compare Tool public reporting in the future.

We presented our MVP vision and guiding principles in the CY 2021 PFS final rule (85 FR 84844 through 84845). We intend for MVP implementation to drive value, obtain comparative performance data, and elevate the patient voice while reducing clinician burden. We strive to achieve meaningful performance measurement, burden reduction, scoring equity, and increased value. The MVP framework was discussed in the CY 2020 and the CY 2021 PFS proposed rules (84 FR 40732 through 40734, and 85 FR 50279, respectively) and CY 2021 PFS final rule (85 FR 84844 through 84845). Our MVP framework calls for linking the quality, cost, and improvement activities performance categories, as well as a foundation of required reporting for the Promoting Interoperability performance category and population health claims-based quality performance category measures. We continue to consider how to best implement an MVP portfolio that balances our MVP goals for transformative change and our five MVP guiding principles as discussed in the CY 2021 PFS final rule (85 FR 84845 through 84546) within current CMS and clinician practice capabilities. For more MVP information see the CY 2023 PFS proposed rule at 87 FR 46264 for discussion of initial MVP implementation steps and §§ 414.1305 Definitions, 414.1318 Subgroups, and 414.1365 MIPS Value Pathways for MVP policies regulatory text.

b. MVPs and APM Participant Reporting

MVPs and APMs share a goal of meaningful performance measurement and burden reduction, along with objectives of scoring equity and advancing value. In the CY 2023 PFS proposed rule (87 FR 46264 and 46265), we included a request for information regarding MVPs and APM participant reporting. Specifically, we sought ideas for how we could obtain more robust reporting of both primary care and specialty care performance measurement information from APM participants. We also sought feedback on how to best address the challenges commenters previously noted regarding specialist reporting of quality performance data to both the APM and MIPS such as increased reporting burden. We requested policy ideas that would encourage the reporting of specialty services performance information in addition to the APP, for example and to the extent feasible, by extending APP scoring policies for the cost and improvement activities performance categories outside the APP, by finding a way to roll MVP quality measure performance data into the APP, or by some other method. We also requested feedback on the benefits and disadvantages of the submitted policy ideas and asked how we should best limit burden and complexity. We continue to seek feedback on ways to better align clinician experience between MVPs and APMs, and to ensure that MVP reporting serves as a bridge to APM participation.

As we move forward with MVP implementation, we will continue to seek feedback on the direction of our MVP framework and its intersection with APMs, including ways to better align clinician experience between MVPs and APMs and to ensure that MVP reporting serves as a bridge to APM participation. We envision MVP reporting to complement APP reporting such that it will enhance performance measurement and available information while minimizing additional burden. We thank commenters for their responses to this request for information. We may consider the information we received and use it to inform future rulemaking.

4. MVP Development and Reporting Requirements

a. MVP Development

(1) Development of New MVPs

As discussed in the CY 2023 PFS proposed rule (87 FR 46265 and 46266), we proposed to modify our MVP development process to include feedback from the general public before the notice and comment rulemaking process. We proposed to evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we would post a draft version of the submitted candidate MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. The general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We stated that we would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we would not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. The following is a summary of the public comments

[454] 42 CFR 414.1365(a)(1).

[455] CMS, *CMS Framework for Health Equity,* available at *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[456] Ibid., at 10–11.

received on the proposed revisions to the process to develop new MVPs and our responses:

Comment: Several commenters supported the proposals to modify the MVP development process. Many commenters indicated support of MVP development processes that promote transparency, collaboration, and regard for specialty expertise through the solicitation of feedback from the public prior to an MVP's proposed adoption. Several commenters stated that the proposed changes will improve transparency in the MVP development process and help to ensure MVPs are best aligned with patient care goals. One commenter expressed the belief that interested parties input will help CMS keep pace with progress in personalized medicine and optimize health care for patients. One commenter recommended that CMS communicate the public feedback period widely through available channels to further improve transparency. One commenter recommended a standard annual timeline for release of MVPs to allow third party intermediaries sufficient time to build and test any changes to MVPs reporting requirements. A few commenters requested clarification of how CMS defines when an MVP is ready for feedback.

Response: We thank commenters for their suggestions to improve upon our proposed modifications to the process for developing new MVPs. We plan to post a draft version of each candidate MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and will communicate the opportunity to provide public feedback on the candidate MVP through QPP standard channels, including QPP listserv messaging. In regards to the request to have a standard timeline each year, we adopted the solicitation of feedback on a ''rolling basis'' to obtain feedback in a timely manner, so that we can receive feedback when an MVP is ready, rather than waiting for a specified public feedback period that begins and ends at the same time each year (85 FR 85855). We will determine if an MVP is ''ready'' for feedback using the criteria for MVP development, which are described in detail in the CY 2022 PFS final rule (86 FR 65405 through 65410).

Comment: One commenter expressed the belief that the proposed revisions to the MVP development and maintenance processes are not adequate or well defined to ensure that the MVPs resonate with specialty practices, and recommended that CMS adopt a process for MVP development and maintenance that is similar to the electronic Clinical Quality Measure (eCQM) annual timeline. The commenter also expressed the belief that the development and maintenance processes do not sufficiently include input from all relevant specialty societies and recommended that CMS create an informal process to ensure transparency and coordination among the relevant specialty societies during the early development of an MVP.

Response: We disagree. We believe our MVP development and maintenance processes in addition to our defined criteria for MVP development (86 FR 65405 through 65410) are adequate and will lead to the development and implementation of MVPs that will lead to better patient care. The MVP development and maintenance processes, as described at *https://qpp.cms.gov/mips/mips-value-pathways/submit-candidate* is structured in a manner to encompass updates that are made to individual measures through annual update measure processes. We believe the MVP development and maintenance processes should be structured in a manner that looks at the MVP holistically to ensure meaningful clinical connections can be made between the measures and improvement activities within the MVP. Since the MVP development and maintenance process already considers the updates made through the elaborate measure maintenance processes, we do not believe it is necessary to also have such an extensive process to develop and maintain MVPs. An elongated process, such as the eCQM annual update would require CMS to delay the implementation of MVPs further, which would by extension delay their availability for reporting by MVP participants. We believe the proposed updates to the MVP development and maintenance processes will allow relevant specialty societies amongst other interested parties ample opportunity to provide input. Providing feedback on draft candidate MVPs ahead of notice and comment rulemaking or updates to implemented MVPs is an opportunity that will be widely available to the public. Overall, we believe our processes are sufficient and allow for an extensive number of opportunities for interested parties to provide feedback to CMS before MVPs are implemented.

Comment: A few commenters expressed that CMS should consider a 60-day feedback period in order to maximize interested parties input.

Response: While we understand the value of an extended public feedback period, there are unfortunately timeline constraints that prevent us from extending the feedback period beyond 30 days. Various factors were taken into consideration when determining the length of the feedback period including that an extended period would reduce the time available for the development of MVPs, possibly delay MVP implementation, and would not consider our current rulemaking timeframe. Before we adopt an MVP, we may discuss the candidate MVP with the interested parties that originally submitted the MVP to us, prepare documents defining the MVP for publication, publish the candidate MVPs and seek feedback on it, process and review the feedback received, determine what feedback would be applied to the candidate MVP, revise the MVP if necessary, and follow our rulemaking processes shortly thereafter. If the public feedback period ended in the midst of our rulemaking processes, we would have to wait until the following year to propose the candidate MVPs through notice and comment rulemaking. Moreover, it is not possible to start the public feedback period earlier, as that would cut into the time needed to develop the candidate MVP. We therefore believe that a 30-day period best balances the concerns described above with providing an opportunity for the public to provide feedback on MVP candidates ahead of their potential proposed adoption. If more time is needed, we note that there also would be an opportunity to submit comments during the notice and comment rulemaking process if the candidate MVP is proposed for adoption.

Comment: A few commenters expressed concern that CMS stated that it would not notify the parties who originally submitted the candidate MVP in advance of rulemaking if changes are made to the MVP Commenters stated that, in most cases, the parties who initially submitted the MVP would include the specialties that are most connected to the procedure, condition, or patient population captured by the MVP. Commenters expressed the belief that it is critical that CMS recognizes the clinical content experts who developed the MVP by providing them with the opportunity to review whether the revised candidate MVP makes clinical sense before it is proposed through rulemaking. A few commenters recommended that CMS establish a process for robust outreach to impacted specialty societies during MVP development to ensure a meaningful and productive dialogue.

Response: We note that if CMS opts to propose a candidate MVP for adoption, any individuals or entities

that originally submitted the candidate MVP or were involved in its development would have the opportunity to provide feedback on any proposed revisions during the notice and comment rulemaking process. We do not believe we need to further expand our outreach, as we intend on leveraging our public feedback periods as an opportunity for impacted specialty societies to provide input, and would also provide the opportunity to provide public comment on the updates to candidate MVPs or implemented MVPs through notice and comment rulemaking.

After consideration of the public comments, we are finalizing our proposed revisions to the process to develop new MVPs as proposed.

(2) MVP Maintenance Process

In the CY 2022 PFS final rule (86 FR 65410), we finalized an annual maintenance process for MVPs that were previously adopted through notice and comment rulemaking. We established a process for soliciting recommendations from interested parties for potential updates to adopted MVPs. As part of this process, beginning in January of the year prior to the performance period, interested parties may submit recommendations to revise an MVP that was previously finalized through rulemaking. Recommendations from interested parties would be accepted on a rolling basis throughout the year. We stated that we would be unable to communicate with interested parties as to whether their recommendations were accepted ahead of rulemaking, and that we would ultimately determine whether updates to an established MVP should be made (86 FR 65410). We stated that we would consult with the interested parties who originally nominated an MVP about any publicly recommended changes to the MVP (86 FR 65410).

In the CY 2023 PFS proposed rule (87 FR 46266), we stated that similar to the proposed revisions to the process for developing new MVPs, (87 FR 46265 and 46266), and for the same reasons, we believe that we should also consider feedback during the MVP maintenance process, from a wide range of interested parties and the general public, prior to proposing changes to an existing MVP through the notice and comment rulemaking process. Therefore, in the CY 2023 PFS proposed rule (87 FR 46266), we proposed to modify the MVP maintenance process such that interested parties and the general public may submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. We stated that if we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. As proposed, the changes to the MVP maintenance process would enable us to receive a wide range of perspectives on potential revisions to MVPs earlier in the maintenance process, which we believe is important in developing MVPs that are meaningful to clinicians, patients, and the general public. We stated that if we decide to make any revisions to an established MVP based on the recommendations submitted, we would adopt such revisions through notice and comment rulemaking. We requested comments on this proposal.

The following is a summary of the public comments received on the proposed revisions to MVP maintenance process and our responses:

Comment: Several commenters supported the proposal to modify the MVP maintenance process to allow the public to submit recommendations for potential revisions to established MVPs.

Response: We thank commenters for their support.

Comment: A few commenters recommended that CMS share all feedback with the MVP developer and one commenter suggested publishing all feedback in the proposed rule.

Response: Through the MVP maintenance process, CMS intends to review all feedback received through the solicitation process, which occurs on a rolling basis throughout the year. Through our review of the feedback received, we will identify any feasible suggestions, which we intend to present and discuss during the MVP maintenance public webinar. We will look into the operational feasibility of publishing feedback we have identified as feasible suggestions ahead of the public webinar. We believe that a public webinar will allow us to gather more timely feedback on potentially feasible and appropriate recommendations, and we do not intend on publishing all feedback received in the proposed rule because we believe publishing all feedback received, regardless of the feedback's relevance to the MVP and whether the suggestion is feasible or not will likely cause confusion for our readers.

After consideration of the public comments, we are finalizing our proposal to modify the MVP maintenance process as proposed.

(3) Revisions to Previously Finalized MVPs

In the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that will be available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year. The seven MVPs are as follows: *Advancing Rheumatology Patient Care; Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes; Advancing Care for Heart Disease; Optimizing Chronic Disease Management; Adopting Best Practices and Promoting Patient Safety within Emergency Medicine; Improving Care for Lower Extremity Joint Repair; and Patient Safety and Support of Positive Experiences with Anesthesia.* In the CY 2023 PFS proposed rule (87 FR 46829 through 46842), we proposed modifications to these seven MVPs because of the proposed removals of certain improvement activities from the improvement activities inventory and the addition of other relevant existing quality measures for MVP participants to select from. We refer readers to Appendix 3: MVP Inventory of this final rule for the public comment received, responses, and finalized modifications to the established MVPs.

(4) New MVPs

Through our development processes for new MVPs (*see* 85 FR 84849 through 84856), we aim to gradually develop new MVPs that are relevant and meaningful for all clinicians who participate in MIPs. In the CY 2023 PFS proposed rule, we proposed five new MVPs (87 FR 46813 through 46829):

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

We continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*. We refer readers to Appendix 3: MVP Inventory, within this final rule where we discuss each proposed new MVP, the public comments received and our responses, and our determinations to finalize these new MVPs.

b. MVP Reporting Requirements

(1) Promoting Interoperability

In the CY 2021 PFS final rule (85 FR 84849 through 84854), we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b).

In the CY 2023 PFS proposed rule (87 FR 46266 through 46267), we referred readers to the changes that we were proposing with regard to the Promoting Interoperability performance category. We stated that we intend for any changes that are finalized for the Promoting Interoperability performance category under traditional MIPS to apply to MVPs. We refer readers to section IV.A.6.c.(4) of this final rule for a discussion of the finalized policies for the Promoting Interoperability performance category that would also apply to MVPs.

c. Reporting MVPs and Team-Based Care

In the CY 2023 PFS proposed rule (87 FR 46267), we clarified how multispecialty groups who practice in a team-based care manner can report MVPs, but did not propose any policies related to this subject matter. If a multispecialty group identifies an MVP that is relevant to its practice, the group may register through the MVP registration process to report that single MVP (86 FR 65415 through 65418). We encourage a multispecialty group to choose an MVP that includes measures that are attributable to all clinician types that participate in its group, if it intends to report as a multispecialty group within the first few years of its MVP reporting. We believe that reporting data that is directly attributed to all clinicians in the group will better drive quality improvement and lead to improved patient outcomes.

We encourage multispecialty groups to consider adopting subgroup reporting before it becomes mandatory in the CY 2026 performance period. Early adoption will allow clinicians within the subgroups to gain familiarity with reporting at the subgroup level before it becomes mandatory. We refer readers to the CY 2023 PFS proposed rule (87 FR 46267) for the discussion of multispecialty groups who practice team-based care reporting MVPs.

d. Scoring MVP Performance

In the CY 2022 PFS final rule, we finalized policies for MVP scoring beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those final policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d)(2), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we intend to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419).

In the CY 2023 PFS proposed rule, we referred readers to our proposed revisions to traditional MIPS scoring policies regarding the determination of benchmarks for administrative claims quality measures (87 FR 46313 and 46314), assigning measure achievement points for topped out quality measures (87 FR 46314 and 46315), improvement scoring for cost measures (87 FR 46315 and 46316), and the changes to the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2023 (87 FR 46298 through 46308). We are finalizing these proposals as described in sections IV.A.10.d.(1)(b)(i), IV.A.10.d.(1)(b)(ii), IV.A.10.d.(1)(c)(i), and IV.A.10.c.(4)(g) of this final rule, respectively. In the CY 2023 PFS proposed rule (87 FR 46267), we noted that in the event these proposals and any other scoring policies for traditional MIPS are adopted as final policy, they would apply to the measures and activities included in the MVP, unless otherwise indicated.

In the CY 2022 PFS final rule, we finalized the subgroup reporting option for clinicians choosing to report MVPs or the APP (86 FR 65392 through 65394). Subgroup reporting is a new option for clinicians, and, for clarity, we discussed all proposals regarding subgroups, including scoring, in one section of the CY 2023 PFS proposed rule (87 FR 46267 through 46275). We referred readers to 87 FR 46271 through 46272 of the CY 2023 PFS proposed rule for our proposals related to subgroup scoring for administrative claims, cost measures, and subgroups that register but do not report. As described in section IV.A.8.e.(4)(b) and IV.A.8.e.(4)(c) of this final rule, we are finalizing our proposals related to subgroup scoring.

e. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to report through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). Additionally, we finalized: (1) A timeline for implementing subgroup reporting (86 FR 65396 and 65397); (2) registration requirements, reporting requirements, and scoring policies for clinicians desiring to report MVPs through subgroups (§ 414.1365; 86 FR 65415 through 65426); (3) definitions of subgroup, single specialty group, multispecialty group, and special status (§ 414.1305; 86 FR 65398 through 65401); (4) subgroup eligibility requirements (§ 414.1318; 86 FR 65401); (5) application of low-volume threshold and special status designations for subgroups (§ 414.1318(a)(2); 86 FR 65401 and 65402); and (6) subgroup inclusions and exclusions (§ 414.1318; 86 FR 65402 and 65403).

In the CY 2023 PFS proposed rule, we proposed to: (1) modify the definitions of single specialty group and multispecialty group (87 FR 46268); (2) add subgroup description requirements to the registration process (87 FR 46269); (3) limit the number of subgroups a clinician may participate in to one subgroup per Taxpayer Identification Number (TIN) (87 FR 46269 and 46270); (4) establish the subgroup determination period (87 FR 46270 and 46271); (5) apply new policies for scoring administrative claims measures and cost measures for subgroups (87 FR 46271 and 46272); and (6) not assign a subgroup final score to registered subgroups that do not submit data (87 FR 46272).

(2) Definitions of a Single Specialty Group and a Multispecialty Group

We previously finalized at § 414.1305 the definitions of a single specialty group as a group that consists of one specialty type and a multispecialty group as a group that consists of two or more specialty types. We also finalized at § 414.1305 the definition of an MVP participant for the purpose of MVP reporting. The definition of MVP Participant established in the CY 2022 PFS final rule (86 FR 65392 through 65394) allows multispecialty groups to participate as a group for MVP reporting only for the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year. Beginning with the CY 2026 performance period/2028 MIPS

payment year, only single specialty groups may participate as a group for MVP reporting, and multispecialty groups that want to report an MVP will be required to form subgroups for that purpose. We believe that the definitions of single specialty group and multispecialty group allow groups to distinguish their specialty type or types and assess the requirement to participate as a subgroup in MVP reporting beginning with the CY 2026 performance period/2028 MIPS payment year.

In the CY 2022 PFS proposed rule (86 FR 39360), we proposed to identify a group's specialty type or types using data from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We received comments expressing concerns that the use of PECOS specialty designations would result in the exclusion of certain clinician types, such as nurse practitioners (NPs) and physician assistants (PAs) (86 FR 65398). We adopted definitions of a single specialty group and a multispecialty group in the CY 2022 PFS final rule but did not finalize PECOS as the data source or specify another data source that we would use to determine a group's specialty type. We noted that we needed additional time to better understand our options to utilize different data sources when making this determination (86 FR 65399).

Having reviewed the available data sources, we noted in the CY 2023 PFS proposed rule our belief that Medicare Part B claims data is the appropriate data source for determining a group's specialty type or types for purposes of MVP reporting (87 FR 46268). Currently, we use PECOS and Medicare Part B claims data to identify clinician specialty for certain purposes. For purposes of public reporting, we rely on PECOS as the primary data source, and for purposes of MIPS eligibility determination, we use both PECOS and claims data. Additionally, we use the information on claims to identify clinician specialty when attributing some of the measures in the cost and quality performance categories.

A clinician's primary specialty designation in PECOS is identified by the clinician in the Medicare enrollment application for physicians and non-physician practitioners. Additionally, there may be instances when a clinician would be allowed to select more than one primary specialty in PECOS.[457] For example, a primary specialty designation of cardiothoracic surgery is not available in PECOS, and therefore, a cardiothoracic surgeon would have two primary specialty designations, one for cardiac surgery and another for thoracic surgery. In such instances, it would be difficult for CMS to identify a clinician's primary specialty using their PECOS designation. The specialty codes used on Medicare Part B claims[458] are not reported by clinicians but are assigned by the Medicare Administrative Contractors (MACs) and derived from the clinician-reported specialty information in PECOS. In instances where more than one specialty code appears on a claim, we determine primary specialty based on the specialty code used for the plurality of the services billed by the clinician. We analyzed the identification of specialty for clinicians using claims data and PECOS data and found a variance rate of less than one percent between the two data sources. In the CY 2023 PFS proposed rule (87 FR 46268), we stated that given the strong alignment between the data sources and our historical use of claims data to identify a clinician's specialty, we believe that Medicare Part B claims data would be the best data source to use to determine a group's specialty type or types for purposes of participation in MVPs.

We noted that in response to our 2022 PFS proposal to use PECOS data in determining specialty, some commenters recommended that, instead of PECOS, CMS should utilize specialty taxonomy codes which they stated were more detailed than PECOS specialty codes (86 FR 65398). While these commenters were not specific in their request, we understood them to be referring to the provider taxonomy codes used on the application to receive a National Provider Identifier (NPI). We agreed with the commenters that in some instances, the health care provider taxonomy code set may include more specificity than the information found in the specialty codes used on Medicare Part B claims. However, currently we do not use this data for other QPP purposes, and we are uncertain of the extent to which it is maintained by clinicians if their circumstances change. While we considered the use of this data as an alternative, we do not believe it is necessary to introduce a new data source at this point, given that subgroup reporting is voluntary at this time.

For these reasons, we proposed in the CY 2023 PFS proposed rule to modify the definition of a single specialty group at § 414.1305 to state that single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims (87 FR 46268). We also proposed to modify the definition of a multispecialty group at § 414.1305 to state that multispecialty group means a group that consists of two or more specialty types as determined by CMS using Medicare Part B claims (*Id.*). We sought public comment on the proposals and requested comment on additional data sources CMS could use to determine a group's specialty type or types.

The following is a summary of the public comments received on the proposed revisions to the definitions of a single specialty group and a multispecialty group and our responses:

Comment: A few commenters supported the use of Medicare Part B claims as the data source to determine the specialty composition of a group. One commenter recommended CMS to provide additional guidance for a group practice to identify their specialty composition.

Response: We acknowledge the commenter's recommendation for CMS to provide guidance on whether a group is a single specialty or a multispecialty group. There is no existing process in place for CMS to provide feedback on the specialty composition of a group. We will take this recommendation into consideration and may explore available options to provide guidance on the specialty composition of a group.

Comment: Many commenters did not support the proposed use of Medicare Part B claims to determine the specialty composition of a group. A few commenters shared their belief that the specialty information indicated on Part B claims is not an accurate representation of the actual care provided by the various clinicians in a multispecialty group. Some commenters expressed concern that the specialty information from Part B claims may not be correct and stated that in the 2020 QPP Experience Report, over 15 percent of MIPS eligible clinicians had more than one specialty identified on their claims.

Response: While we acknowledge that there may not always be a perfect match between the information on specialty included on Medicare Part B claims and the clinical focus of an individual clinician, we are also not aware of an alternative data source that would provide a closer match. We understand the commenters' concerns on identifying a single specialty for some clinicians using Medicare Part B claims. As is the case where we currently use Medicare Part B claims to determine

[457] *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf.*

[458] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf.*

specialty (see 87 FR 46268), we will determine primary specialty based on the specialty code used for the plurality of the services billed by the clinician in instances where a clinician has more than one specialty indicated on their Medicare Part B claims.

Comment: A few commenters recommended specialty attestation as part of the subgroup registration process in lieu of the Medicare Part B claims data to identify the specialty composition of a group.

Response: We acknowledge the commenter's recommendation to allow specialty attestation as part of the subgroup registration process to accurately attribute the specialty based on the scope of care provided by a clinician. The definition of an MVP participant finalized in the CY 2022 PFS final rule (86 FR 65392 through 65394) allows multispecialty groups to participate as a group for MVP reporting only for the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year. Beginning with the CY 2026 performance period/2028 MIPS payment year, only single specialty groups may participate as a group for MVP reporting, and multispecialty groups must form subgroups for reporting an MVP. As a result, we believe that groups need to know of their specialty composition and their ability to participate as a group or a subgroup for reporting an MVP ahead of the subgroup registration process to make changes in their administrative workflows accordingly. Additionally, we anticipate that allowing specialty attestation as part of the subgroup registration process would require CMS to implement additional criteria for validating the specialty composition of a group and may cause confusion and add operational complexity.

Comment: Several commenters expressed concern that beginning in the CY 2026 performance period/2028 MIPS payment year, only clinicians in single specialty groups may participate as a group for MVP reporting, and multispecialty groups must form subgroups for reporting an MVP. These commenters expressed concern about the administrative burden associated with dividing large groups into smaller groups. Some of the commenters expressed particular concern that the requirements for multispecialty practices to report on MVPs via subgroups would require groups that might have a single clinical focus to divide due to different specialties indicated on their Medicare claims (either closely related physician specialties (for example, internal medicine and family practice) or clinicians whose clinical focus is not represented in Medicare specialty data (for example, NPs and PAs)). A few commenters requested further guidance for implementing subgroups in anticipation of their future requirement for MVP reporting.

Response: As we established in the CY 2022 PFS final rule (86 FR 39360), beginning in the CY 2026 performance period/2028 MIPS payment year, only clinicians in single specialty groups may participate as a group for MVP reporting and multispecialty groups must form subgroups for reporting an MVP. We did not propose any change to that requirement in this proposed rule. We acknowledge the commenters' concerns related to the potential increase in administrative burden that may be caused by this requirement in the future. We note that we have made no proposal to make MVP reporting mandatory during the CY 2026 performance period/2028 MIPS payment year. Under the finalized policy, subgroup reporting is only mandatory for multispecialty groups choosing to participate in MVP reporting. However, we note that it is our intent to sunset traditional MIPS in the future and make MVP reporting mandatory for all MIPS eligible clinicians. We recognize the commenters' concerns related to the potential classification of a group with a single clinical focus as a multispecialty group that would be required to form subgroups. To assist groups in understanding the operational implications of these requirements, we anticipate providing additional guidance as appropriate in the future. We will continue to consider ways in which we can achieve the goals of more focused reporting via subgroups and ensure that these subgroups best represent clinical coherence. Any changes would be proposed via future rulemaking.

After consideration of the public comments, we are finalizing the revised definitions of a single specialty group and a multispecialty group at § 414.1305 as proposed.

(3) Subgroup Registration Requirements

(a) Background

We established at § 414.1365(b) a registration process for clinicians who choose to report MVPs through a subgroup. We refer readers to the CY 2022 PFS final rule (86 FR 65415 through 65418) for additional details on subgroup registration timeline and requirements.

(b) Subgroup Description Requirement

In the CY 2022 PFS final rule (86 FR 65399), we defined a subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. We did not propose any criteria for limiting the composition of a subgroup but did solicit comment on criteria that we could consider in the future (86 FR 39362), such as establishing a threshold requiring 75 percent of the eligible clinicians in a group or subgroup to be of the same or a related specialty to form a subgroup.

We believe the comments we received on the request for future consideration of subgroup criteria in the CY 2022 PFS proposed rule reflect the reality that clinicians practice in many ways within a group TIN (86 FR 65399 and 65400). We believe that we may need to establish limits on subgroups in order to further our goals of measuring as many clinicians as possible using the measures that are most relevant to their practice. We are concerned that if we do not establish restrictions or requirements in the future we may not move meaningfully towards that goal. However, given that subgroups will be newly available for the CY 2023 performance period/2025 MIPS payment year and will be voluntary, we do not believe we should yet establish those policies.

To inform our future subgroup policies, we desire to better understand how group TINs form subgroups and how group TINs choose to organize their subgroups. For this reason, in the CY 2023 PFS proposed rule (87 FR 46269), we proposed that as part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. We stated we would identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text-only field, if the options we provide do not correctly describe the subgroup. We explained in the proposed rule that we would not evaluate or approve the narrative description, if submitted. Rather, we intend to collect and review the information to better inform our understanding of subgroups and the different ways groups would choose to form subgroups. We noted that we believe that receiving the information

about the subgroup directly from the group TIN itself would fill a gap in our understanding of the nature of subgroup formation during the transition to MVPs that cannot be filled merely by reviewing PECOS or claims-based group specialty information. We stated that we understand requiring such reporting would create some additional burden, but we believe such burden is modest and worth the effort to inform future development of subgroup policies. Furthermore, we stated that we are attempting to mitigate this burden by permitting subgroups to select from certain common scenarios (for example, clinicians with the same specialty designation, practicing at the same geographic location, or providing care to the same patient population, etc.) for groups to form subgroups, when appropriate, instead of drafting a narrative description.

We noted that we are not intending for these narratives to be lengthy but expect the narratives to be short descriptions of the nature of practice and appropriately reflect the composition of a subgroup. We offered some illustrative examples for the narrative description:

- *Example 1:* This subgroup represents our cardiovascular service line, which includes cardiologists, cardiothoracic surgeons, and other associated professionals.
- *Example 2:* This subgroup represents our west side practice, which uses one electronic health record (EHR) platform and collaborates on patient care across orthopedic surgeons, physical therapists, NPs, and other associated clinicians.

We also noted that we believe that the availability of subgroups will facilitate our efforts to increase health equity. In part, we believe that by creating a smaller group of clinicians to analyze, we can better understand care at the patient and community level. This is important for measuring and improving health equity because subgroup data could be utilized to identify gaps in clinical outcomes, patient characteristics, and specialist care availability on a more targeted level than shown by examining TIN-level data. We stated that we also believe that group practices may share this same interest in improving health equity. For example, a group may have clinicians practicing in different locations and may choose to organize their subgroups to focus on certain underserved populations based on geography or income. We noted that we hope to better inform our understanding of clinicians supporting this goal through narrative descriptions of subgroup organization.

The following is a summary of the public comments received on the proposed addition of the subgroup description requirement to the previously established subgroup registration process and our responses:

Comment: Several commenters supported the proposed description requirement as part of the subgroup registration process. The commenters generally appreciated the flexibility for clinicians in a group to choose an appropriate subgroup relevant to their care needs.

Response: We thank the commenters for their support. We agree with the commenters that not establishing restrictions on the composition of a subgroup at this time offers flexibility for groups to split into subgroups based on their care needs. We believe that it will also reduce the administrative complexity and burden associated with subgroup reporting that could potentially discourage clinician participation in MVP reporting.

Comment: A few commenters did not support the proposed subgroup description requirement at subgroup registration. The commenters expressed concern about the associated burden for a subgroup to submit the narrative description annually, and recommended CMS to consider templates or checkboxes in lieu of the narratives.

Response: We acknowledge the commenters' concern on the associated burden to submit a description of the subgroup. As described in the CY 2023 PFS proposed rule (87 FR 46269), we intend to identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup in lieu of the narrative requirement. We intend to use a workable design, such as checkboxes, drop down menu, etc., for the key scenarios that subgroups could select from. If a subgroup selects an option from the available scenarios that accurately reflects the composition of their subgroup, the subgroup will not need to submit a separate narrative. We recognize the associated burden for subgroups relevant to this proposal and note that the text-only field to submit a narrative for the subgroup description is optional. We expect that a subgroup would need to use the text-only field in instances where none of the available key scenarios describe the construct of their subgroup. We do not intend to provide a template for the narrative requirement as we believe that a template may be too limiting for subgroups that choose to submit a narrative and it would add additional burden for subgroups that do not need to submit a narrative. We believe that the composition of subgroups may change yearly due to the clinicians joining or leaving a group, and therefore, subgroups should be required to submit a description during the annual subgroup registration process. We will continue to monitor the participation trends for subgroup registration and reporting and will consider appropriate updates to the subgroup description requirements and explore options to alleviate the subgroup registration burden for future performance periods.

After consideration of the public comments, we are finalizing the subgroup description requirement for subgroup registration as proposed.

(c) Limitation of One Subgroup per TIN–NPI Combination

In the CY 2022 PFS final rule (86 FR 65414 and 65415), we finalized at § 414.1318(c)(2) that subgroups will have their performance assessed at the subgroup level across all the MIPS performance categories. Additionally, in the CY 2022 PFS proposed rule we did not propose any criteria for the composition of subgroups (86 FR 39362). We must nonetheless place some restrictions on the allocation of a group TIN's clinicians among subgroups to properly score each subgroup. Clinicians in small groups are eligible to register as subgroups and report using Medicare Part B claims. While we establish a subgroup identifier as part of the registration process, this subgroup identifier would not be present on any claims data. If we were to allow a clinician to register under more than one subgroup in a single group TIN, we would be unable to determine to which subgroup a particular claim should be connected. Therefore, we proposed at § 414.1318(a)(3) that an individual eligible clinician, as represented by a TIN–National Provider Identifier (NPI) combination, may register for no more than one subgroup within a group's TIN. We noted that we did not propose any other restrictions or requirements on the composition of subgroups at this time. We also proposed to limit a clinician to a single subgroup per group TIN to overcome current limitations in scoring certain cost and quality measures.

In the CY 2023 PFS proposed rule (87 FR 46271 and 46272), we proposed to evaluate clinicians in subgroups using measures in the cost performance category, and the population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group's performance. As explained in the proposed rule, we made the proposal due to current technical limitations related to

attribution and risk adjustment of such measures but are working to potentially overcome those limitations in the future. CMS calculates administrative claims measures using Medicare claims data. This does not require any additional reporting by clinicians. If we were to allow a clinician to be a part of more than one subgroup within a single group TIN, however, we would be unable to identify which subgroup the clinician was part of for the purposes of attributing cost measures, population health measures, and outcomes-based administrative claims measures. We will continue to explore the options for allowing an individual clinician (NPI) to participate in multiple subgroups under a group TIN as we are working to potentially overcome challenges with attribution of the claims-based measures to the clinicians in a subgroup.

We recognized that the proposal to limit each TIN–NPI combination to a single subgroup per group TIN would limit how a group may establish its subgroups. We stated that we believe there may be clinicians who work in different capacities within a single group TIN (for example, a clinician who works in a cardiology clinic on Mondays and the primary care clinic Tuesday–Friday) and could be considered to work in multiple subgroups within a single group TIN. For this reason, we noted that we are interested in hearing perspectives from groups on how common this is, and if there are ways that we could match a clinician to a subgroup for measures reported through Medicare Part B claims or calculated using administrative claims.

The following is a summary of the public comments received on the proposal to limit a clinician, as identified by a TIN–NPI combination, to one subgroup within a group's TIN and our responses:

Comment: A few commenters supported the proposal limiting a clinician (NPI) participation to only one subgroup per TIN.

Response: We thank the commenters for their support.

Comment: Several commenters opposed the proposal limiting an individual clinician (NPI) to participate in only one subgroup per TIN. A few commenters shared their belief that clinician participation in multiple subgroups under a TIN would allow clinicians to report on all the measures relevant to their scope of care.

Response: We recognize that there may be instances where a clinician may be involved in care delivery in different capacities within the same TIN, and therefore, could reasonably be placed in more than one applicable subgroup under the TIN. However, as described in the CY 2023 PFS proposed rule (87 FR 46269 through 46272), due to issues that we identified with patient attribution and scoring of administrative claims measures at the subgroup level, we are not able to appropriately match a clinician to a subgroup for attribution and scoring of the administrative claims measures if the clinician is part of multiple subgroups under the TIN. We will continue to explore options to assess these measures at the subgroup level and propose any changes in future rulemaking.

After consideration of the public comments, we are finalizing the proposed policy at § 414.1318(a)(3) that an individual clinician, as represented by a TIN–NPI combination may register for no more than one subgroup within a group's TIN.

(d) Subgroup Determination Period

In the CY 2022 PFS final rule, we established the definition of a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI (86 FR 65399). We also codified at § 414.1318(a) that, for a MIPS payment year, low-volume threshold criteria and special status for subgroups are determined at the group level in accordance with §§ 414.1305 and 414.1310. We also established at § 414.1365(b) a process for clinicians to register as a subgroup for the purpose of reporting the measures and activities in an MVP (86 FR 65415 through 65418). Previously, we defined a MIPS determination period—the period of activity we review to identify clinicians who are eligible to participate in MIPS—to mean, in relevant part, a 24-month assessment period consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and (2) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs (§ 414.1305; 83 FR 59727 through 59730). In order to be eligible to participate in MIPS for the applicable performance year, an individual clinician or a group must meet or exceed the low-volume threshold criteria specified under § 414.1305 during the MIPS determination period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. Additionally, an individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second 12-month segment of the MIPS determination period will be assessed based solely on the results of such segment.

In the CY 2022 PFS final rule, we did not discuss how CMS would assess the low-volume threshold for individual clinicians and groups for the purpose of subgroup participation. Specifically, we did not discuss whether any special considerations were necessary when applying the MIPS determination period for clinicians participating as subgroups. Currently, we review claims and PECOS data from a MIPS determination period to determine MIPS eligibility for an individual clinician and a group. The initial 12-month segment of the MIPS determination period spans from October 1 of the calendar year 2 years prior to the applicable performance period to September 30 of the calendar year preceding the applicable performance period and includes a 30-day claims run out. Individual clinicians and groups receive their initial eligibility information prior to the applicable performance period but do not know their final eligibility determination until November or December of the applicable performance period.

Using a 2-year MIPS determination period is incompatible with the framework we have established for subgroup participation in MVPs. For example, for the CY 2023 performance period/2025 MIPS payment year, individual clinicians and groups that choose to participate as subgroups would only know their preliminary eligibility at the time of subgroup registration. We noted that we believe that by using the preliminary eligibility information, clinicians and groups could assess their ability to participate as subgroups early in the performance period and we do not wish to limit subgroup participation for groups that are otherwise eligible based on an eligibility assessment that is not made until after registration is completed. Therefore, in the CY 2023 PFS proposed rule (87 FR 46270 and 46271), we proposed to add at § 414.1318(a)(4) that CMS will apply the low-volume

threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the initial 12-month segment of the applicable MIPS determination period. Under this proposal, an individual eligible clinician or group determined to be MIPS eligible based on the low-volume threshold determination under § 414.1305 during the initial 12-month segment of the MIPS determination period would continue to be eligible for an applicable performance period regardless of the results of the second segment of the low-volume threshold determination. Additionally, we proposed to make conforming changes at § 414.1318(a)(1) to state that, except as provided under paragraph (a)(2) of this section and subject to (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310. We noted that we were not proposing to make any further changes to the application of low-volume threshold and special status as described under § 414.1318(a)(1).

In summary, to form a subgroup under our proposal, we noted that a group would need to be eligible to participate in MIPS as a group and have at least one MIPS eligible clinician in the subgroup who was also a MIPS eligible clinician during the initial 12-month segment of the MIPS determination period. Such an individual eligible clinician or group would continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. A subgroup may thus include an individual clinician who does not exceed the low-volume threshold during the first segment of the MIPS determination period only if the subgroup has at least one MIPS eligible clinician during the first 12-month segment of the MIPS determination period and the affiliated group also meets the low-volume threshold during the first 12-month segment of the MIPS determination period. We noted that we believe this would also allow practices to identify and place clinicians in appropriate subgroups, choose the measures and activities relevant to subgroups, make administrative changes to their workflows and EHR systems, and comprehensively capture clinician performance through subgroups. Using the first segment of the MIPS determination period would also be consistent with the use of the first segment of the MIPS determination period for virtual groups (see § 414.1315(c)(1)(*ii*); 83 FR 59743 and 59744).

We sought public comment on these proposals.

The following is a summary of the public comments received for our proposal to apply the low-volume threshold for clinician participation in subgroups using the eligibility from the first 12-month segment of the 24-month MIPS determination period and our responses:

Comment: A few commenters supported the proposal to apply the low-volume threshold for clinician participation in subgroups using the initial 12-month segment of the 24-month MIPS determination period.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal to add at § 414.1318(a)(4) that CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the initial 12-month segment of the applicable MIPS determination period. We are also finalizing conforming changes at § 414.1318(a)(1) as proposed.

(4) Subgroup Reporting and Scoring

(a) Subgroups Reporting the APM Performance Pathway (APP)

We refer readers to section IV.A.5.b of this final rule for our policies related to subgroups reporting the APP.

(b) Subgroup Scores for Administrative Claims Measures and Cost Measures

In the CY 2022 PFS final rule, we established at § 414.1318(c)(2) that subgroups will have their performance assessed at the subgroup level across all the MIPS performance categories (86 FR 65414 and 65415). We also established in the quality performance category that subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available (86 FR 65421 and 65422). In establishing this policy, we noted our concern about the ability of subgroups to meet the case minimum for an administrative claims measure and our interest in including population health measures in the subgroup's score for the MVP.

In establishing our policies for scoring the cost performance category in MVPs, we noted in the CY 2022 PFS final rule that we had received a comment that expressed concern that multi-specialty groups may take advantage of the option to report at the subgroup level to avoid being assessed on cost measures (86 FR 65422). We stated that while we intend to monitor subgroup implementation and assess the potential for gaming, we acknowledge the risk of a multi-specialty group forming subgroups in order to avoid being measured in the cost performance category.

As previously established at § 414.1325(a)(2)(i), measures in the cost performance category, as well as population health measures (which are part of the foundational layer of MVPs) and outcomes-based administrative claims measures in the quality performance category, are not reported directly by clinicians. Instead, CMS calculates these measures based on Medicare administrative claims data. Each measure includes an attribution and risk adjustment methodology within the specifications, which are available for review at *https://qpp.cms.gov/*. These measures are created and tested for validity and reliability using Medicare administrative claims data, which includes the identification of the TIN and the clinician's NPI. However, because subgroups are established exclusively for the purpose of participation in the Quality Payment Program, we are unable to identify a subgroup using existing or future claims data, and therefore, it may not be possible to test these measures for validity and reliability for subgroups using claims data. While we believe in general that subgroups can be measured in the same manner as we measure groups, there are complications related to the establishment of subgroups. Subgroups differ from groups in a couple of key ways: First, the creation of a subgroup does not change the nature of the group, so a patient could be attributed to both a group and a subgroup. In addition, a group TIN is not required to allocate all clinicians into subgroups. This affects measures in different ways depending on the attribution methodology of a measure. For example, in the total per capita cost measure, months are attributed to a particular group TIN or TIN–NPI based on specific primary care services. In this measure, costs are assigned to a single group TIN for the purpose of measuring the group TIN and a single TIN–NPI for the purpose of measuring the TIN–NPI. We stated in the CY 2023 PFS proposed rule (87 FR 46271) that we believe we could assign a patient to a single subgroup, as we have also proposed to limit NPIs to a single subgroup per TIN. However, we stated that since we do not have an existing data source for subgroup composition, we are unable to

examine the data to determine if performance on the measure is reliable and valid at the subgroup level.

For these reasons, we proposed in the CY 2023 PFS proposed rule (87 FR 46271 and 46272) to assess subgroups on measures in the cost performance category, and population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group. We proposed to modify § 414.1365(d)(3)(i)(A)(*1*) to read that a subgroup is scored on each selected population health measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We also proposed to add § 414.1365(d)(3)(i)(B)(*1*) so that a subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points. In addition, we proposed to add § 414.1365(d)(3)(ii)(A) to state that a subgroup is scored on each cost measure included in the MVP that they select and report based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).

We noted that we are concerned that measuring subgroups based on their affiliated group score for these measures may detract from our efforts to generate more clinically relevant and granular information about clinician performance (87 FR 46271). We stated that for this reason, we intend to pursue potential technical solutions to these issues in the future, to enable us to measure clinicians in subgroups on these measures at the subgroup level. We further stated that even if we address these technical issues, we still would be concerned that clinicians may use the opportunity to form subgroups to avoid being measured on cost as discussed in the public comment we received on our CY 2022 PFS proposal (86 FR 65422). We stated that if we are able to address the technical limitations in the future and evaluate performance at the subgroup level, we would anticipate developing policies similar to our existing policy for population health measures to use the affiliated group score if we are unable to calculate the measures for the subgroup. This would allow us to focus our measurement at the subgroup level but limit the opportunity of groups to use the formation of subgroups to avoid being measured in the cost performance category. Since we were uncertain if we would be able to address these technical issues, we did not propose a policy in the CY 2023 PFS proposed rule.

We also noted that we believe the registration information we receive from subgroups for CY 2023 performance period/2025 MIPS payment year will help us to learn more about the nature of subgroups and better test our measures (87 FR 46271).

We sought public comment on these proposals.

The following is a summary of the public comments received on our proposals to score subgroups on certain measures based on their affiliated group and our responses:

Comment: Several commenters supported our proposal to assess subgroups on measures in the cost performance category, and population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group score.

Response: We thank the commenters for their support.

Comment: Many commenters opposed our proposal to assess subgroups on measures in the cost performance category, and population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group. Many of these commenters expressed concern that measuring subgroups on the basis of the performance of the affiliated group would detract from the intention and focus of subgroup reporting. One commenter suggested that it would be very unlikely that subgroup reporting would be used to avoid assessment in the cost performance category. Many of these commenters suggested an alternative scoring methodology in which measures would be calculated for both the subgroup and affiliated group, and the higher score would be used.

Response: We agree with some of the concerns identified by the commenters. As noted in the proposed rule, we are concerned that measuring subgroups based on their affiliated group score for these measures may detract from our efforts to generate more clinically relevant and granular information about clinician performance. However, we believe that the technical issues related to testing and attribution in particular need to be examined in more detail before we can move forward with measuring clinicians on these measures at the subgroup level. We appreciate the alternative suggestion provided by the commenters but note that we would need additional information to determine if subgroups would be advantaged or disadvantaged by calculating measures based on administrative claims at the subgroup level. Establishing a scoring hierarchy or requiring the scoring of such measures at the subgroup level would not be appropriate until we are able to learn more about the scoring of these measures in subgroups and may determine how to best mitigate the risks that may arise from subgroup scoring of these measures. We will continue to investigate ways to ensure that subgroups are measured at the subgroup level as much as possible while ensuring that measurement is fair and does not allow clinicians to improve performance merely by reporting as part of a subgroup.

After consideration of the comments, we are finalizing our proposal to assess subgroups on measures in the cost performance category, and population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group by modifying § 414.1365(d)(3)(i)(A)(1) to read that a subgroup is scored on each selected population health measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points; adding § 414.1365(d)(3)(i)(B)(1) so that a subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points; and adding § 414.1365(d)(3)(ii)(A) to state that a subgroup is scored on each cost measure included in the MVP that they select and report based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).

(c) Scoring for Subgroups That Register but Do Not Report

As described in the CY 2022 PFS final rule (86 FR 65415 through 65418), groups interested in participating as subgroups for reporting the measures and activities in an MVP must adhere to the registration process established at § 414.1365(b). To be assessed on their performance at a subgroup level, clinicians participating as subgroups must meet the reporting requirements outlined at § 414.1365(c). We expect subgroups to register with the intent to submit data for the measures and activities in an MVP because they wish to be assessed based on their performance at the subgroup level. We also believe there will be instances where a subgroup would register but not submit data for the applicable performance period or clinicians in a registered subgroup would choose to participate in MIPS via a different reporting option instead of reporting as a subgroup. We considered whether we should assign a score for a subgroup regardless of their submission status. In the CY 2023 PFS proposed rule (87 FR 46272), we stated that at this point in time, we want to encourage groups to explore the subgroup reporting option and not penalize subgroups that do not submit data. During the voluntary years of subgroup reporting, we do not intend to assign a subgroup score in instances when we do not receive any MVP data for clinicians in registered subgroups. However, we expect that MIPS eligible clinicians in registered subgroups would participate in MIPS via another available reporting option as they would be subject to the MIPS payment adjustment under the TIN. Under the existing scoring hierarchy established in the CY 2022 PFS final rule (86 FR 65536 and 65537), a clinician is assigned the highest of the available final scores associated with the clinician's TIN/NPI.

For these reasons, in the CY 2023 PFS proposed rule (87 FR 46272), we proposed at § 414.1318(b)(1) that we will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period. Additionally, we proposed to make conforming changes at § 414.1318(b) to state that, except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance. We noted that we intend to continue monitoring the participation trends for subgroup reporting and reevaluate scoring for registered subgroups that do not submit data as we move towards mandatory subgroup reporting in the future.

The following is a summary of the public comments received on our proposal to not assign a final score for a subgroup that registers but does not submit data for the applicable performance period and our responses:

Comment: A few commenters supported our proposal to not calculate a score for a subgroup that registers but does not report data, stating that groups would be more likely to register as subgroups if they could change that status after it is completed.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal at § 414.1318(b)(1) to not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period. We are also finalizing conforming changes at § 414.1318(b) as proposed.

(d) Subgroup Examples

In the CY 2023 PFS proposed rule, we included a series of tables intending to demonstrate how scores would be calculated for clinicians participating in different configurations of groups and subgroups (87 FR 46272 through 46275). We included these examples to better illustrate the interplay of our finalized policies and proposals. We anticipate including similar information in educational material that can be found at *https://qpp.cms.gov/resources/resource-library*.

9. APM Performance Pathway

a. Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in performance year 2021, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation.

b. APP Reporting Options

Under the APP, MIPS eligible clinicians in an APM Entity that participates in a MIPS APM may report to MIPS and be scored (subject to certain limitations) at the individual clinician, group, or APM Entity level (85 FR 84859 through 84866). In that rule, we excluded Virtual Groups from reporting the APP. At that time, the concept of MIPS Value Pathway (MVP) subgroup reporting, through which a subset of MIPS eligible clinicians within a group TIN may report and be scored as a standalone MVP Participant, had not yet been introduced; however, we note that our subsequent use of the term ''subgroup'' may have caused confusion in light of its use in MVPs. In the CY 2022 PFS final rule, we codified policies related to subgroups at § 414.1318 ((§§ 414.1318 and 414.1365; 86 FR 65671), by which we meant the reporting of the APP by a subset of MIPS eligible clinicians within an APM Entity. In that rule, we stated that because we already identify the MIPS eligible clinicians who are MIPS APM participants based on Participation Lists for each APM, it is unnecessary to require MIPS APM participants to register as subgroups for purposes of reporting the APP (86 FR 65397 and 65398). We stated that beginning with performance year 2023, we will use Participation Lists to identify the MIPS eligible clinicians within a group TIN that should be included in the subgroup of APM participants for purposes of reporting the APP (86 FR 65398). We also codified at § 414.1318(c)(2) that subgroups would be scored according to the applicable MVP or APP scoring rules. However, under § 414.1367, which governs APP reporting and scoring, no changes were made to reflect the introduction of subgroup-level reporting of the APP.

Recognizing that there is ambiguity in our current rules, we proposed in the CY 2023 PFS proposed rule (87 FR 46275) to modify the text at § 414.1318(c)(2) to remove the reference to subgroup scoring of the APP, and therefore, disallow reporting of the APP by a subset of a group. As discussed in the proposed rule, the change is not intended as a change in policy; it is not our intent to permit MIPS eligible clinicians within an APM entity to be scored at a level in between a group and the individual clinician.

Notwithstanding the foregoing, we stated that we recognize that MIPS eligible clinicians may have an interest in reporting as subgroups in the APP, and as we described later in that section of the propose rule, we considered as an alternative to the proposed conforming change whether to permit subgroups as a level of reporting the APP, and to modify § 414.1367 accordingly. We noted that we believe there could be scenarios where a group may have an interest in reporting the APP through subgroups. For example, if a large multi-specialty TIN had specialists of different types participating in MIPS APMs, and, therefore, who are eligible for APP scoring, it would be possible that a subgroup within that TIN—perhaps primary care providers working out of a single EHR or practice site—would be interested in reporting the APP using

only the data generated by MIPS eligible clinicians in that subgroup. Additionally, particularly after MVP reporting is more widely performed, we recognized that clinicians using subgroup reporting for MVPs may have an easier time joining APMs and reporting the APP if they are able to maintain their reporting at the same level, thereby strengthening MVPs as a glide path to APM participation.

To permit subgroup reporting of the APP, we noted that we would need to enable a subgroup registration option for APP reporters, which would inevitably introduce additional administrative burden for the subgroups that would report. Aside from needing to register in order to be recognized as a subgroup, all other aspects of APP reporting for subgroups under the alternative proposal would be the same as for other reporting levels as established at § 414.1367. We requested comments on the proposed conforming change and the alternative we considered. In particular, we requested comments on which option would best balance the reporting flexibilities with administrative burdens, with the understanding that it may be necessary to revisit these policies in future rulemaking as MVP and APP policies continue to develop, we sought comment on the proposal.

The following is a summary of the public comments received on the proposed revisions to the regulation text, the alternative we considered, and our responses:

Comment: One commenter expressed general support for the alternative proposal to allow subgroup reporting of the APP.

Response: We appreciate the commenter taking time to note their support of this alternative policy. We understand that allowing subgroup reporting would create additional flexibility for reporting, particularly among groups that have participants in more than one model or of more than one practice type. Only one commenter indicated a preference for the alternative policy approach, and while we understand that the flexibility that approach offers could be valued by some participants, we do not believe that there is currently any need for the implementation of this policy in the short term. However, as MVPs become more widely available and multispecialty groups begin reporting on more diverse measure sets, there may be more demand for subgroup reporting of the APP in the future.

After consideration of the public comments, we are finalizing the proposed modification to § 414.1318(c)(2) to remove the reference to subgroup scoring of the APP policy as proposed. Therefore, we will remove the references to subgroup reporting of the APP in from § 414.1318(c)(2) to conform with current policy. We may revisit this policy in future rulemaking.

10. MIPS Performance Category Scoring

a. Quality Performance Category

As discussed in section III.G.4.[459] and elsewhere in the proposed rule (87 FR 46155 through 46157, 46275 through 46276), we sought comment on the potential addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions.

In the proposed rule (87 FR 46154 through 46155, 46275 through 46276), we sought feedback on the potential future inclusion of two new measures in the APP measure set: MUC21–136: Screening for Social Drivers of Health and MUC21–134: Screen Positive Rate for Social Drivers of Health. The National Quality Forum (NQF) provided conditional support for these two social determinants of health measures during the 2021–2022 cycle and indicated the measures would be appropriate for consideration in the Shared Savings Program.[460] The measure MUC21–136: Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for health-related social needs, which is consistent with the priorities of the agency and program including Meaningful Measures 2.0 priority areas.[461] The measure MUC21–134: Screen Positive Rate for Social Drivers of Health assesses the percentage of patients who screened positive for health-related social needs.

We encouraged readers to review the Social Determinants of Health Measure and Future Measure Development—Request for Information (RFI) discussed at section III.G.4. of the proposed rule. We refer readers to sections XX (Shared Savings Program) and XX (MIPS quality performance category) of this final rule for further discussion of the addition of the Social Determinants of Health measures.

We did not receive any additional comments specific to the potential future incorporation of these measures into the APP.

[459] Erroneously cited as section III.J.4 in the proposed rule.

[460] *https://www.qualityforum.org/setting_priorities/partnership/map_final_reports.aspx.*

[461] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

b. Improvement Activities Performance Category

Section 414.1367(c)(3) provides that the improvement activities performance category score for MIPS eligible clinicians, groups, and APM Entities reporting via the APP is calculated in accordance with § 414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities. We assign scores to each MIPS eligible clinician in the improvement activity performance category for participating in MIPS APMs, and MIPS eligible clinicians must earn 40 points in order to receive full credit in this performance category. On an annual basis, we conduct a review of the governing documentation of all MIPS APMs to determine the Improvement Activities that are required by each such APM, and have in all cases found that each MIPS APM requires participants to engage in such Improvement Activities as would earn participants a performance category score of no less than 40 points, which as discussed previously in the proposed rule is the maximum score for this performance category (§ 414.1380(a)(1)(iii)). The list of required activities for each MIPS APM is compared to the MIPS list of improvement activities and the MIPS APM's participants that report the APP are scored in accordance with MIPS to determine if the APM meets the requirements for awarding full credit (40 points) for Improvement Activities to the participants in the MIPS APM.

We clarified that, even though § 414.1367(c)(3) permits the reporting of additional improvement activities, such reporting would not supersede the automatic award of the maximum score described previously in this section of the proposed rule. Because the reporting of additional improvement activities does not serve any Improvement Activity scoring purpose, we would not use any Improvement Activity performance category submissions for scoring under the APP where the participants were already entitled to full credit for this performance category. This clarification is particularly relevant in instances where an APM Entity is eligible for reweighting of the two remaining performance categories of quality and promoting interoperability. We noted that we understand it is possible that, for example, a data submission from the Application Programming Interface (API) of a TIN or individual within an APM Entity could contain incidental Improvement Activity performance information that was collected automatically, though not

for the purpose of a MIPS submission or scoring. We clarified that the submission of Improvement Activity performance information in this type of circumstance would not constitute a submission of data for the purpose of scoring the improvement activities performance category under the APP. Therefore, incidental submissions such as the type in this example would never be the sole basis for an APM Entity to be scored under the APP.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, and 86 FR 65431 through 65445, respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In the CY 2023 PFS proposed rule (87 FR 46276 through 46280), we proposed to:

- Amend the definition of the term ''high priority measure'' to include quality measurement pertaining to health equity.
- Replace the ''Asian language survey completion'' variable with ''language other than English spoken at home,'' ''Spanish language spoken at home,'' and ''Asian language spoken at home'' variables in the case-mix adjustment model for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey.
- Increase the data completeness criteria threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.
- Modify the MIPS quality measure set as described in Appendix 1 of the CY 2023 PFS proposed rule, including through the addition of new measures, updates to specialty sets, the removal of existing measures, and substantive changes to existing measures.

(b) Quality Data Submission Criteria

(i) Submission Criteria for Quality Measures, Excluding the CAHPS for MIPS Survey Measure

The Meaningful Measures Initiative provides for the identification of high priority areas for quality measurement and quality improvement, which identifies the core quality of care issues that advances our work to improve patient outcomes (83 FR 59719). In order to further identify priority areas for MIPS quality measurement, we defined the term high priority measure at § 414.1305, for years beginning with the CY 2019 performance period/2021 MIPS payment year, as an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure (83 FR 59761). Generally, if an applicable outcome measure is not available, a MIPS eligible clinician must report a high priority measure (§ 414.1335(a)(1)). To incentivize the voluntary adoption of high priority measures, a MIPS eligible clinician may earn bonus points for reporting such a measure (§ 414.1380(b)(1)(v)(A)). As significant and persistent inequities in healthcare outcomes exist in the United States, we are committed to developing innovative solutions that support access to high quality care and promote health equity, including the exploration of solutions to measure health equity within MIPS. Health equity is a priority area across CMS programs, including MIPS.

Thus, in the CY 2023 PFS proposed rule, we proposed to amend the definition of the term high priority measure to include health equity measures. Specifically, starting with the CY 2023 performance period, we proposed to amend the definition of the term high priority measure at § 414.1305 to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure (87 FR 46276 and 46277). As noted in the CY 2023 PFS proposed rule, we believe that it is imperative to include quality measures pertaining to health equity as high priority measures in order to incentivize the adoption of health equity measures by MIPS eligible clinicians (87 FR 46277).

We solicited public comment on the proposal to amend the definition of the term high priority measure to include the recognition of health equity-related quality measures. The following is a summary of the public comments received.

Comment: Most commenters supported the proposal to amend the definition of the term high priority measure to include health equity-related measures starting with the CY 2023 performance period.

Response: We appreciate the support from commenters.

Comment: Many commenters recommended that CMS outline specific guidance indicating what characteristics would classify a measure as health-equity related. Commenters inquired whether measures with outcomes indicating variation among patient populations could be classified as health-equity related, along with measures specifically aimed at addressing equity. A few commenters recommended that health equity-related measures include measures that evaluate social risk factors and demographic data, and track varying degrees of access to care based on social determinants, as measured by factors such as insurance coverage, healthcare benefits, and the types of specialties and settings of care available to a patient.

Response: We appreciate commenters' request for additional guidance regarding what classifies a measure as a ''health equity-related measure'' for the purpose of a high priority designation. We recognize that a health equity-related measure may vary in structure, in which a measure could be structured to directly address health equity or structured to include elements or factors that address an aspect of health equity. We are focusing on a person-centric approach as part of an overarching CMS Quality Strategy, which strives toward creating a care journey that is free from inequity while optimizing opportunities and access for underserved populations. We are identifying measurable interventions to close gaps in quality care and health outcomes. As we consider the inclusion of additional health-equity related measures under MIPS, we note that we have defined the term ''health equity'' as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identify, socioeconomic status,

geography, preferred language, and other factors that affect access to care and health outcomes.'' We intend to use this definition as we consider potential measures for future use in MIPS.

Comment: One commenter recommended that measures which fall under the definition of a high priority measure be validated, tested, and endorsed by the National Quality Forum (NQF).

Response: As we have previously stated (83 FR 53636; 84 FR 62954), we request that interested parties consider when submitting a quality measure for possible inclusion whether the measure is ''beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing.'' While we consider whether or not a measure is fully tested, it is not the only relevant standard. Separately, we note that we opt to participate in the pre-rulemaking process that assesses and evaluates measures from the Measures Under Consideration (MUC) List for the potential implementation of such measures in MIPS under section 1890A of the Act, which may not result in a consensus-base entity (CBE) endorsement (for example, NQF endorsement). Nonetheless, this process provides a comprehensive review of the measures from multi-stakeholder workgroups.

Comment: A few commenters suggested that in addition to the proposal to amend the definition of the term high priority measure to include health equity-related measures, CMS should provide technical assistance pertaining to identifying and measuring health care disparities in electronic medical records.

Response: We appreciate the feedback from commenters. As we increase the number of health equity-related quality measures under MIPS, we intend to explore approaches to technical assistance. Also, we intend to collaborate with The Office of the National Coordinator for Health Information Technology (ONC), which has efforts focused on the development of standards and capabilities within certified health information technology supporting the capture and sharing of data that can provide insights into health disparities.

After consideration of public comments, and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46276 and 46277), we are finalizing, as proposed, the proposal in § 414.1305 to amend the definition of the term high priority measure to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure.

(ii) Submission Criteria for the CAHPS for MIPS Survey Measure

The CAHPS for MIPS Survey measures patients' experience of care within a group, virtual group, and APM Entity, including Shared Savings Program ACOs. The survey measures ten dimensions of patient experience of care, known as summary survey measures, for which patients may be the best, if not only source of information. The CAHPS for MIPS Survey is optional for all groups, virtual groups, and APM Entities of 2 or more eligible clinicians reporting via traditional MIPS, and is required for Shared Savings Program ACOs reporting via the APM Performance Pathway (APP).

(A) CAHPS for MIPS Survey Measure Case-Mix Adjustment Model

Under the CAHPS for MIPS Survey measure, we adjust summary survey measure scores for case-mix to promote meaningful comparison of the performance of MIPS groups despite differences in their patient populations (81 FR 77120). The case-mix adjustment model for CAHPS for MIPS Survey measure includes the following case-mix adjustors as of the CY 2022 performance period: age; education; self-reported general health status; self-reported mental health status; proxy response; Medicaid dual eligibility; eligibility for Medicare's low-income subsidy; and Asian language survey completion (86 FR 65444 and 65445).

Only a small percentage of CAHPS for MIPS Survey participants who report speaking a language other than English at home actually complete the survey in that language. We believe that collecting information on the language spoken by the participant at home as a case-mix adjustor rather than the language used by the respondent to complete the survey is likely to capture language preference more accurately, as well as response patterns of participants with similar experiences, for a more meaningful comparison of performance between MIPS groups. Furthermore, more accurately capturing preferred language aligns with CMS's effort to provide culturally and linguistically appropriate services (CLAS), which are intended to advance health equity, improve quality, and help eliminate health care disparities.[462] Other CMS-administered CAHPS Surveys, such as the Hospital CAHPS Survey, include preferred language variables rather than survey language variables for case-mix adjustment. Furthermore, analysis of CY 2019 performance period measure data for the CAHPS for MIPS Survey found that adding case-mix adjustors for Spanish language spoken at home, Asian language(s) spoken at home, and other language spoken at home has minimal impacts on scoring for most groups, and slightly positively impacts the scores of groups with substantial patient populations who speak a language other than English at home. Therefore, we proposed in the CY 2023 PFS proposed rule to revise the CAHPS for MIPS Survey measure case-mix adjustment model to remove the existing adjustor for Asian language survey completion and to add adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home (87 FR 46277).

We solicited public comment on the proposal to revise the CAHPS for MIPS Survey measure case-mix adjustment model.

Comment: Several commenters supported our proposal to revise the CAHPS for MIPS Survey measure case-mix adjustment model to remove the existing adjustor for Asian language survey completion and to add adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home. Commenters noted that this change will capture more culturally appropriate data and more accurately capture language preference.

Response: We agree that revising the CAHPS for MIPS Survey measure case-mix model to include adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home on clinician profile pages will capture more culturally appropriate data and more accurately capture language preference, while also providing for a more meaningful comparison of performance between MIPS groups.

Comment: One commenter noted that their support is contingent on us providing sufficient data demonstrating that the revised scoring better reflects the quality of care provided. In particular, the commenter requested more detail on how this revision would

[462] Centers for Medicare & Medicaid Services. Achieving Health Equity. Available at *https://www.cms.gov/Outreach-and-Education/MLN/WBT/MLN1857916-OMH-AHE/OMHAHE/ahe/lesson01/09/index.html.*

improve the validity and reliability of the scores.

Response: We agree that any revision to the scoring of the CAHPS for MIPS Survey measure should better reflect the quality of care given, and at a minimum, maintain the reliability and validity of the scores. Based on internal analysis of existing CAHPS for MIPS data, this change to the case-mix adjustment model did not have a substantial impact on scores for most groups and had a small positive impact on scores for groups with a large proportion of patients reporting speaking a language other than English at home, which suggests a slight improvement in measurement of patient experience by the survey. Regarding the validity of the measure, we believe that language other than English spoken at home more accurately captures language preference than language of survey completion. Regarding measure reliability, analyses of existing CAHPS for MIPS data showed that across all of the summary survey measures, changes in reliability were extremely small.

After consideration of public comments, and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46277), we are finalizing the proposal to revise the CAHPS for MIPS Survey measure case-mix adjustment model.

(aa) Adding Items Related to Health Disparity and Price Transparency to the CAHPS for MIPS Survey Measure

We are interested in gathering information directly from patients related to health disparities and price transparency. In the CY 2023 PFS proposed rule (87 FR 46155 through 46157), we requested information regarding the future consideration of additional and modified questions related to health disparities and price transparency to the CAHPS for MIPS Survey measure. Specifically, we solicited public comment on the following items: (1) the potential future inclusion of health disparities and price transparency questions and whether there are other questions that should be considered for potential future inclusion in the CAHPS for MIPS Survey measure; and (2) the potential for creating a shortened version of the CAHPS for MIPS Survey measure such that it would be more applicable to specialty groups. We thank commenters for their responses regarding this request for information. We may consider the information provided by commenters to inform future rulemaking.

(iii) Data Completeness Criteria

In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), the data completeness criteria threshold was established to reflect a threshold of at least 50 percent (81 FR 77125). The data completeness criteria threshold increased from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and was maintained at a threshold of at least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, the data completeness criteria threshold was increased from at least 60 percent to at least 70 percent (84 FR 62952). The data completeness criteria threshold of at least 70 percent was maintained for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). We continue to believe that it is important to incrementally increase the data completeness criteria as MIPS eligible clinicians, groups, and virtual groups gain experience with MIPS.

We believe that the incorporation of higher data completeness thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevent selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, and 86 FR 65436). We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632 and 86 FR 65436). The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632 and 86 FR 65436).

We previously noted concerns raised regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, and 84 FR 62951). We want to ensure that an appropriate, yet achievable, data completeness threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period (as described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76), we believe that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold without jeopardizing their ability to participate and perform well under MIPS.

In the CY 2023 PFS proposed rule, we proposed to increase the data completeness criteria from 70 percent to 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. Specifically, we proposed in § 414.1340(a)(4) that, for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, a MIPS eligible clinician or a group submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs must submit data on at least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer (87 FR 46277 and 46278). Similarly, we proposed in § 414.1340(b)(4), for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, that a MIPS eligible clinician or a group submitting quality measures data on Medicare Part B claims measures would need to submit data on at least 75 percent of the MIPS eligible clinician or group's patients seen during the corresponding performance period to which the measure applies (87 FR 46277 and 46278). As noted in the CY 2023 PFS proposed rule, we believe that increasing the data completeness criteria threshold to 75 percent for the CY 2024 performance period/2026 MIPS payment year and the CY 2025 performance period/2027 MIPS payment year provides MIPS eligible clinicians with ample time prepare for a higher standard as most clinicians already meet or exceed this standard.

We solicited public comment on the proposals to increase the data completeness criteria threshold from at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. The following is a summary of the public comments received.

Comment: Many commenters supported the proposal to increase the data completeness criteria threshold

from at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

Response: We appreciate the support from commenters.

Comment: Several commenters opposed the proposal to increase the data completeness criteria threshold from at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. Commenters indicated that increasing the data completeness threshold would unnecessarily increase reporting burdens for individual MIPS clinicians, groups, and virtual groups. A few commenters emphasized that some clinicians are still recovering from the ongoing COVID–19 PHE. A few other commenters indicated that clinicians are being held to a higher standard in MIPS compared to other quality programs. One commenter expressed concern that subregulatory guidance is generally not available late in the performance year, which could result in a change in reporting strategy that makes it challenging to satisfy data completeness requirements. One commenter recommended that the data completeness criteria threshold be maintained to at least 75 percent for at least 5 years and not exceed a threshold of at least 80 percent.

Response: We disagree with commenters that increasing the data completeness criteria threshold would unnecessarily increase the reporting burden for individual MIPS eligible clinicians, groups, and virtual groups. Individual MIPS eligible clinicians, groups, and virtual groups will have had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent and will have more than 12 months to prepare for an increased data completeness criteria threshold before such threshold becomes effective for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

We recognize that some individual MIPS eligible clinicians, groups, and virtual groups continue to experience the effects from the COVID–19 public health emergency. For this reason, in the CY 2022 PFS final rule (86 FR 65437 through 65438), we maintained the data completeness criteria threshold of at least 70 percent for the CY 2023 performance period/2025 MIPS payment in response to concerns from commenters regarding an increase to the data completeness criteria threshold amidst the COVID–19 public health emergency. Maintaining the data completeness criteria threshold of at least 70 percent was intended to reduce burden and provide additional time for MIPS eligible clinicians, groups, and virtual groups to adopt the final policy changes and recover fiscally from the pandemic. In establishing data completeness criteria thresholds in advance of an applicable performance period, we believe it is advantageous to delineate the expectations for MIPS eligible clinicians, groups, and virtual groups in order for them prepare for a transition to higher data completeness criteria threshold, particularly the increase in data completeness criteria threshold of at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

We recognize that other CMS quality programs may have different data completeness criteria thresholds. While the commenter did not specify a CMS quality program or outline specific reporting requirements regarding data completeness that differ from MIPS, we believe that reporting requirements for CMS quality programs such as data completeness criteria, data validation, patient population eligible for a measure, measure specification requirements, case minimum standards, or measure exclusions or exceptions may not be directly comparable. Therefore, we believe that it is not accurate to conclude that the overall reporting burden of a CMS quality program is less than another CMS quality program merely because the former CMS quality program has a lower data completeness criteria threshold than the latter program. We note that reporting requirements may not only differ across CMS quality programs, but reporting requirements may differ by measure within a program. Thus, we believe that the reporting requirements such as the data completeness criteria threshold under other CMS quality programs should not be dispositive when determining the data completeness threshold for MIPS as reporting requirements for other CMS quality programs may not be directly comparable to the reporting requirements established under MIPS.

In response to the comment indicating that subregulatory guidance not being available until late in the performance period and may cause challenges in satisfying data completeness criteria requirements, we note that all reporting requirements for the quality performance category are established through the rulemaking process and published in the applicable calendar year PFS final rule. Although the commenter did not specify the type of subregulatory guidance that is published late in a performance period potentially impacting a MIPS eligible clinician, group, or virtual group from meeting the data completeness criteria requirements, we note that there are instances in which we publish subregulatory guidance toward the latter part of a performance period such as the list of MIPS quality measures that will be suppressed or truncated for the applicable performance period, which is published before the end of the performance period; and the list of MIPS quality measures impacted by ICD–10 coding changes that become effective October 1 of an applicable performance period, which is published prior to the applicable performance period. We recognize that the publication of MIPS quality measures impacted by ICD–10 coding changes, which would result in truncation or suppression, is in the latter part of a performance period. We note that it is not technically feasible for us to publish such information prior to October 1 of an applicable performance period given that such coding changes are not effective until October 1 of a calendar year. We strive to provide subregulatory guidance as soon as technically feasible.

Furthermore, we believe that it is critical to increase data completeness thresholds over time to more accurately assess a MIPS eligible clinician's performance on quality measures and prevent any selection bias. A data completeness criteria threshold of less than 100 percent reduces burden and accommodates operational issues that may arise during data collection within the initial years of the program. We have previously provided notice to MIPS eligible clinicians in order for them to take the necessary steps to prepare for higher data completeness criteria thresholds in future years (82 FR 53632, 83 FR 59758, and 84 FR 62951). We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS.

Comment: Several commenters expressed concern regarding the proposal to increase the data completeness criteria threshold from at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years due to potential issues with taxpayer identification numbers (TINs), which include more than one site of service. Commenters emphasized that in many cases, specialties may provide services across multiple sites, but not all sites participate in MIPS or use the same registry or EHR that the clinician

chooses to use for MIPS reporting, and such clinician would face challenges if data from these additional sites need to be included to meet the data completeness threshold. Some commenters indicated that the data completeness criteria threshold should not increase until EHR reporting is more widely adopted and integrated across clinicians and settings. A few commenters noted that the proposal would have a disproportionately negative impact on small and rural practices, which are significantly less likely to have an EHR. One commenter raised the concern that clinicians continue to lack access to timely notifications when a patient is included in the denominator of a quality measure. The commenter encouraged CMS to establish a process that will allow practices to verify which patients should be in the denominator of a selected measure on a timely basis, including when clinicians have a scheduled service with regular updates occurring monthly at minimum.

Response: We acknowledge the concerns from commenters regarding certain eligible clinicians that may face different systems for capturing and reporting information across sites of services. However, we believe in the importance of incrementally increasing the data completeness criteria threshold, and believe that by finalizing the policy as proposed for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, eligible clinicians who may face this issue will have had sufficient time to address data collection across sites of service where they may practice. We believe that the use of EHRs and eCQMs can reduce burden associated with meeting higher data completeness standards, as collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. We continue to encourage individual MIPS eligible clinicians, groups, and virtual groups, including small and rural practices, to explore EHR adoption and reporting of eCQMs to reduce burden. However, where individual MIPS eligible clinicians, groups, and virtual groups continue to engage in other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or Qualified Clinical Data Registries (QCDRs), we believe this incremental increase in the data completeness threshold would not present a substantial burden.

In regard to the comment encouraging CMS to establish a process that will allow practices to verify which patients should be in the denominator of a selected measure on a timely basis, including when clinicians have a scheduled service with regular updates occurring monthly at minimum, we note that CMS does not collect real-time information from MIPS eligible clinicians regarding patient encounters, and future patient encounters, that would allow for a determination or estimation of whether a patient is in the denominator of a selected measure. We encourage eligible clinicians to work with their health IT vendors, or other intermediaries including registries and QCDRs to explore such functionality.

Also, we recognize that the increase in the data completeness criteria threshold would impact APM Entities such as Medicare Shared Savings Program ACOs that are preparing to transition to reporting MIPS CQMs or CQMs under the APP, and face additional considerations around the aggregation of data across ACO participant sites. We recognize that Medicare Shared Savings Program ACOs are developing workflows and the necessary infrastructure for data aggregation across systems in order to be able to report all-payer for MIPS CQMs and eCQMs. We recognize that an increase in the data completeness criteria threshold would increase the amount of data Medicare Shared Savings Program ACOs are required to aggregate across ACO participants; however, we believe that while Medicare Shared Savings Program ACOs are developing data aggregation approaches, they would be able to target the increased data completeness criteria threshold of at least 75 percent as part of their planning activities.

Comment: A few commenters recommended that CMS consider establishing different data completeness thresholds for different types of measures.

Response: We disagree with the commenters that there should be differing data completeness thresholds for different types of measures. We believe that not having a consistent data completeness threshold across the MIPS quality measures would create confusion and increase undue burden because individual MIPS eligible clinicians, groups, virtual groups, and APM Entities (Medicare Shared Savings Program ACOs) reporting on multiple measures with varying data completeness thresholds may inadvertently report data at the incorrect data completeness criteria threshold for one or more measures and would experience additional data aggregation complexities in having their EHRs, registries, and/or QCDRs account for various data completeness criteria thresholds per measure across all sites within a TIN(s).

Comment: A few commenters recommended that CMS converse with interested parties and quality measurement experts when establishing the target ceiling for the data completeness criteria threshold and the timeline for achieving such threshold.

Response: CMS has adopted and will continue to adopt updates to the data completeness criteria threshold through regulation, which affords the public, including all interested parties and quality measure experts, the opportunity to comment. We appreciate the comments we receive and may consider such information to inform future rulemaking.

Comment: One commenter requested that CMS provide the rationale for increasing the data completeness criteria threshold and the data used to inform such decision.

Response: We refer the reader to our discussion above and in prior rulemaking regarding our belief that the incorporation of higher data completeness thresholds ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, and 86 FR 65436). As we have previously noted, we want to ensure that an appropriate, yet achievable, data completeness threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period (as described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76). As MIPS eligible clinicians, groups, and virtual groups have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 6 years (from CY 2017 performance period to CY 2022 performance period), we believe that such experience has prepared MIPS eligible clinicians, groups, and virtual groups to be able to meet incremental increases in the data completeness criteria threshold. CMS will have maintained the data completeness criteria threshold at 70 percent for four years by CY 2024, and we believe that the signaling of our intent to continue to raise the threshold in the future (*see* 81 FR 77120, 82 FR 53632, 83 FR 59758, and 86 FR 65436) has provided adequate time for MIPS eligible clinicians, groups, and virtual

groups to transition from a data completeness criteria threshold of at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. Therefore, we believe that it is feasible for eligible clinicians, groups, and virtual groups to achieve a higher data completeness threshold of at least 75 percent, for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years without jeopardizing their ability to participate and perform well under MIPS.

Comment: One commenter requested for CMS to explain how the achieved percent of data completeness would be validated, given that the denominator is for all payers.

Response: All-payer data is required to be reported for MIPS CQMs and eCQMs under MIPS. Each MIPS CQM and eCQM reported must meet the data completeness criteria. In order to access the Quality Payment Program system for data submission, users are required to attest that they agree to the Statement of Truth. The Statement of Truth requires that a user certifies that to the best of their knowledge that all the information that they will be submitting will be true, accurate, and complete. If a user becomes aware that any submitted information is not true, accurate, and complete, the user must correct such information promptly. As part of the Statement of Truth, a user acknowledges their understanding that the knowing omission, misrepresentation, or falsification of any submitted information may be punishable by criminal, civil, or administrative penalties, including fines, civil damages, and/or imprisonment. If it is determined that an individual MIPS eligible clinician, group, or virtual group did not adhere to the terms of the Statement of Truth during an audit, the individual MIPS eligible clinician, group, or virtual group not only violated the terms of the Statement of Truth and may be subject to penalty, but did not meet the reporting requirements under MIPS. As part of our data validation verification process, we conduct audits.

After consideration of public comments, and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46277 and 46278), we are finalizing, as proposed, the proposals in §§ 414.1340(a)(4) and 414.1340(b)(4) as follows:

- For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, a MIPS eligible clinician or a group submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs must submit data on at least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer.
- For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, that a MIPS eligible clinician or a group submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician or group's patients seen during the corresponding performance period to which the measure applies.

(c) Selection of MIPS Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding to the list, as appropriate, new measures; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2022 PFS final rule (86 FR 65687 through 65968); CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality measure set, as described in Appendix 1 of the CY 2023 PFS proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2023 performance period, we proposed a measure set of 194 MIPS quality measures in the inventory (87 FR 46278 through 46279).

The new MIPS quality measures that we proposed to include in MIPS for the CY 2023 performance period and future years can be found in Table Group A of Appendix 1 of the CY 2023 PFS proposed rule. For the CY 2023 performance period, we proposed 9 new MIPS quality measures, which includes 1 administrative claims measure; 1 composite measure; 5 high priority measures, and 2 patient-reported outcome measures).

In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. We proposed modifications to existing specialty sets and new specialty sets as described in Table Group B of Appendix 1 of the CY 2023 PFS proposed rule. Specialty sets may include: new measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 3, 2022, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 7 of MIPS under the Quality Payment Program.[463] These recommendations were based on the MIPS quality measures finalized in the CY 2021 PFS final rule and the 2021 Measures Under Consideration List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with were proposed in the CY 2023 PFS proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as described in Tables Group A and Group B of Appendix 1 of the CY 2023 PFS proposed rule (87 FR 46458 through 46471; 87 FR 46471 through 46713), we refer readers to Table Group C of Appendix 1 of the CY 2023 PFS proposed rule for a list of quality measures and rationales for measure removal (87 FR 46714 through 46722). We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959). For the CY 2023 performance period, we proposed to remove 15 MIPS quality measures and partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use

[463] Message to the Quality Payment Program listserv on January 3, 2022, entitled: ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2023 Performance Year of the Merit-based Incentive Payment System (MIPS).''

in MVPs. We refer readers to Table Group DD of Appendix 1 of the CY 2023 PFS proposed rule for further information regarding the proposals to retain such measures for retention for use in relevant MVPs (87 FR 46789 through 46792). Of the 15 MIPS quality measures proposed for removal, the following pertains to such measures: 1 MIPS quality measure is duplicative to a proposed new MIPS quality measure; 4 quality measures are duplicative of current measures; 7 MIPS quality measures that do not align with the Meaningful Measure Initiative (that is, measures that are unable to produce a benchmark or have limited adoption, or are a standard of care); 2 MIPS quality measures that are under the topped out lifecycle; and 1 measure is extremely topped out. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (83 FR 59763 through 59765). We noted our belief that the proposal to remove the quality measures described in Table Group C of the CY 2023 PFS proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria (87 FR 46714).

Also, we proposed substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of the CY 2023 PFS proposed rule (87 FR 46724 through 46788). We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 and 65442). We proposed substantive changes to 75 MIPS quality measures, which includes 2 quality measures proposed to be retained for utilization under MVPs (we refer readers to Table Group DD of Appendix 1 of the proposed rule for such measures that are proposed for retention for use in relevant MVPs). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive.

Lastly, we proposed substantive changes to CMS Web Interface measures that are available as a collection and submission type for Medicare Shared Savings Program ACOs meeting reporting requirements under the APP. The substantive changes to the CMS Web Interface measures can be found in Table Group E of Appendix 1 of the CY 2023 PFS proposed rule (87 FR 46792 through 46799). Relatedly, in the CY 2023 PFS proposed rule (87 FR 46148 through 46150), we proposed to establish CMS Web Interface benchmark policies for the APP under Medicare Shared Savings Program (at § 425.512) that would be applied retroactively starting with performance year 2022. The CMS Web Interface benchmark policies previously established at § 425.502(b) under the Medicare Shared Savings Program were revised in the CY 2021 PFS final rule, in which the provisions under § 425.502(b) were sunset with performance year 2022 and not applied to the APP under the Medicare Shared Savings Program. For performance year 2021, we stated in the CY 2021 PFS final rule that the CMS Web Interface measure benchmarks developed for the Medicare Shared Savings Program for performance year 2020 would be utilized (85 FR 84724). However, we inadvertently failed to consider the policies that would apply for purposes of establishing benchmarks for the CMS Web Interface measures applicable to the APP starting with performance year 2022, and as a result, benchmark policies for the CMS Web Interface measures were not established for the APP under the Medicare Shared Savings Program. We noted that the absence of benchmark policies for the APP under the Medicare Shared Savings Program impacts MIPS. Section 414.1380(b)(1)(ii)(B) provides that MIPS benchmarks for the CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program. Due to the absence of benchmark policies for the APP under the Medicare Shared Savings Program, CMS Web Interface measure benchmarks were not established starting with performance year 2022. As described in the CY 2023 PFS proposed rule (87 FR 46148 through 46150), we proposed to establish CMS Web Interface benchmark policies for the APP under Medicare Shared Savings Program, in which the retroactive adoption of benchmark policies previously established at § 425.502(b) would be applied for performance year CY 2022 (and future performance years as applicable under the Medicare Shared Savings Program). Thus, for the CY 2022 performance period/2024 MIPS payment year (the last year for which the CMS Web Interface is available as a collection and submission type under traditional MIPS for groups, virtual groups, and APM Entities), the CMS Web Interface benchmarks created for the APP under the Medicare Shared Savings Program would be utilized under MIPS.

In this final rule, we are further elaborating on the impact of the retroactive adoption of benchmark policies previously established at § 425.502(b) for the APP under the Medicare Shared Savings Program would have on MIPS for the CY 2022 performance period/2024 MIPS payment year. In the CY 2023 PFS proposed rule (87 FR 46148 through 46150), we proposed to correct our inadvertent indication that a Medicare Shared Savings Program benchmark would not be created for the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226). In the CY 2022 PFS final rule (86 FR 65262), we noted the CMS Web Interface measure Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226) and two other CMS Web Interface measures did not have benchmarks for performance year 2022 and would not be scored. Pursuant to § 414.1380(b)(1)(ii)(B) and absent this correction, the CMS Web Interface measure, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226), would not have a benchmark and would not be scored under MIPS the CY 2022 performance period/2024 MIPS payment year. With the establishment of a benchmark for the CY 2022 performance period/2024 MIPS payment year, the CMS Web Interface measure, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226), will be scored under MIPS.

We believe that the scoring of the CMS Web Interface measure, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226), would likely be beneficial to the overall quality performance category score for a group, virtual group, or APM Entity given that there would be an opportunity to earn more achievement points as an additional CMS Web Interface measure would be scored; and would not result in additional administrative burden given that groups, virtual groups, and APM Entities are already required to report on all CMS Web Interface measures, including CMS Web Interface measures without benchmarks. We refer readers to section III.G.4.c.(2) of this final rule for the discussion regarding the rationale for establishing a benchmark and scoring the CMS Web Interface measure, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID#226)

for the APP under the Medicare Shared Savings Program.

Lastly, we recognize that some groups, virtual groups, and APM Entities intending to report on the CMS Web Interface measures for the CY 2022 performance period/2024 MIPS payment year may continue to be impacted by the COVID–19 public health emergency or may be affected by other extreme and uncontrollable circumstances (EUC) (such as a Federal Emergency Management Agency (FEMA)-designated major disaster). Groups, virtual groups, and APM Entities may apply for the 2022 MIPS EUC Exception if an EUC affects their ability to collect data for a specific MIPS performance category or categories.[464] The EUC policy provides for the reweighting of one or more performance categories (*see* § 414.1380(c)(2)).

We solicited public comment on the proposals to modify the quality performance category measure set.

We refer readers to Table Groups A through E of Appendix 1 of this final rule for a summary of public comments received regarding the proposed modifications to the MIPS quality measure set for the CY 2023 performance period and the discussion regarding final decisions. We refer readers to section III.G.4.c.(2) of this final rule regarding the finalized, as proposed, policy that establishes benchmark policies for the APP under the Medicare Shared Savings Program.

After consideration of public comments, and for the reasons stated above (and in the aforementioned Table Groups A through E of Appendix 1 of this final rule) and in the CY 2023 PFS proposed rule (87 FR 46278 and 46279), we are finalizing with modification a measure set of 198 MIPS quality measures in the inventory for the CY 2023 performance period, which includes the following:

- Implementation of 9 new MIPS quality measures: 1 administrative claims measure;1 composite measure; 5 high priority measures, and 2 patient-reported outcome measures;
- Removal of 11 MIPS quality measures: 1 quality MIPS measure is duplicative to a new quality measure; 4 MIPS quality measures are duplicative to current quality measures; 3 MIPS quality measures do not align with the Meaningful Measures Initiative (that is, measures that are unable to produce a benchmark or have limited adoption, or are a standard of care); 2 MIPS quality measures are under the topped-out lifecycle; and 1 MIPS quality measure is extremely topped out;
- Partial removal of 2 MIPS quality measures: 2 MIPS quality measures removed from traditional MIPS and retained for use in MVPs; and
- Substantive changes to 76 MIPS quality measures.

(i) Screening for Social Drivers of Health Proposed Measure

Established evidence demonstrates that factors beyond the clinical realm are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[465] [466] Specifically, social risk factors account for 50 to 70 percent of health outcomes.[467] [468] [469] Indeed, the Physicians Foundation surveyed 8,500 physicians in 2018 and found that almost 90 percent of respondents reported their patients had a serious health problem linked to poverty or other social conditions.[470]

Health-related social needs (HRSNs), which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[471] In 2017, the CMS Innovation Center launched the Accountable Health Communities (AHC) Model to test the impact of addressing the HRSNs of Medicare and Medicaid beneficiaries.[472] [473] [474] [475] Although there are other models of care that address HRSNs, the AHC Model is one of the first Federal pilots to test whether systematically identifying and addressing core HRSNs—through screening, referral, and community navigation—improves healthcare costs, utilization, and outcomes.[476] Moreover, as described in the CMS Equity Plan for Improving Quality in Medicare, complex interactions among individual need, clinician practice/behavior, and availability of community resources significantly impact healthcare access, quality, and ultimately costs.[477] [478]

Conceptually, HRSNs exist along a continuum with other equity-related terms—such as ''social determinants of health'' and ''social risk factors''—used to describe upstream factors that can adversely affect the health of individuals and communities. Often conflated and even used interchangeably, the variety of terms has created confusion, as well as concern, prompting leaders in the field to adopt ''drivers of health'' (DOH) instead.[479]

[464] The deadline to submit the 2022 MIPS EUC Exception application is Tuesday, January 3, 2023, by 8:00 p.m. Eastern Time. To apply, sign into your Quality Payment Program account, select ''Exceptions Application'' on the left-hand navigation and then select ''Extreme and Uncontrollable Circumstances.''

[465] Zhang, Y., Li, J., Yu, J., Braun, R.T., Casalino, L.P. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open. 2021;4*(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

[466] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA, 324*(10), 975–983. Available at *https://doi.org/10.1001/jama.2020.13129*.

[467] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*.

[468] Khullar, D. (September, 2020). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care Team-Based Approach for Advancing Health Equity.

[469] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*.

[470] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*.

[471] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[472] Centers for Medicare & Medicaid Services. (June, 2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[473] Alley, D.E., Asomugha, C.N., Conway, P.H., & Sanghavi, D.M. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine 374*(1):8–11. Available at *https://doi.org/10.1056/NEJMp1512532*.

[474] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives, 7*(5). Available at *https://doi.org/10.31478/201705b*.

[475] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at *https://innovation.cms.gov/innovation-models/ahcm*.

[476] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[477] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf*.

[478] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[479] ''What We Need To Be Healthy—And How To Talk About It,'' Health Affairs Blog, May 3, 2021.

Hereafter, we utilize DOH terminology to more holistically capture aforementioned and related concepts, while minimizing potential misinterpretation and/or negative connotation.

We believe that consistently addressing DOH will have two significant benefit for MIPS . First, because DOH disproportionately impact individuals and communities that are disadvantaged and/or underserved by the healthcare system, the promotion of screening for these factors would support clinician practices and health systems in actualizing an expressed commitment to address disparities in care, implementing associated equity measures to track progress, and improving overall health equity.[480]

Second, patient-level DOH data through screening is essential in the long-term to encourage meaningful collaboration among clinicians and community-based organizations, and implement and evaluate related innovations in healthcare and social service delivery.

As a first step towards addressing DOH to close health equity gaps among patients served by MIPS-eligible clinicians, we propose the adoption of an evidence-based DOH measure (we refer readers to Table Group A.3 of Appendix 1 of the CY 2023 PFS proposed rule for the proposed measure information (87 FR 46460 and 46461) that would support identification of specific DOH associated with inadequate healthcare access and adverse health outcomes among patients. We noted that the measure would enable systematic collection of DOH data. This standardized measure would enable clinicians to systematically address DOH affecting individual patients; thereby, improving not only early identification of risk and/or need, but also prompt referral to relevant resources as well as stronger clinical-community linkages. Further, collecting DOH data could promote more focused collaboration between clinicians/health systems and appropriate community-based organizations to guide cross-sector resource allocation and ultimately improved patient outcomes.

The ''Screening for Social Drivers of Health'' measure assesses the percent of patients who are 18 years or older screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety. Under our Meaningful Measures Framework,[481] the measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close equity gaps and promote health equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [482] The development and proposal of this measure also aligns with the CMS strategic pillar to advance health equity by addressing the health disparities that underlie our health system [483] and the 5 CMS health equity priorities for reducing disparities in health: [484]

Priority 1: Expand the Collection, Reporting, and Analysis of Standardized Data.

- Priority 2: Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps.
- Priority 3: Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities.
- Priority 4: Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services.
- Priority 5: Increase All Forms of Accessibility to Health Care Services and Coverage.

We solicited public comment regarding the proposal to include and implement the ''Screening for Social Drivers of Health'' measure as part of the CY 2023 performance period MIPS quality measure inventory (87 FR 46279 and 46280). For a summary of the public comments received regarding the proposal, we refer readers to Table Groups A of Appendix 1 of this final rule. After consideration of public comments, and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46279 and 46280), we are finalizing the implementation of the ''Screening for Social Drivers of Health'' measure as proposed (we refer readers to Table Group A of Appendix 1 of this final rule for the discussion pertaining to this MIPS quality measure).

(d) MIPS Quality Performance Category Health Equity Request for Information

The CY 2023 PFS proposed rule contained a request for information pertaining to health equity within the quality performance category, which focused on aspects of the development and implementation of health equity measures (that is, solicited comment on measure concepts; and implementation challenges and barriers) for the quality performance category as we seek to enhance and increase the number of MIPS quality measures in future years that address and/or incorporate factors pertaining to health equity (87 FR 46280 through 46282).

We thank commenters for their responses regarding this request for information. We may consider the information provided by commenters to inform future rulemaking.

(e) Developing Quality Measures That Address Amputation Avoidance in Diabetic Patients Request for Information

The CY 2023 PFS proposed rule contained a request for information regarding the development of MIPS quality measures that address amputation avoidance in diabetic patients, which focused on the identification of measure concepts around this topic that would lead to improved patient outcomes, and proactive care in an attempt to avoid amputation (87 FR 46282 through 46283).

We thank commenters for their responses regarding this request for information. We may consider the information provided by commenters to inform future rulemaking.

(2) Cost Performance Category

(a) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through

doi:10.1377/hblog20210429.335599. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20210429.335599/*.

[480] American Hospital Association. (December, 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf*.

[481] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[482] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[483] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[484] Centers for Medicare & Medicaid Services, CMS Framework for Health Equity 2022–2032. Available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

59776, 84 FR 62959 through 62979, 85 FR 84877 through 84881, and 86 FR 65445 through 65461, respectively) for a description of the statutory basis for and existing policies pertaining to the cost performance category.

In the CY 2023 PFS proposed rule (87 FR 46283 and 46284), we proposed to update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group.

(b) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties. For more information about past revisions to the operational list, we refer readers to 84 FR 62968 through 62969 and 86 FR 65452 through 65453. The current operational list is available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*. Additionally, as required by section 1848(r)(2)(I) of the Act, information on resource use (or cost) measures currently in use in MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of engagement with interested parties, and the percent of expenditures under Medicare Parts A and B that are covered by cost measures must be provided on the website of CMS not later than December 31 of each year.

In prior rulemaking, we have included episode-based measures that focus on specific procedures and conditions in the operational list of care episode and patient condition groups and codes (84 FR 62968 through 62969 and 86 FR 65452 through 65453). Section 1848(r)(2)(D)(ii) of the Act specifies that in establishing the care episode groups, we must take into account the patient's clinical problems at the time items and services are furnished during an episode of care, such as the clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, and the principal procedures or services furnished, as well as other factors we determine appropriate. Section 1848(r)(2)(D)(iii) of the Act specifies that in establishing the patient condition groups, we must take into account the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period, such as 3 months), as well as other factors we determine appropriate. Currently, in the operational list there are 21 care episode groups, which served as the basis for the 15 procedural episode-based measures and the 6 acute inpatient medical episode-based measures that have been established for the cost performance category (83 FR 59767 through 59773, 84 FR 62962 through 62968, and 86 FR 65446 through 65453), and 2 patient condition groups, which served as the basis for the 2 chronic condition episode-based measures that have been established for the cost performance category (86 FR 65446 through 65453). Given that population-based measures, such as the MSPB Clinician and total per capita cost measures, focus on a broader range of patient care, CMS and interested parties have considered them to be distinct from episode-based measures. Therefore, we did not include these two population-based measures in the operational list after they were comprehensively re-evaluated in 2019 and revised for use in MIPS beginning with the CY 2020 performance period/CY 2022 MIPS payment year (84 FR 62974 through 62977). This distinction between episode-based measures and population-based measures also reflects development status as episode-based measures were developed specifically for use in MIPS, while the original versions of the MSPB Clinician and total per capita cost measures were first used in the Value Modifier (VM) program before being adapted for MIPS for the CY 2017 performance period/CY 2019 MIPS payment year (81 FR 77166 through 77168). For additional background on the population-based measures currently in use in MIPS please refer to 84 FR 62969 through 62977.

We proposed to add the MSPB Clinician measure to the operational list as a care episode group. Consistent with section 1848(r)(2)(D)(ii) of the Act, the MSPB Clinician measure takes into account the patient's clinical diagnoses at the time of an inpatient hospitalization and includes the costs of various items and services furnished during an episode of care. The MSPB Clinician measure is constructed using many aspects of the same logic as episode-based measures based on the care episode groups currently on the operational list. Both the MSPB Clinician and the episode-based measures are based on clearly-defined episodes and include the services that are clinically related to the clinician's role in the care being assessed. Further, the MSPB Clinician measure attributes episodes under medical Medicare Severity—Diagnosis Related Groups (MS–DRGs) to clinician groups billing at least 30 percent of evaluation and management (E/M) services during an inpatient stay, which is the same attribution logic as the one used for acute inpatient medical episode-based measures. Therefore, designating the MSPB Clinician measure as a care episode group alongside the episode-based measures would ensure that these similarities are reflected in the operational list. For more information on the MSPB Clinician measure, we referred readers to the CY 2020 PFS final rule (84 FR 62974 through 62977) and to the measure specification documents that are available on the QPP Resource Library at *https://qpp.cms.gov/about/resource-library*.

In the CY 2023 PFS proposed rule (87 FR 46284), we noted that at this time we did not propose to add the total per capita cost measure to the operational list as a care episode group or patient condition group. The measure is not constructed based on episodes of care; rather, it includes all costs after a primary care-type relationship has been identified. It also does not focus on specific patient conditions as it aims to include all patients where this clinician-patient relationship has been identified. More detailed information on the total per capita cost measure is included in

the measure specifications documents available at the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library*.

In the CY 2023 PFS proposed rule (87 FR 46284), we noted that we did not intend for the proposal to detract from the importance of episode-based measures or affect our plans to continue developing episode-based measures for potential use in MIPS. There are 7 episode-based measures under development and 4 anticipated episode-based measures to begin development this year. The operational list as revised to reflect the proposal is available on the MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*. We sought public comment on the proposal.

The following is a summary of the public comments received on the proposed revisions to the operational list of care episode and patient condition groups and codes and our responses:

Comment: Several commenters expressed support for the proposal to add the MSPB Clinician measure to the operational list as a care episode group, stating that they support any changes to cost measures that would improve meaningful and accurate measurement. A couple of commenters expressed concern that this proposal would create further complexity and administrative burden for clinicians, with one commenter suggesting that a delay in implementation of this proposal would allow clinicians to provide their feedback on the MSPB Clinician measure.

Response: The proposal was not intended to modify the MSPB Clinician measure itself or change the way in which the measure is attributed to clinicians. We do not believe the proposal would create any additional burden for clinicians or result in any additional complexities for the cost performance category or MIPS in general. We also note that the MSPB Clinician measure has been in use in the MIPS program since 2020 (84 FR 62974 through 62977), and underwent extensive testing and received considerable stakeholder input prior to its implementation in the program. Additionally, since the measure's implementation in the MIPS program, stakeholders have continued to have the opportunity to provide feedback on the measure via the QPP Help Desk for CMS's future consideration. Therefore, we believe that it is not necessary to delay the finalization of this proposal by a year to gather stakeholder feedback, as suggested by the commenter.

Comment: Several commenters expressed concern that designating the MSPB Clinician measure as a care episode group would detract CMS from developing new episode-based cost measures. A few commenters further urged CMS to continue developing new episode-based cost measures. One commenter expressed support for the Emergency Medicine episode-based cost measure that was recently developed, noting that there currently are limited MIPS cost measures for emergency physicians.

Response: The development of episode-based cost measures that focus on specific procedures and conditions continues to be one of the CMS's priorities for the cost performance category. Our proposal to add the MSPB Clinician measure to the operational list as a care episode group would have no impact on CMS's plans to continue developing episode-based cost measures for potential inclusion in the MIPS program in future years, as noted in the CY 2023 PFS proposed rule (87 FR 46284). Five episode-based measures (including Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related Conditions episode-based measures) were developed recently, and five additional episode-based measures (including Chronic Kidney Disease [CKD], End-Stage Renal Disease [ESRD], Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis episode-based measures) are currently under development. Please refer to the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*) for more detail on the episode-based measure development activities.

Comment: One commenter requested clarification as to whether the case minimum of the MSPB Clinician measure would change from 35 episodes to 20 episodes, if the proposal is finalized. The commenter did not note concerns about the proposal if the case minimum and measure construction remained the same, but expressed concerns that a lower case minimum would have impact on attribution. Another commenter requested clarification on whether the scoring for the cost performance category would change if the MSPB Clinician measure is added to the operational list as a care episode group. Finally, another commenter urged CMS to share the relevant data on the new MSPB Clinician measure with physicians and seek their feedback on that data and the measure itself prior to implementing the measure.

Response: We did not propose to modify the MSPB Clinician measure's specifications, including the previously established case minimum. Therefore, the measure's 35-episode case minimum that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77171) and codified under § 414.1350(c)(2) would not change. Additionally, this proposal would not have an impact on the scoring methodology for the cost performance category. We further note that given that the measure is calculated with administrative claims data and does not require data submission from clinicians, the measure does not result in any additional burden for clinicians.

Regarding the comment requesting data on the measure, prior to implementation, CMS gathered extensive feedback from clinicians and other stakeholders on the measure specifications and testing results through many different avenues, as described in the CY 2020 PFS final rule (84 FR 62974 through 62977). Since the measure implementation, clinicians have received data on the MSPB Clinician measure, described in the *2021 MIPS Performance Feedback Patient-Level Data Reports Supplement* document available for download at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2036/2021%20MIPS%20Performance%20Feedback%20Patient-Level%20Data%20Reports%20Supplement.pdf*.

After consideration of the public comments we received, we are finalizing our proposal to update the operational list of care episode and patient condition groups and codes by adding the MSPB Clinician cost measure as a care episode group as proposed.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886) and the CY 2022 PFS final rule (86 FR 65462 through 65466). We also refer readers to 42 CFR 414.1305 for the definitions of

improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We did not propose any changes to the traditional MIPS improvement activities policies for the CY 2023 performance period/2025 MIPS payment year. However, we proposed changes to the improvement activities Inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding four new improvement activities; modifying five existing improvement activities; and removing six previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had conducted numerous interviews with highly performing organizations of all sizes and had conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including the patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 71259) and the comments received in response to the MIPS and APMs RFI in relation to the improvement activities performance category, which sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

For the CY 2018 performance period/2020 MIPS payment year, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program CY 2018 performance period/2020 MIPS payment year and future years through subregulatory guidance.[485] In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for the CY 2019 performance period/2021 MIPS payment year and for future years, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the improvement activities Inventory. This process included the requirement to submit a nomination form similar to the one we utilized for CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity, the interested parties must submit a nomination form (OMB control # 0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix to the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 to the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 to the CY 2020 PFS final rule (84 FR 63514 through 63538), Tables A, B, and C in the Appendix 2 to the CY 2021 PFS final rule (85 FR 85370 through 85377), and Tables A, B, and C in the Appendix 2 to the CY 2022 PFS final rule (86 FR 65969 through 65997) for our previously finalized improvement activities Inventories. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

We proposed to add four new improvement activities, modify five existing improvement activities, and remove six previously adopted improvement activities for the CY 2023 performance period/MIPS payment year and future years. We refer readers to Appendix 2 of the CY 2023 PFS proposed rule (87 FR 46800 through 46812) for more details.

All the new improvement activities that we proposed are responsive to the Administration's goal of advancing health equity for all, as outlined in the President's January 20, 2021, Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (*https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*). Additionally, all the proposed new improvement activities address Priorities for Reducing Disparities in Health, as described in the CMS Framework for Health Equity (*https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*).

The first proposed new improvement activity, IA_AHE_XX titled ''Use Security Labeling Services Available in Certified Health Information Technology (IT) for Electronic Health Record (EHR) Data to Facilitate Data Segmentation'' would promote the adoption of technology certified to the Security tags—summary of care-send and Security tags—summary of care-receive criteria at 45 CFR 170.315(b)(7) and (b)(8) in the ONC Health IT Certification Program (87 FR 46285).[486] [487] ONC finalized updated versions of these criteria as part of the ONC 21st Century Cures Act Final Rule (85 FR 25702), which are available for certification by health IT developers. Security tagging allows sharing of certain portions of an EHR while not sharing others, such as sensitive information related to drivers of health. We referred readers to the 2015 Edition final rule (80 FR 62647) for further details. As proposed, the improvement

[485] CMS, *Annual Call for Measures and Activities: Fact Sheet, https://www.cms.gov/Medicare/Quality-IniCtiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf.*

[486] For more information see: *HealthIT.gov.* (2020). *§ .(b)() Security tags—summary of care-receive. https://www.healthit.gov/test-method/data-segmentation-privacy-receive#cures_ccg.*

[487] For more information see: *HealthIT.gov.* (2020). *§ .(b)() Security tags—summary of care-send. https://www.healthit.gov/test-method/data-segmentation-privacy-send#cures_ccg.*

activity would involve clinicians working with their EHR vendors to implement technology meeting the security tags criteria in practice systems and clinic workflows. We noted that we believe that implementing this technology would improve interoperability while protecting patient privacy, thus improving care delivery and patients' care experience (87 FR 46286).[488] We also noted that we believe this activity is likely to improve patient outcomes because protection of patient privacy and increased interoperability helps improve patient care delivery. As proposed, the improvement activity would address the CMS Framework for Health Equity Priority 1, Expand the Collection, Reporting, and Analysis of Standardized Data.[489]

The proposed new improvement activity IA_AHE_XX titled ''Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients'' supports both CMS Framework for Health Equity Priority 1 and Priority 3, Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities (87 FR 46286). Eligible clinicians would receive improvement activity credit for creating and implementing a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population, which may include analysis of sexual orientation and gender identity (SO/GI) data to identify and address disparities in care. Actions to implement this activity may include identifying target goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and ONC's United States Core Data for Interoperability [USCDI] as finalized at 45 CFR 170.213), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories. LGBTQ+ individuals face health disparities and challenges navigating and accessing healthcare.[490] [491] We refer readers to the ONC USCDI website at *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi* for further information. Due to lack of clinician training about providing culturally competent and sensitive care for LGBTQ+ individuals, several studies indicate that LGBTQ+ patients, especially gender minority patients, have high rates of negative healthcare experiences.[492] [493] [494] This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on improving care for LGBTQ+ patients. We believe this activity has the potential to improve clinical practice and care delivery because training clinicians about working with LGBTQ+ patients may lead to more positive care experiences and health outcomes (87 FR 46286).[495]

Another proposed new improvement activity, IA_EPA_XX titled ''Create and Implement a Language Access Plan'' directly responds to the CMS Framework for Health Equity Priority 4, Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services (87 FR 46286). This activity involves eligible clinicians' creating and implementing a language access plan to address communication barriers for individuals with limited English proficiency. The language access plans should align with standards for communication and language assistance defined in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. We believe that accurate patient-clinician communication, delivered and received in a culturally competent manner, is an essential aspect of improving equity in healthcare and patient outcomes (87 FR 46286).[496] [497] The proposed improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on language access. We noted that we believe the proposed improvement activity has the potential to improve clinical practice and care delivery and is likely to result in improved patient outcomes, because research indicates the importance of accurate clinical communication in achieving positive patient outcomes.[498]

The fourth proposed new improvement activity, IA_ERP_XX titled ''COVID–19 Vaccine Promotion for Practice Staff'' supports CMS Framework for Health Equity Priority 3. COVID–19 vaccination rates in the U.S. can be improved significantly, particularly in underserved communities (87 FR 46286).[499] Disparities in COVID–19 vaccination rates have been observed specifically among healthcare workers, with physicians and advanced practiced staff being more likely to be vaccinated than nurses and support staff. Also, it has been reported that Black and younger health care workers have lower vaccination rates than other groups of

[488] For information about the standards in the certification criteria as well as other standards supporting security tags, see: *HealthIT.gov*. Security tags for sensitive information. *https://www.healthit.gov/isa/security-tags-sensitive-information*.

[489] Centers for Medicare and Medicaid Services. (2022). *CMS framework for health equity. https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*.

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healthcare workers.[500] The proposed improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on COVID–19 vaccination. We noted that we believe this activity has the potential to improve clinical practice and is likely to result in improved outcomes and public health, as research indicates the importance of vaccination in reducing the severity and spread of COVID–19 (87 FR 46286 through 46287).[501]

We also proposed a number of modifications focused on combining activities where possible and other administrative changes (87 FR 46287). A particularly important proposed modification to an existing activity is focused on Priority 1 of the CMS Framework for Health Equity, Expand the Collection, Reporting, and Analysis of Standardized Data. We proposed to: (1) recategorize the IA_CC_14 improvement activity, currently titled ''Practice improvements that engage community resources to support patient health goals,'' from the Care Coordination subcategory to the Achieving Health Equity subcategory, and (2) re-name and re-focus the improvement activity on obtaining and acting on drivers of health data (87 FR 46287). More specifically, the proposed updated improvement activity with a new ID, IA_AHE_XX, would be titled ''Practice Improvements that Engage Community Resources to Address Drivers of Health.'' We proposed to modify this improvement activity description to include 'drivers of health' terminology, which better encompasses both 'social determinants of health (SDOH)' and 'health-related social needs (HSRN)' concepts (87 FR 46287). We also proposed to update the list of these factors in the description to reflect a more comprehensive array of drivers of health. The proposed modifications build on ongoing efforts to advance health equity in accordance with the Advance Equity Pillar of the CMS Strategic Plan (*https://www.cms.gov/cms-strategic-plan*). We noted that we believe the proposed modifications will better enable eligible clinicians to not only improve clinical practice by screening for and addressing drivers of health, but to also receive credit for their efforts (87 FR 46287). Furthermore, we anticipated such efforts will be associated with improved clinical outcomes because of the potential impact of social drivers of health and other upstream factors on both healthcare and health status.[502] [503] Finally, the proposed modifications would also more clearly align this activity with available evidence and other CMS work in this area, including the CMS Innovation Center's Accountable Health Communities (AHC) Model, designed to test how ''addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs.'' [504]

The following is a brief summary of the public comments received on the proposed revisions to the improvement activities Inventory:

Comments were generally supportive of the proposed revisions to the improvement activities Inventory. We received many comments that were particularly supportive of the proposals' focus and potential impact on advancing health equity. Feedback was received in support of each of the proposed new activities individually, with a very large number of commenters expressing appreciation for the proposed new activity, Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients. Commenters also supported the proposed new activity, Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data, with one stating that ''security labeling for this purpose is essential to the provision of equitable care.'' We received one comment regarding the proposed improvement activity titled ''COVID–19 Vaccine Achievement for Practice Staff'' that suggested we provide an exclusion for staff that have a medical contraindication to the vaccination and a comment that questioned the use of the phrase ''fully vaccinated.''

After consideration of the public comments, we are finalizing all proposals as proposed except for the following: for one proposed new activity, ''COVID–19 Vaccine Achievement for Practice Staff,'' we have made changes to the activity description in response to the public comments, as follows: Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100 percent of office staff in the MIPS eligible clinician's practice staying up-to-date with COVID–19 vaccinations in accordance with the Center for Disease Control and Prevention (*https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html*). Please note that those who are determined to have a medical contraindication specified by CDC recommendations are excluded from this activity. For one proposed activity modification, IA_PSPA_7, Use of QCDR data for ongoing practice assessment and improvements, we are finalizing as proposed with the exception of making one formatting change to the activity description, changing the 'or' to 'OR,' to make it clear that the requirements of the activity have not increased. We refer readers to Appendix 2 to this final rule for the public comments we received on our proposals and our detailed responses.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category). For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199–77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), and CY 2022 PFS final rule (86 FR 65466–65490).

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[504] Accountable Health Communities Model | CMS Innovation Center.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2021 PFS final rule at § 414.1320(g)(1) (85 FR 84886) (subsequently re-designated as § 414.1320(h)(1) (86 FR 65671)), for the 2024 MIPS payment year, and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the CY 2025 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2023, up to and including the full CY 2023 (January 1, 2023 through December 31, 2023). We did not propose any changes to the Promoting Interoperability performance category performance period that we established under § 414.1320(h)(1).

(c) CEHRT Requirements

The Promoting Interoperability Program and the QPP require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition.

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (also referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (also referred to as the 2015 Edition Cures Update) and introduced new 2015 Edition certification criteria. In connection with these updates, ONC also finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. In response to additional calls for flexibility in response to the public health emergency (PHE) for COVID–19, ONC published an interim final rule with comment period on November 4, 2020 entitled, ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule'') (85 FR 70064). In this interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023 for 45 CFR 170.315(b)(10), ''electronic health information ((EHI) export'').

In the CY 2021 PFS final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Promoting Interoperability Program or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022 date established in the ONC interim final rule for health IT developers to make updated certified health IT available. After this date, health care providers will be required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023. We did not propose any changes to this final policy.

We remind readers that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the EHR reporting period and performance period established for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected EHR reporting period or performance period of a minimum of any consecutive 90 days in CY 2023, including the final 90 days of 2023 (86 FR 45460 through 45462 and 86 FR 65466, respectively). The eligible hospital, CAH, or MIPS eligible clinician is not required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the EHR reporting period or performance period they have selected.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

i. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

(A) Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 performance period/CY 2023 MIPS payment year. In the CY 2022 PFS final rule (86 FR 65466 through 65467), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2022 performance period/ 2024 MIPS payment year.

(B) State PDMPs' Progress and Previous Interested Parties' Feedback

In the CY 2020, CY 2021, and CY 2022 PFS final rules (84 FR 62992 through 62994, 85 FR 84887 through 84888 and 86 FR 65467), we described the concerns expressed by interested parties that they believed it was premature for the Promoting Interoperability performance category to require the Query of PDMP measure and score it based on performance. In the CY 2022 PFS proposed rule (86 FR 39410) we discussed our support of efforts to expand the use of PDMPs, describing Federally supported activities aimed at developing a more robust and standardized approach to EHR–PDMP integration, and additional discussions on the feedback we have received from health IT vendors and MIPS eligible clinicians thus far. For more detailed information, we refer readers to the CY 2022 PFS proposed rule (86 FR 39410).

We heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These interested parties stated that EHR

developers may face significant cost burdens if they fully develop numerator and denominator calculations and are then required to change the specification at a later date. Interested parties have stated that the costs of additional development would likely be passed on to health care providers without additional benefit, as this development would be solely for the purpose of calculating the measure, rather than furthering the clinical goal of the measure. While we recognize that a numerator/denominator-based measure remains challenging, we also note (as discussed in more detail later in this section) that the widespread availability of PDMPs across the country, and recent progress toward solutions for connecting PDMPs with health care provider EHR systems, has made use of PDMPs feasible through a wide variety of approaches.

(C) Current Status of PDMP Adoption

Today, all 50 States and several localities host PDMPs.[505] The final State to establish a PDMP, the State of Missouri, passed legislation to address this issue in 2021, and is currently working to make its PDMP operational. A 2021 American Medical Association report found that physicians and others used State PDMPs more than 910 million times in 2020.[506] An assessment of PDMPs conducted by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research (IIR) found an increase in the number of PDMPs that are integrated with Health Information Exchanges (HIEs), EHRs, and/or Pharmacy Dispensing Systems (PDSs), with 44 PDMPs integrated in 2021 reflecting an increase from 28 PDMPs with at least one type of integration in 2017. We refer readers to Table 90 for the report's findings on the type of integration and the number of PDMPs that have implemented that type of integration in 2021.

TABLE 90: PDMP Integration – Type and Number of PDMPs*

Type of Integration	# of PDMPs
EHR and PDS	35
HIE and EHR	20
HIE, EHR, and PDS	18
EHR only	5
HIE only	1
PDS only	1

* PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.

Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a free, Federally supported interstate exchange hub for PDMP data. RxCheck is connected to 50 out of 54 PDMPs in states and territories and does not require clinicians to pay to have the PDMP data integrated into the EHR.

The goal of the project is to allow any health care provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual State PDMPs that are also live on RxCheck. This solution enables health care providers to query PDMPs via existing connections to health information exchange networks. Most States use either RxCheck or Prescription Monitoring Program (PMP) InterConnect or both to facilitate the sharing of PDMP information between States, allowing health care providers to query other States' PDMP information from within their own State PDMP.[507]

We also note that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, has focused on ways to address the nation's opioid epidemic. The SUPPORT for Patients and Communities Act included new requirements for PDMP enhancement and integration, to help reduce opioid misuse and overprescribing and promote the effective prevention and treatment of opioid use disorder beginning in October of 2021. Enhanced Federal matching funds were available to States to support related PDMP design, development, and implementation activities during FYs 2019 and 2020.

(D) Changes to the Query of PDMP Measure and Related Policies

(aa) Change to the Query of PDMP Measure Description

The description of the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. In the CY 2023 PFS proposed rule (87 FR 46289), beginning with the performance period in CY 2023, we proposed to require the Query of PDMP measure for MIPS eligible clinicians participating in the Promoting Interoperability performance category. In the CY 2023 PFS proposed rule (87 FR 46291 through 46292), we noted that should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we proposed

[505] Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

[506] American Medical Association, 2021 Overdose Epidemic Report, *https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf.*

[507] GAO–21–22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs.

two exclusions beginning with the performance period in CY 2023: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

We noted in the CY 2023 PFS proposed rule (87 FR 46289) that should we finalize the proposals to require the Query of PDMP measure and the associated exclusions, we believe the inclusion of the phrase ''except where prohibited and in accordance with applicable law'' in the description of the Query of PDMP measure and in the language of the exclusion would be duplicative and potentially cause confusion. Therefore, we proposed to remove the phrase ''except where prohibited in accordance with applicable law'' from the measure description should our proposals to require the Query of PDMP measure and the associated exclusions be finalized. In the CY 2023 PFS proposed rule (87 FR 46289), we referred readers to our proposed measure description that would reflect this proposed change and additional proposed policy changes for the Query of PDMP measure.

We invited comment on this proposal, but we did not receive any comments.

(ab) Requiring the Query of PDMP Measure

In the CY 2022 PFS final rule (86 FR 65466 through 65467), we noted that the decision to maintain the Query of PDMP as an optional measure for CY 2022 considered the current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act, our ongoing review of alternative measure approaches, and concerns from interested parties about the current readiness across States for implementation of the existing measure. We also noted that this measure can play an important role in helping health care providers to improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions (86 FR 65467); maintaining it as an optional measure with bonus points signals to the clinician and vendor community that this is an important measure which can help spur development and innovation to reduce barriers and challenges (86 FR 65467).

We continue to believe that PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking dispensed controlled substances and improving prescribing practices. Efforts to expand the use of PDMPs and integrate PDMPs with health information technology systems are supported by Federal interested parties including ONC, the Centers for Disease Control and Prevention (CDC), the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Query of PDMP measure offers a way to reward health care providers who participate in current PDMP initiatives, including those supported by Federal partners.

While work continues to improve standardized approaches to PDMP and EHR interoperability, we believe that it is feasible at this time to require MIPS eligible clinicians to report the current Query of PDMP measure, which requires reporting a ''yes/no'' response. Given our policies for the Query of PDMP measure that included increasing the eligible bonus points to reward MIPS eligible clinicians that could report the measure, as well as the recent progress in the availability of PDMPs in all 50 States, and solutions which support accessibility of PDMPs to health care providers, we believe MIPS eligible clinicians have had time to grow familiar with what this measure requires of them, even as technical approaches to the use of PDMPs continue to advance. By requiring a ''yes/no'' response the measure allows MIPS eligible clinicians to use a variety of technical solutions to conduct a query of the PDMP and receive credit for the measure.

Therefore, beginning with the performance period in CY 2023, we proposed to require MIPS eligible clinicians to report the Query of PDMP measure (which requires reporting a ''yes/no'' response) for the Promoting Interoperability performance category (87 FR 46289). We noted that we would maintain the associated points at 10 points and referred readers to the CY 2023 PFS proposed rule (87 FR 46298 through 46307) and section IV.A.6.c.(4)(d)(i) of this final rule for further discussion of our scoring methodology and concurrent finalized changes. As a result of the proposal, the maximum total points available for the Electronic Prescribing Objective would remain at 20 points for CY 2023.

We solicited public comment on this proposal, and also sought feedback on ways CMS can ensure coordination and alignment with varying State requirements for PDMPs. Additionally, we invited public comment on what information returned from the PDMP query would be clinically significant. The following is a summary of the comments received.

Comment: Several commenters supported our proposal to require the Query of PDMP measure. One commenter thanked CMS for keeping the measure optional until the ecosystem was developed enough to allow widespread use, without adding additional technical burdens. A few commenters supported this proposal stating that this policy will help address and combat the opioid epidemic, and bring awareness to prescribers.

Response: We agree that after several years as an optional measure, and given the more widespread use and availability of PDMPs, requiring the Query of PDMP measure is viable at this time. We also appreciate that commenters continue to recognize our efforts towards combatting the opioid epidemic.

Comment: Several commenters did not support our proposal to require the Query of PDMP measure. A few commenters stated that our proposal would be administratively burdensome, as well as costly for those MIPS eligible clinicians facing various challenges with EHR–PDMP integration. Other commenters stated that this requirement would be challenging for those MIPS eligible clinicians who lack an integrated PDMP, or for those whose EHR technology remains under development. Another commenter expressed that without standards across state lines, there is wide variation with PDMP implementation and the integration with CEHRT. Some commenters stated that many States and clinicians are continuing to make enhancements to their EHRs, to include RxCheck functionality, and asked that CMS postpone requiring the measure one additional year to further advance and integrate their EHR technology. Another commenter stated that many MIPS eligible clinicians are incapable of interconnecting their EHR with a PDMP, making this measure impossible to complete, especially in a State where such integrated functionality is not practical or possible.

Response: We appreciate the concerns raised by the commenters. We agree with the commenters that not all MIPS eligible clinicians have a fully operational statewide PDMP or a fully integrated EHR–PDMP. We recognize that without full integration, it is possible that the actions required to

satisfy the Query of PDMP measure could be time-consuming for clinicians and potentially cause clinical disruption. For these reasons, we are adopting an additional exclusion for the Query of PDMP that will be available only for the CY 2023 performance period/2025 MIPS payment year. As stated in section IV.A.6.c.(4)(d)(iii) of this final rule, the exclusion allows any MIPS eligible clinician for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023, to exclude the Query of PDMP measure. We expect that this time-limited exclusion will allow MIPS eligible clinicians time to resolve any remaining barriers to reporting the measure.

Comment: Several commenters did not support our proposal, stating that there is limited evidence supporting the overall relationship between querying a PDMP and a reduction in opioid-related consequences. One commenter stated that despite the rise in usage and availability of PDMPs, the overall drug-related mortality rates are also rising, leading to an inverse relationship between the measure and the intended outcome.

Response: We recognize that the Query of PDMP measure by itself will not resolve the opioid epidemic, but we believe the measure is an important step for MIPS eligible clinicians to gain additional awareness when prescribing Schedule II opioids, and Schedule III and IV drugs to their patients. It will give prescribing clinicians insight into the broader clinical picture and prescribing history of their patient, and ultimately, improve the safety and quality of care.

Comment: One commenter expressed concern that patients may suffer harm as the proposal would place undue administrative burden on MIPS eligible clinicians having to query a PDMP for patients based on medications prescribed, taking away from clinical time. Another commenter stated that the proposed policy could have unintended consequences, as patients requiring the use of opioids would be further stigmatized, leaving them less likely to receive the care they need, and ultimately, denial of care and patient mistreatment.

Response: We reiterate that the Query of PDMP measure requires a minimum of one query of a PDMP during the 90-day performance period selected by the clinician. Additionally, our goal is not to alter clinical standards, deviate from clinically appropriate prescribing practices, nor replace clinical time with administrative responsibilities. Rather, we believe that requiring the measure is one step towards increasing overall awareness when prescribing Schedule II opioids and Schedule III and IV drugs. We do not believe that the act of querying a PDMP should have unintended consequences on the patient, or result in the denial of clinically appropriate care or the mistreatment of patients. Instead, we believe that this measure may aid prescribing clinicians in early identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. We view this measure as an important step in ensuring safe prescribing practices, and potentially avoiding unintended consequences from overprescribing.

(ii) Changes to the Query of PDMP Measure To Include Schedules II, III and IV

The Query of PDMP measure was adopted in the CY 2019 PFS final rule (83 FR 59800 through 59803) as one of two measures under the Electronic Prescribing Objective intended to support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers, and focusing on the advanced use of CEHRT. The measure description for the Query of PDMP measure is as follows: for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law (83 FR 59800 through 59803).

Under the Controlled Substances Act (CSA),[508] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential. We refer readers to Table 91 for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*[509]

[508] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq.*

[509] See also *https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf.*

TABLE 91: Controlled Substance Schedules, Descriptions, and Examples*

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, Demerol, OxyContin, Percocet, morphine, codeine, and amphetamine
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Tylenol with Codeine and anabolic steroids
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Xanax, Klonopin, Valium, and Ativan
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Cough syrups containing codeine

* GAO-21-22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. section 812, and the U.S. Drug Enforcement Administration.

PDMPs are operated at the State level and individual State requirements for reporting and use differ from State to State.[510] Currently, every State collects data on schedules II, III, and IV.[511] Some States collect information about certain non-controlled substances that are potentially subject to abuse or on all prescription drugs.[512] While State laws vary, we note that most State PDMPs require physicians and dispensing pharmacists to review a patient's prescribing information for the past 12 months prior to prescribing or dispensing any Schedule II, III, and IV controlled substances.[513]

PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. As stated in the CY 2023 proposed rule (87 FR 46290), we believe that expanding the requirements of the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids will further support HHS initiatives related to the treatment of opioid and substance use disorders by expanding the types of drugs included in the Query of PDMP measure while aligning with the PDMP requirements in a majority of States. We also stated that we believe this expansion to include additional Scheduled drugs would facilitate more informed prescribing practices and improve patient outcomes. Therefore, beginning with the performance period in CY 2023, we proposed to expand the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids (87 FR 46290 through 46291).

Proposed Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with policy for the Query of PDMP measure with regard to Schedule II opioids, we proposed that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug (87 FR 46290 and 46291). We also noted that this measure would include all permissible prescriptions and dispensing of Schedule II opioids and Schedule III or IV drugs, no matter the dosage prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities. We also noted that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date, by the same MIPS eligible clinician would not require multiple queries of the PDMP and only one query would have to be performed for this measure. MIPS eligible clinicians would have flexibility to query the PDMP using data from CEHRT in any manner allowed under State law.

We invited public comment on these proposals, and the following is a summary of the comments received.

Comment: Several commenters supported our proposal to include Schedule III and IV drugs in addition to Schedule II opioids in the Query of PDMP measure. Some commenters stated that including Schedule III and IV drugs would balance PDMP engagement with minimizing compliance burden. One commenter stated that limiting the Query of PDMP to Schedule II opioids alone causes additional burden on the MIPS eligible clinician as they would need to focus on one class of drugs versus several, and therefore, this proposal would reduce overall clinician burden. One commenter stated that our proposal to include Schedule III and IV drugs would reduce organizational and developer burden by minimizing the need to build specialty logic reports into their existing EHRs.

Response: We agree that the proposal to include Schedule III and IV drugs in addition to Schedule II opioids should reduce burden by eliminating the need

[510] For additional information, we refer readers to *https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf*; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605194/*; and *https://www.pdmpassist.org/Policies/Legislative/StatutesAndRegulations*.

[511] *https://www.pdmpassist.org/State*.

[512] GAO report, GAO–21–22 Prescription Drug Monitoring Programs.

[513] *https://www.pdmpassist.org/State*.

to limit the query to only Schedule II opioids.

Comment: One commenter asked that CMS provide additional detail regarding which specific drugs would be included in the Query of PDMP measure.

Response: We refer readers to Table 83: Controlled Substance Schedule, Descriptions, and Examples in the CY 2023 PFS proposed rule (87 FR 46291), and in Table 91 where we outline the schedule drug classes, along with examples of drugs specific to that schedule (in other words, the schedule is inclusive of, but not limited to, those drugs). Clinicians should be able to determine which specific drugs would be included in the measure by referencing the schedules.

Comment: A few commenters did not support our proposal to include Schedule III and IV drugs in the Query of PDMP measure. A few commenters stated their concerns about simultaneously proposing to both require and expand this measure, amidst clinical best practices continuing to be developed with PDMPs in general. One commenter stated that implementing additional proposals such as this may prove costly and burdensome. One commenter did not support our proposal, stating that including Schedules III and IV drugs would not be clinically appropriate, nor would their inclusion achieve CMS's goal of addressing the opioid epidemic.

Response: We do not agree that expanding the scope of which scheduled drugs are included in the Query of PDMP measure would lead to additional burden. We believe that expanding the scope would reduce burden because MIPS eligible clinicians would query additional drug options instead of focusing their time and effort on querying one class of drugs, which would minimize the need to create specialty reports within their EHR specific to capturing one class of drugs We appreciate and understand the comment regarding continued challenges some MIPS eligible clinicians face with EHR–PDMP integration. For the reasons discussed in our response to comments in section IV.A.6.c.(4)(d)(iii), we are adopting an additional exclusion for the Query of PDMP measure that will allow any MIPS eligible clinician for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023 to exclude the Query of PDMP measure for the CY 2023 performance period/2025 MIPS payment year.

(iii) Exclusions

In CY 2019 PFS proposed rule, we proposed an exclusion for MIPS eligible clinicians from reporting the Query of PDMP measure beginning with CY 2020 when the measure would have been required by the Promoting Interoperability performance category (83 FR 35922 through 35923). The proposed exclusion was: Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. In the CY 2019 PFS final rule, we finalized the Query of PDMP measure as optional for CY 2019, and thus we did not finalize the proposed exclusion (83 FR 59803). We also stated that we would propose policy for CY 2020 in future rulemaking. To date, we have not adopted any exclusions for this measure because it has remained optional for CY 2020 (84 FR 62992 through 62994), CY 2021 (85 FR 84887 through 84888), and CY 2022 (86 FR 65466 through 65467).

In the CY 2023 PFS proposed rule (87 FR 46289 through 46290), we proposed to require MIPS eligible clinicians to report the Query of PDMP measure for the Promoting Interoperability performance category beginning with the performance period in CY 2023. We noted in the proposed rule that should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we believe that an exclusion for the measure would be needed for MIPS eligible clinicians (87 FR 46291 and 46292). Therefore, we stated that we have revisited the exclusion we proposed in the CY 2019 PFS proposed rule (83 FR 35922 through 35923) and proposed a modified version in the CY 2023 PFS proposed rule (87 FR 46291 and 46292). Specifically, we noted that if we were to finalize the proposal to require the Query of PDMP measure, we proposed the following exclusion beginning with the performance period in CY 2023: Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period. In addition, we noted that if we finalize the proposal to require the Query of PDMP measure, we proposed a second exclusion beginning with the performance period in CY 2023: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. We adopted this same exclusion previously for the e-Prescribing measure (82 FR 53679). We believe this exclusion is also applicable to the Query of PDMP measure based on similar feedback we received from prior rulemaking, where fewer than 100 encounters were supported as an appropriate cutoff number (82 FR 53680). We also proposed that if a MIPS eligible clinician claims an exclusion for the Query of PDMP measure, we would redistribute the points associated with the Query of PDMP measure to the e-Prescribing measure under the Electronic Prescribing objective (87 FR 46292).

We invited public comment on these proposals, and the following is a summary of the comments received.

Comment: Some commenters supported our proposed exclusions for the Query of PDMP measure. One commenter stated that the proposed exclusions reasonably balance the need to prevent inappropriate prescribing against potential cost and administrative burdens.

Response: We thank the commenters for their support.

Comment: Some commenters supported our proposed exclusions for the Query of PDMP measure, but urged CMS to consider adding an additional exclusion for those MIPS eligible clinicians who do not have an integrated EHR–PDMP, who are unable to meet the requirements, or who are in the process of advancing their technology. Two commenters asked that CMS consider adopting an exclusion for patients receiving opioids for chronic conditions, chronic treatment plans, long-established illnesses, and certain medical diagnoses. One commenter asked that CMS consider adopting an exclusion that allows the MIPS eligible clinician to decide which patients should trigger a query of the PDMP based on the clinician-patient relationship.

Response: We thank the commenters for their feedback. While the Query of PDMP measure requires at least one query of a PDMP, it does not require that MIPS eligible clinicians query the PDMP for all patients, nor are there specifications indicating which disease process or patient type to query. Therefore, we do not agree that we should include a disease, condition, or patient-specific exclusion. As we discussed in our response to comments in section IV.A.6.c.(4)(d)(i) above, we are adopting an additional exclusion for the Query of PDMP measure that will allow any MIPS eligible clinician for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023 to exclude the Query of PDMP measure for the CY 2023 performance period/2025 MIPS payment year.

After consideration of the public comments, we are finalizing our proposal to require MIPS eligible clinicians to report the Query of PDMP measure (which requires reporting a ''yes/no'' response) for the Promoting Interoperability performance category, beginning with the CY 2023 performance period. The measure will be worth 10 points, but they will no longer be bonus points because the measure will be required. We are finalizing our proposal to remove the phrase ''except where prohibited in accordance with applicable law'' from the measure description. We are finalizing our proposal to expand the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids. As such, the new measure description will read:

Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with policy for the Query of PDMP measure with regard to Schedule II opioids, we are finalizing that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug. This measure includes all permissible prescriptions and dispensing of Schedule II opioids and Schedule III or IV drugs, no matter the dosage prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities. We are finalizing that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date, by the same MIPS eligible clinician do not require multiple queries of the PDMP and only one query needs to be performed for this measure. MIPS eligible clinicians have flexibility to query the PDMP using data from CEHRT in any manner allowed under State law.

We also are finalizing our proposal to include the following two exclusions for the Query of PDMP measure: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. After consideration of the comments we have received, we are finalizing a third exclusion for the Query of PDMP measure: (3) Any MIPS eligible clinician for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023. Exclusion (3) is available only for the CY 2023 performance period/2025 MIPS payment year. If a MIPS eligible clinician claims an exclusion for the Query of PDMP measure, we would redistribute the points associated with the Query of PDMP measure to the e-Prescribing measure under the Electronic Prescribing objective.

(e) Health Information Exchange (HIE) Objective: Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

(i) Background on the Health Information Exchange Objective

The Health Information Exchange (HIE) objective and its associated measures for MIPS eligible clinicians hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. The Health Information Exchange objective currently includes three measures: Support Electronic Referral Loops by Sending Health Information; Support Electronic Referral Loops by Receiving and Reconciling Health Information; and Health Information Exchange Bi-Directional Exchange. For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59807 through 59812) and the CY 2021 PFS final rule (85 FR 84888 through 84893).

In the CY 2021 PFS final rule (85 FR 84888 through 84893), we finalized the HIE Bi-Directional Exchange measure, under the Health Information Exchange objective. The HIE Bi-Directional Exchange measure is worth 40 points, the maximum number of points of the Health Information Exchange objective, and was finalized as an alternative to reporting on the two existing Health Information Exchange objective measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. To meet the measure requirements, MIPS eligible clinicians must attest to the following statements:

- Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy;
- Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners; and
- Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.

We stated that by enabling bi-directional exchange of information between health care providers and aggregating data across health care providers with disparate systems, HIEs (including a wide range of organizations facilitating health information exchange) can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings (CY 2021 PFS proposed rule, 85 FR 50300). We further described how participation in HIEs can amplify health care providers' capacity to share information beyond what a health care provider can achieve through the sending and receiving actions described in the existing measures under the Health Information Exchange objective, for instance, by facilitating information exchange when a health care provider is unaware of another health care provider's need to receive information about a patient (CY 2021 PFS proposed rule, 85 FR 50300). By finalizing this measure for MIPS eligible clinicians, we sought to ensure that health care providers participating in the Promoting Interoperability performance category would be rewarded for connecting to exchange arrangements that can enable this type of robust information sharing.

(ii) Background on TEFCA

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted

Exchange Framework and Common Agreement, or TEFCA. ONC's goals for TEFCA are: [514]

- Goal 1: Establish a universal policy and technical floor for nationwide interoperability;
- Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and
- Goal 3: Enable individuals to gather their health care information.

Since we adopted the HIE Bi-Directional Exchange measure, important additional developments have occurred with respect to TEFCA.[515] On January 18, 2022. ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [516] and Common Agreement Version 1.[517] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as the Common Agreement) is a contract that advances those principles. The Common Agreement and the Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF),[518] which is incorporated by reference in the Common Agreement, establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other—all under commonly agreed-to terms. The Common Agreement is a legal contract that QHINs[519] can sign with the ONC Recognized Coordinating Entity (RCE),[520] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) [521] Providers.[522] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[523] Compared to most nationwide exchange today, the Common Agreement also includes an expanded set of Exchange Purposes [524] beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination—all built upon common technical and policy requirements and to meet key needs of the U.S. health care system. This flexible structure allows interested parties to participate in the way that makes the most sense for them, while also supporting simplified, seamless exchange.

The QTF,[525] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN)[526] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable information exchange modalities, including querying and message delivery across participating entities.

In general, the information to be exchanged within the TEFCA ecosystem allows for the use of Health Level Seven (HL7®) Implementation Guide for Clinical Document Architecture (CDA®) Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 (C–CDA 2.1) document format, including data defined as part of U.S. Core Data for Interoperability (USCDI), with allowance for flexibility to further expand the content to support a multitude of use cases.[527] The Common Agreement and the QTF do not require HL7® Fast Healthcare Interoperability Resource (FHIR®) based exchange. TEFCA allows for the optional exchange of FHIR content using more traditional, established standards to enable the transport of that content. However, TEFCA can nonetheless be a strong catalyst for network enablement of FHIR maturation. To that end, the RCE released a 3-year FHIR Roadmap for TEFCA Exchange, which lays out a

[514] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch*.

[515] For more information on current developments related to TEFCA, we refer readers to *www.HealthIT.gov/TEFCA*.

[516] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf*.

[517] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[518] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf*.

[519] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-*.

[520] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage interested parties to create a roadmap for expanding interoperability over time.

[521] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[522] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[523] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[524] Exchange Purpose(s): means the reason, as authorized by [the] Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of [the] Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose. *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 *(Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[525] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf*.

[526] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[527] User's Guide to the Trusted Exchange Framework and Common Agreement—TEFCA (Jan 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-Users-Guide.pdf*.

deliberate strategy to add FHIR-based exchange under TEFCA in the near future.[528]

(iii) Enabling Exchange Under TEFCA Measure

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects interested parties across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such interested parties would be: (1) signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement[529] under the Common Agreement); (2) in good standing (that is, not suspended) under that agreement; and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient access to more health information. The Common Agreement requires strong privacy and security protections for all entities who elect to participate, including entities not covered by the Health Insurance Portability and Accountability Act (HIPAA).[530]

By connecting to a network that connects to a QHIN or directly to a QHIN, a MIPS eligible clinician can share health information in the same manner as described in the attestation statements previously finalized for the HIE Bi-Directional Exchange measure in the CY 2021 PFS final rule 85 FR 84888 through 84893). By connecting to an entity that connects to a QHIN, or connecting directly to a QHIN, that supports sharing information on patients as part of a Framework Agreement[531], a MIPS eligible clinician would be thereby enabling bi-directional exchange with other health care providers as described in Statement 1 of the HIE Bi-Directional Exchange measure. Since participation in a Framework Agreement as a QHIN, Participant, or Sub-participant will be open to all qualifying entities and will not be restricted by use of a single vendor, a connection via a Framework Agreement would also satisfy the requirements of Statement 2 of the HIE Bi-Directional Exchange measure. Finally, as discussed above, the technical requirements for exchanging information by entities through the Common Agreement and Framework Agreements utilize standards included in certified technology referenced under the CEHRT definition (see 42 CFR 414.1305), including the ability to exchange and receive data using the C–CDA standard (see certification criteria at 45 CFR 170.315(b)(1) and (b)(2)), thus health care providers participating in a Framework Agreement can use the functions of CEHRT to support bi-directional exchange with an HIE.

To offer health care providers more opportunities to earn credit for the Health Information Exchange objective, and given the alignment between enabling exchange under TEFCA and the existing HIE Bi-Directional Exchange measure, in the CY 2023 PFS Proposed rule, we proposed to add an additional measure through which a MIPS eligible clinician could earn credit for the Health Information Exchange objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we proposed to add the following new measure to the Health Information Exchange objective beginning with the performance period in CY 2023: Enabling Exchange Under TEFCA measure (87 FR 46292 through 46295). We proposed MIPS eligible clinicians would have three reporting options for the Health Information Exchange objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable); (2) report on the HIE Bi-Directional Exchange measure; or (3) report on the proposed Enabling Exchange Under TEFCA measure.

We proposed the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange objective. Under the current scoring methodology finalized in the CY 2021 PFS final rule, the Health Information Exchange objective is worth a total of 40 points (85 FR 84894). We noted in CY 2023 PFS proposed rule (87 FR 46298 through 46307), the proposed changes to the scoring methodology beginning with the performance period in CY 2023 such that the Health Information Exchange objective would be worth no more than 30 points. Therefore, under the proposal, the proposed Enabling Exchange Under TEFCA measure would be worth 30 points. We proposed this change to the scoring methodology as a result of our proposal in the CY 2023 PFS proposed rule (87 FR 46289 through 46290) to make the Query of PDMP measure required and worth 10 points. However, should we not finalize the Query of PDMP measure proposal, we proposed the Enabling Exchange Under TEFCA measure would be worth 40 points (the current total point value of the Health Information Exchange objective). In no case could more than 40 points, total, be earned for the Health Information Exchange objective.

We noted that we believe the new measure for Enabling Exchange Under TEFCA that we proposed in the CY 2023 PFS proposed rule (87 FR 46292 through 46295) would incentivize MIPS eligible clinicians to exchange information by connecting directly or indirectly to a QHIN and support health information exchange at a national level. We also noted that we believe that fulfillment of this measure is an extremely high value action. The overall TEFCA goal of establishing a universal floor of interoperability across the country aligns with our commitment to promoting and prioritizing interoperability and exchange of healthcare data. Incentivizing health care providers to enable exchange under TEFCA is a critical component to advancing healthcare data exchange nationwide. We proposed a MIPS eligible clinician would report the Enabling Exchange Under TEFCA measure by attestation, and the measure would require a ''yes/no'' response. A ''yes'' response would enable a MIPS eligible clinician to earn the proposed 30 points allotted to the Health Information Exchange objective. We proposed that a MIPS eligible clinician would attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is

[528] FHIR® Roadmap for TEFCA Exchange Version 1 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf*.

[529] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[530] Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-*

[531] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy; and

- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Similar to the HIE Bi-Directional Exchange measure, to successfully attest to this measure, we stated that a MIPS eligible clinician must use the capabilities of CEHRT to support bi-directional exchange under a Framework Agreement, which includes capabilities that support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the other measures under the Health Information Exchange objective, which point to the use of CEHRT to support the exchange of the clinical data within the CCDS or the USCDI.

We noted in the CY 2023 PFS proposed rule (87 FR 46292 through 46295) that we believe there are numerous certified health IT capabilities that can support bi-directional exchange under a Framework Agreement. For instance, participants may exchange information under a Framework Agreement by using technology certified to the criterion at 45 CFR 170.315(b)(1), ''Care coordination—Transitions of care,'' to transmit C–CDAs across a network. Where supported, participants could also utilize API technology certified to either the criterion at 45 CFR 170.315(g)(8), ''Design and performance—Application access—data category request,'' or (g)(10), ''Design and performance—Standardized API for patient and population services,'' as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable exchange of data in the CCDS or USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information under a Framework Agreement for transitions of care, including modules certified to certification criteria at 45 CFR 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at 45 CFR 170.315(e)(1), ''Patient engagement—View, download, and transmit to 3rd party,'' which supports patient access to their information; and the certification criterion at 45 CFR 170.315(g)(6), ''Design and performance—Consolidated CDA creation performance,'' which supports creation of a summary of care record. We recognized that entities that will connect directly or indirectly to a QHIN are currently interacting with health care providers using certified health IT in a variety of ways, and, as with the Bi-Directional HIE Exchange measure, noted that we believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data under a Framework Agreement.

The Enabling Exchange Under TEFCA measure could offer health care providers an alternative to earn credit for the Health Information Exchange objective. The Enabling Exchange Under TEFCA measure would not require a MIPS eligible clinician to assess whether they participate in a health information exchange that meets the attributes of attestation Statement 2 under the HIE Bi-Directional Exchange measure regarding exchange across a broad network of unaffiliated exchange partners including those using disparate EHRs. These attributes are key to the goals of TEFCA, which aims to offer health care providers a uniform set of expectations around information sharing regardless of which network for information exchange they participate in.

We invited public comment on these proposals, and the following is a summary of the comments received:

Comment: Many commenters supported our proposal to add the Enabling Exchange Under TEFCA measure under the Health Information Exchange objective. Several commenters stated that this measure is an important step towards fostering interoperability and nationwide data exchange, aiding to fill information gaps, and to reduce burdens placed on MIPS eligible clinicians. Many commenters supported our proposal sharing that they applaud CMS' efforts to improve information exchange, engage in efforts toward implementation, and prioritize a commitment to advancing healthcare data exchange nationwide. Several commenters supported our proposal stating that this measure will minimize costly and unnecessary administrative burdens on MIPS eligible clinicians and their care teams. Another commenter stated that this measure will build alignment across vendors, allowing interoperable data exchange across the healthcare continuum. One commenter stated their appreciation for a measure that applies to MIPS eligible clinicians as opposed to capabilities and capacities of their chosen vendor. Some commenters supported our proposal stating that this measure will lend itself to a seamless and coordinated approach to improving care for patients, allowing for a more accurate exchange of health information. A few commenters supported our proposal, emphasizing their appreciation for offering this as an additional option requiring a yes/no response, versus a measure utilizing a numerator-denominator approach.

Response: We thank commenters for their feedback and agree that our proposal to add the Enabling Exchange Under TEFCA measure is an important step towards our efforts to improve the exchange of health information, promote interoperability, and offer options that best serve MIPS eligible clinicians individually. We believe the addition of this third measure option will aid in reducing administrative burden on MIPS eligible clinicians by offering an additional option that may work best with their chosen approach to information exchange. We appreciate that commenters support our commitment to advancing healthcare data exchange. Enabling the exchange of health information across the continuum is fundamental to the Promoting Interoperability performance category, so we appreciate that commenters recognize and support these efforts.

Comment: Some commenters did not support our proposal to add the Enabling Exchange Under TEFCA measure under the Health Information Exchange objective. One commenter stated that some networks do not yet facilitate the live exchange of production data, therefore CMS should consider postponing this measure as an option, so as not to place additional burden on EHR vendor support staff. Another commenter stated concerns with implementation burden on small or independent practices, limiting rural MIPS eligible clinicians and small practices from participating. This commenter further stated that this measure fails to account for the clinical relevance of the information used at the point of care, as they see no value in querying for data at all times. Lastly, this commenter stated that MIPS eligible clinicians are often unaware of their health system's engagement with TEFCA, placing additional burden on the MIPS eligible clinician having to

defer to others who have this information.

Response: We thank commenters for their feedback, but disagree that this measure will create additional burden on MIPS eligible clinicians, and instead believe that we are reducing burden by offering an additional option to satisfy the Health Information Exchange objective. Given this is one of three options to complete the objective, MIPS eligible clinicians can choose the measure option that works best for their practice, with their chosen vendor. We appreciate the commenters' concerns related to clinical relevance of the information exchanged via health information networks, but we disagree because the measure requirements specify that while exchange must be enabled for the specified patients, they do not require data to be exchanged if there is no clinical reason to do so. We believe that this measure offers MIPS eligible clinicians another alternative towards our larger effort to continue to promote interoperability by allowing the exchange of health information with minimal administrative burden on MIPS eligible clinicians and their support staff.

In the CY 2023 PFS proposed rule (87 FR 46295), we requested comment on other ways that TEFCA can advance CMS policy and program objectives, including how TEFCA can support exchange of information required under other measures in the Promoting Interoperability performance category. For instance, we asked how can TEFCA support exchange of information specified under the Public Health and Clinical Data Exchange and the Patient Access to their Health Information objectives. We would like to thank commenters for their feedback in response to our request for information on other ways that TEFCA can advance CMS policy and program objectives. We may consider these suggestions in future rulemaking.

After consideration of the public comments, we are finalizing our proposal to add the following new measure to the Health Information Exchange objective beginning with the performance period in CY 2023: Enabling Exchange Under TEFCA measure. MIPS eligible clinicians will have three reporting options for the Health Information Exchange objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable); (2) report on the HIE Bi-Directional Exchange measure; or (3) report on the Enabling Exchange Under TEFCA measure. We finalized our proposal to require the Query of PDMP measure above in section IV.A.6.c.(4)(d)(i) of this final rule; therefore, we are also finalizing our proposal that the Enabling Exchange Under TEFCA measure will be worth 30 points, the total amount of points available for the Health Information Exchange Objective. We are finalizing our proposal that a MIPS eligible clinician will report the Enabling Exchange Under TEFCA measure by attestation, and the measure will require a ''yes/no'' response; a ''yes'' response would enable a MIPS eligible clinician to earn the 30 points allotted to the Health Information Exchange Objective. We are finalizing our proposal that a MIPS eligible clinician will attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy; and
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

(f) Modifications to the Public Health and Clinical Data Exchange Objective

(i) Background

The Promoting Interoperability performance category for MIPS eligible clinicians has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange objective. Effective responses to public health events, such as the COVID–19 PHE, require a fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). Health care providers collect these data for patient care, and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

There are five measures under the Public Health and Clinical Data Exchange objective: Immunization Registry Reporting; Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59795, 59815 through 59817). In the CY 2022 PFS final rule (86 FR 65469 through 65475), we finalized the requirement for MIPS eligible clinicians to report two of the five measures associated with the Public Health and Clinical Data Exchange objective, beginning with the performance period in CY 2022: Immunization Registry Reporting; and Electronic Case Reporting. These two measures will put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening two important public health functions: (1) case surveillance; and (2) vaccine uptake. Requiring these measures will enable nationwide automated case reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies. (See *https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html https://www.healthit.gov/topic/safety/safer-guides*.)

(ii) Revisions to Active Engagement

(A) Background

The Promoting Interoperability performance category has been an important mechanism for encouraging data exchange between health care providers and public health agencies through the Public Health and Clinical Data Exchange objective. We believe requiring MIPS eligible clinicians to report on the Immunization Registry Reporting measure and Electronic Case Reporting measure will motivate EHR vendors to implement the necessary capabilities in their products and encourage MIPS eligible clinicians to engage in the reporting activities described in the measures.

Despite these gains, ensuring that the nation's thousands of MIPS eligible clinicians implement and initiate data production for these vital public health capabilities remains an ongoing and important effort. The Promoting Interoperability performance category provides an opportunity to continue strengthening the incentives for MIPS eligible clinicians to engage in these essential reporting activities. Without adequate incentives, it will be difficult to attain the comprehensive data exchange needed to ensure fast,

complete, actionable data in response to future public health threats.

In the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864), beginning with the EHR reporting period in 2016, we established a definition for active engagement under the Public Health and Clinical Data Registry Reporting objective (subsequently renamed for MIPS the Public Health and Clinical Data Exchange objective, see 83 FR 59815 through 59817). Active engagement is defined as when an eligible professional (now a MIPS eligible clinician) is in the process of moving towards sending ''production data'' to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term ''production data'' refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers. We established the following three options for eligible professionals to demonstrate active engagement:

- *Option 1—Completed registration to submit data:* The eligible professional registered to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the eligible professional is awaiting an invitation from the PHA or CDR to begin testing and validation. Eligible professionals that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period;
- *Option 2—Testing and validation:* The eligible professional is in the process of testing and validation of the electronic submission of data. The eligible professional must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in the eligible professional not meeting the measure; and
- *Option 3—Production:* The eligible professional has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

For more information about the current options for active engagement, we refer readers to the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864).

(B) Revisions to Options for Active Engagement

The three active engagement options provided flexibility for eligible professionals and MIPS eligible clinicians to meet the measures under the Public Health and Clinical Data Registry Reporting objective/Public Health and Clinical Data Exchange objective in a variety of ways, but they did not provide an incentive to move through the options and get to option 3, production, where there is the ongoing electronic submission of data. Option 1, completed registration to submit data, was an important option in 2016 as many PHAs and CDRs were starting to come online, and thus the provision of this option recognized that many eligible professionals were just beginning to engage in electronic data exchange with PHAs and CDRs. Now, many years have passed, and we believe that MIPS eligible clinicians have had ample time to complete option 1.

Thus, we proposed in the CY 2023 PFS proposed rule (87 FR 46296 through 46297) to consolidate current options 1 and 2 into one option beginning with the performance period in CY 2023, as follows:

- Proposed Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation). The MIPS eligible clinician must first register to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted. Registration must be completed within 60 days after the start of the performance period,[532] while awaiting an invitation from the PHA or CDR to begin testing and validation. MIPS eligible clinicians that have registered in previous years do not need to submit an additional registration for subsequent performance periods. Upon completion of the initial registration, the MIPS eligible clinician must begin the process of testing and validation of the electronic submission of data. The MIPS eligible clinician must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within a performance period would result in the MIPS eligible clinician not meeting the measure.

MIPS eligible clinicians could select this option if they have previously completed the initial registration (existing Option 1). They could also select this option if they are currently in the process of testing and validation (existing Option 2).

- Proposed Option 2. Validated Data Production (current option 3, production). The MIPS eligible clinician has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

Under this proposal, a MIPS eligible clinician must demonstrate their level of active engagement at either proposed Option 1 (pre-production and validation) or proposed Option 2 (validated data production) to fulfill each measure.

We invited public comment on these proposals, and the following is a summary of the comments received.

Comment: Many commenters supported the proposal to modify the active engagement options under the Public Health and Clinical Data Exchange objective. A few commenters expressed their support for consolidating the active engagement options, stating that the original option 1 (completed registration to submit data) requires very little effort from the clinician to achieve, does little to promote public health reporting, and is often used by clinicians to simply ''check the box'' and get measure credit. Some commenters supported the proposal because they believe it forces health care providers to truly engage in efforts to achieve a status of validated data production. Other commenters supported CMS' goal that all health care providers nationwide be actively sending public health data to registries so that future public health threats can be monitored.

Response: We believe that it is crucial to have all clinicians actively submitting production data to immunization and electronic case reporting registries. We have consulted with CDC and they believe that immunization and electronic case reporting registries are ready to accept registrations and are able to move clinicians from registration to testing almost immediately. Thus, we believe the proposed option 1—pre-production and validation more accurately reflects the current environment.

Comment: Several commenters supported our proposal stating that CMS' increased emphasis on promoting public health and clinical data by better capturing this data presents a critical opportunity to prevent devastating consequences and misdiagnoses. Other commenters stated that this proposal would enable MIPS eligible clinicians to monitor future public health threats, assess geographic gaps, and ensure

[532] In the CY 2023 PFS proposed rule (87 FR 46296), we inadvertently referred to the EHR reporting period instead of the performance period.

active engagement through adherence to the measure requirements.

Response: We agree that this is an opportunity for MIPS eligible clinicians to be more involved and engaged with the data exchange process. We agree that with engagement comes awareness, and the ability to improve existing processes.

Comment: Some commenters did not support the proposal to modify the active engagement options under the Public Health and Clinical Data Exchange objective stating that the PHE is still ongoing and many practices/MIPS eligible clinicians have had to re-tool their practices just to function during this challenging time. The commenters requested CMS revisit this proposal after the COVID–19 PHE is over. Another commenter urged CMS to reconsider this proposal and supported the measure as currently structured, with separate options for pre-production and validation. The commenter stated that the separate options for pre-production and validation give practices more time to negotiate and test new and changing technical integration policies that are often needed to bring reporting up to the production stage.

Response: We understand the burdens MIPS eligible clinicians presently face due to the COVID–19 PHE. We do not believe that it is important to differentiate between those MIPS eligible clinicians who have registered and those who have begun testing and validation. Based on input from CDC, we understand that in general, many clinicians who register are immediately invited to begin testing and validation.

(C) Reporting Requirement for Level of Engagement

MIPS eligible clinicians currently are not required to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange objective. We believe that this information would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding MIPS eligible clinicians and moving them to the Validated Data Production phase. During the recent COVID–19 PHE, we recognized the importance of public health reporting (as discussed further the CY 2023 PFS proposed rule, 87 FR 46295 and 46296), and we believe that knowing the level of active engagement that a MIPS eligible clinician selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage. Our goal is for all health care providers nationwide to be at the Validated Data Production stage so that data will be actively flowing, and public health threats can be monitored. Therefore, for the Public Health and Clinical Data Exchange objective, in addition to submitting responses for the required measures and any optional measures a MIPS eligible clinician chooses to report, we proposed in the CY 2023 PFS proposed rule (87 FR 46296 through 46297) to require MIPS eligible clinicians to submit their level of active engagement, either Pre-production and Validation or Validated Data Production (as proposed in section IV.A.6.c.(4)(f)(ii)), for each measure they report beginning with the performance period in CY 2023. We noted in the proposed rule that if our proposal to reduce the three current options of active engagement to two options is not finalized, we proposed to require MIPS eligible clinicians to submit one of the three current options of active engagement for each measure they report.

We invited public comment on these proposals, and the following is a summary of the comments received.

Comment: Several commenters supported our proposal to require MIPS eligible clinicians to report their level of active engagement for measures in the Public Health and Clinical Data Exchange objective stating they understood CMS' need to capture engagement information.

Response: We thank commenters for their support.

Comment: A commenter asked for clarification on what to submit if clinicians in a group are at different levels of active engagement.

Response: If MIPS eligible clinicians who are choosing to report for MIPS as a group are at different levels of active engagement, the group should consider submitting the level of active engagement that best reflects the composition of the group (for example, the level that reflects the status of the majority of the MIPS eligible clinicians in the group).

Comment: Several commenters did not support our proposal to require MIPS eligible clinicians to report their level of active engagement for measures in the Public Health and Clinical Data Exchange objective, stating that this additional reporting requirement is burdensome, especially during the COVID–19 PHE.

Response: We do understand that many MIPS eligible clinicians remain affected by the COVID–19 PHE, however, we believe the burden of submitting the level of active engagement is very small, and we estimate in section V.B.9.g. that it will take 30 seconds to submit the level of active engagement.

(D) Changes to the Duration of Active Engagement Options

MIPS eligible clinicians currently are not required to advance from one option of active engagement to the next within a certain period of time. Beginning with the performance period in CY 2023, we proposed in the CY 2023 PFS proposed rule (87 FR 46297) that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level in the next performance period for which they report a particular measure. For example, under this proposal, if a MIPS eligible clinician submits the Immunization Registry Reporting measure for the performance period in CY 2023 at the level of active engagement for proposed Option 1 (Pre-production and Validation), the clinician must submit the Immunization Registry Reporting measure at the level of active engagement for proposed Option 2 (Validated Data Production phase) for the next performance period in CY 2024, or they would fail to satisfy the Public Health and Clinical Data Exchange objective. To use an optional measure as an example to illustrate this proposal, if a MIPS eligible clinician chooses to submit the Syndromic Surveillance Reporting measure for the performance period in CY 2023 at the level of active engagement for proposed Option 1 (Pre-production and Validation) and then chooses to submit the Syndromic Surveillance Reporting measure for a later performance period, the clinician would have to submit the measure at the level of active engagement for proposed Option 2 (Validated Data Production phase) for the next performance period for which they choose to submit the measure. The options for active engagement assume the same PHA or CDR is used by the MIPS eligible clinician. In the event a MIPS eligible clinician chooses to switch between one or more CDRs or PHAs, we proposed they would be permitted to spend one additional performance period at the Pre-production and Validation phase to assist with onboarding to the new CDR or PHA. As electronic transmission of high-quality data is achieved at the Validated Data Production phase, we want all MIPS eligible clinicians to reach this level.

We invited public comment on these proposals, and the following is a summary of the comments received.

Comment: One commenter did not support our proposal to limit the amount of time a MIPS eligible clinician may spend in Option 1 (Pre-production and Validation) to one performance period, before progressing to Option 2 (Validated Data Production). This commenter stated that CMS should leave the measure requirements the same for the CY 2023 performance period, allowing MIPS eligible clinicians additional time for testing and validation.

A few commenters asked CMS to consider exclusions for those MIPS eligible clinicians who attempt to move from option 1 to option 2 after one year but are unable do so due to circumstances outside of their control. Another commenter stated that staffing and resource constraints faced by public health agencies have made it challenging for MIPS eligible clinicians to complete the onboarding, testing, and validation processes necessary to fulfill the requirements. One commenter stated that public health agencies offer a limited amount of time for MIPS eligible clinicians to move from invitation to testing, making this requirement difficult. A few commenters recommended a delay in the effective date for this policy for 6–12 months to account for circumstances such as unexpected staff shortage or backlog (for example, in case a public health agency is unable to accommodate everyone who wants to be on board).

Response: We acknowledge commenters' concerns regarding the lack of control MIPS eligible clinicians may have when moving through the levels of active engagement. We recognize that MIPS eligible clinicians' successful progression through the levels of engagement is partially dependent on the readiness, resources and capabilities of the PHAs to which they report. We further recognize that public health capacity remains somewhat variable and constrained—particularly as PHAs continue to direct resources to the COVID–19 PHE response efforts. For these reasons, we are delaying by one year the implementation of the proposed requirement that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure, such that it will apply beginning with the performance period in CY 2024. We believe that this delay will provide MIPS eligible clinicians the additional time needed and thus believe that it is not necessary to adopt additional exclusions.

After consideration of the public comments we received, we are finalizing proposed Option 1 (Pre-production and Validation) and proposed Option 2 (Validated Data Production) as proposed. A MIPS eligible clinician must demonstrate their level of active engagement at either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production) to fulfill each measure beginning with the CY 2023 performance period. We are also finalizing our proposal to require MIPS eligible clinicians to submit their level of active engagement, either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production), for each measure they report beginning with the performance period in CY 2023. We are also finalizing the proposal that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation (Option 1) level of active engagement per measure, and that they must progress to the Validated Data Production (Option 2) level in the next performance period for which they report a particular measure. We are finalizing this proposal with a modification that the policy will apply beginning with the CY 2024 performance period. We are also finalizing the proposal that in the event a MIPS eligible clinician chooses to switch between one or more CDRs or PHAs, they will be permitted to spend one additional performance period at the Pre-production and Validation phase to assist with onboarding to the new CDR or PHA.

(E) Public Health Reporting and Information Blocking

The ONC 21st Century Cures Act final rule (85 FR 25642) implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. The 21st Century Cures Act final rule established a regulatory definition of information blocking, under which information blocking is, in general, a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider (actors) [533] that, except as required by law or covered by an exception in 45 CFR part 171, subparts B or C, is likely to interfere with (as defined in 45 CFR 171.102) access, exchange, or use of EHI.[534] [535] For a health care provider (as defined in 45 CFR 171.102), information blocking (see 45 CFR 171.103) means a practice (except as required by law or covered by an exception defined in 45 CFR part 171) that is likely to interfere with access, exchange, or use of EHI that the health care provider knows is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.[536] [537]

ONC recently released an information blocking frequently asked question (FAQ) (IB.FAQ43.1.2022FEB) that highlights important points about public health reporting and information blocking.[538] Specifically, if an actor is required to comply with another law that relates to the access, exchange, or use of EHI, failure to comply with that law may implicate the information blocking regulations. As an example, where a law requires actors to submit EHI to public health authorities, an actor's failure to submit EHI to public health authorities could be considered an interference under the information blocking regulations. For example, many States legally require reporting of certain diseases and conditions to detect outbreaks and reduce the spread of disease. Should an actor that is required to comply with such a law fail to report, the failure could be an interference with access, exchange, or use of EHI under the information blocking regulations. Practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking, consistent with additional ONC frequently asked questions.[539]

[533] Actor is defined in 45 CFR 171.102 as ''health care provider, health IT developer of certified health IT, health information network or health information exchange.''

[534] For purposes of the definition of information blocking, for the period before October 6, 2022, electronic health information is defined in 45 CFR 171.103(b). As of that date, electronic health information will be defined as it is in 45 CFR 171.102.

[535] In order for a practice to be considered information blocking, additional requirements at 45 CFR 171.103(a)(2) or (a)(3) apply, depending on the type of actor engaging in the practice.

[536] For other types of actors (health IT developers of certified health IT and health information networks or health information exchanges, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

[537] The exceptions to the definition of information blocking (practices that are required by law or covered by an exception in 45 CFR part 171, subparts B or C) described in the previous sentence apply to this definition as well.

[538] See *https://www.healthit.gov/curesrule/faq/would-not-complying-another-law-implicate-information-blocking-regulations.*

[539] See *https://www.healthit.gov/curesrule/faq/how-would-any-claim-or-report-information-blocking-be-evaluated.*

(g) Changes to the Scoring Methodology for the Performance Period in CY 2023

For ease of reference, Table 92 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2023 performance period/2025 MIPS payment year as revised to reflect the policies finalized in this final rule.

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TABLE 92: Objectives and Measures for the Promoting Interoperability Performance Category for the Performance Period in CY 2023

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history*.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; 2. writes fewer than 100 permissible prescriptions during the performance period; or 3. for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient,	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT	exchanges the summary of care record.			
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA* MIPS eligible clinicians would attest to the following: ● Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. ● Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange: The MIPS eligible clinician	Provide Patients Electronic Access to Their Health	Number of patients in the denominator (or patient	Number of unique patients seen by the MIPS eligible	N/A

Objective	Measure	Numerator	Denominator	Exclusion
provides patients (or patient-authorized representative) with timely electronic access to their health information.	Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.	clinician during the performance period.	
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the

Objective	Measure	Numerator	Denominator	Exclusion
				start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

* Signifies a final policy adopted in the CY 2023 PFS final rule.

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In the CY 2023 PFS proposed rule, we made various proposals that would affect the scoring of the objectives and measures for the performance period in CY 2023 (87 FR 46298 through 46309).

In proposing to make the Query of PDMP measure required, we noted we would retain the 10 points associated with it, which are allocated as bonus points for the performance period in CY 2022. To accommodate this change if our proposal is finalized, we proposed to reduce the points associated with the Health Information Exchange objective measures from the current 40 points to 30 points beginning with the CY 2023 performance period. (CY 2023 PFS proposed rule, 87 FR 46289 through 46290).

The Public Health and Clinical Data Exchange objective, with its two required measures, is currently worth only 10 points. Despite requiring certain measures to make the objective more effective in promoting public health data electronic exchange, the total number of points did not change between CY 2021 and CY 2022. We noted that we believe that increasing the point value of the Public Health and Clinical Data Exchange objective would create a more meaningful incentive for MIPS eligible clinicians to engage in the electronic reporting of public health information and recognize the importance of public health systems affirmed by the COVID–19 pandemic. Increasing the point value would make the Public Health and Clinical Data Exchange objective a more central piece of the Promoting Interoperability performance category and better incentivize MIPS eligible clinicians to implement these essential public health data exchange capabilities. Without adequate incentives, there remains a risk that MIPS eligible clinicians will simply not prioritize implementing these capabilities, which are essential to ongoing efforts to address COVID–19 and will be indispensable for responding to future public health threats and emergencies. Increasing the point value would more appropriately incentivize MIPS eligible clinicians to engage in the electronic reporting of public health information and would align the value of the objective with the objective's importance and the effort necessary to meet the required measures.

Thus, we proposed to increase the points allocated to the Public Health and Clinical Data Exchange objective from 10 to 25 points to better align with the true value of this objective beginning with the CY 2023 performance period. We noted that we believe assigning 25 points to the objective reflects the importance of comprehensive, nationwide health care data exchange between MIPS eligible clinicians and public health agencies. Nationwide health care data exchange would provide immense value to the public by improving the speed and effectiveness of public health responses, as well as to MIPS eligible clinicians, since better public health response reduces pressure on clinicians, which can be overwhelmed in a public health crisis. To balance the increase in the points associated with the Public Health and Clinical Data Exchange objective, we proposed to reduce the points

associated with the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25 points beginning with the CY 2023 performance period. We proposed to revise the regulatory text for scoring the Promoting Interoperability performance category at § 414.1380(b)(4)(ii)(B) and (C) to reflect the proposals for scoring the objectives and measures. (CY 2023 PFS proposed rule, 87 FR 46305 through 46306)

We invited public comment on these proposals, and the following is a summary of the comments received:

Comment: Several commenters supported our proposals to modify the existing scoring methodology for the Query of PDMP measure, the Health Information Exchange objective measures, the Public Health and Clinical Data Exchange objective, and the Provide Patients Access to their Health Information measure. One commenter stated that these modifications would be less cumbersome, easier to understand, and more effectively highlight important objectives. One commenter stated that they support our proposal to increase the number of points allocated to the Public Health and Clinical Data Exchange Objective, as this shows CMS's recognition of the important efforts that should continue in order to effectively move clinicians and health care organizations toward electronically submitting data to public health agencies.

Response: We thank commenters for their support. We appreciate that commenters recognize our efforts towards further reducing administrative burden and highlighting objectives that are integral to the Promoting Interoperability performance category. We agree with commenters that moving MIPS eligible clinicians and health care organizations towards a more interoperable state is an important step towards interoperability.

Comment: Some commenters supported our proposal to modify the scoring methodology to reflect our proposal to require the Query of PDMP measure. One commenter stated that the scoring revision will help address the opioid crisis, which has not gone away during the COVID–19 PHE. Another commenter stated that they support changing the scoring methodology from optional bonus points to an assigned 10 points, making the Electronic Prescribing objective worth a total of 20 points.

Response: We believe that after offering bonus points for several performance periods and increasing the bonus points from 5 to 10 points in the CY 2021 PFS final rule (85 FR 84887 and 84888), 10 points reflects the importance of this measure as a tool to help combat the opioid epidemic. Therefore, increasing the number of points allocated to the objective by requiring the Query of PDMP measure (such that the points allocated to the measure would no longer be bonus points) demonstrates our continued commitment to combatting the opioid epidemic.

Comment: Some commenters did not support our proposal to modify the scoring methodology for the Query of PDMP measure. One commenter stated that CMS should not finalize this proposal, as they are also not supportive of requiring the Query of PDMP measure. Another commenter stated that with many MIPS eligible clinicians are incapable of interconnecting their EHR technology with PDMP systems, CMS should not require the Query of PDMP measure, and therefore, not finalize converting the 10 bonus points to assigned points.

Response: We agree with the commenters that not all MIPS eligible clinicians have a fully operational statewide PDMP or a fully integrated EHR–PDMP. We recognize that without full integration, it is possible that the actions required to satisfy the Query of PDMP measure could be time-consuming for clinicians and potentially cause clinical disruption. For these reasons, we are adopting an additional exclusion for the Query of PDMP that will be available only for the CY 2023 performance period/2025 MIPS payment year, as explained in section IV.A.6.c.(4)(a)(iii), above. We do not agree with commenters that the 10 points should remain as bonus points. As we have previously stated, more MIPS eligible clinicians are able to successfully complete the requirements of the measure versus those who cannot, and as we discussed in section IV.A.6.c.(4)(a)(i) of this final rule we believe it is important to require the Query of PDMP measure.

Comment: Some commenters did not support our proposal to reduce the number of points associated with the Health Information Exchange objective measures from the current 40 points to 30 points. One commenter stated that the 10 points for the Query of PDMP measure should not be reassigned from the Health Information Exchange objective, given the current efforts towards supporting information exchange.

Response: We thank commenters for their feedback. The Health Information Exchange objective remains fundamental to the Promoting Interoperability performance category. However, we believe that finalizing an additional reporting option, the Enabling Exchange under TEFCA measure (section IV.A.6.c.(4)(e)(iii)) will reduce the administrative efforts for MIPS eligible clinicians with regard to the Health Information Exchange objective, and the point reduction reflects this. We want to express our commitment to combatting the opioid epidemic, therefore we disagree that the points should not be redistributed to the Query of PDMP measure.

Comment: A few commenters supported our proposal to increase the points allocated to the Public Health and Clinical Data Exchange objective. One commenter stated that this represents an important step to improving our nation's public health information infrastructure. Another commenter stated that increasing the points allocated to this objective will better incentivize MIPS eligible clinicians to implement these essential public health data exchange capabilities, bolstering the interoperability and robustness of data exchange between healthcare and public health, and will make the objective a more central piece of the Promoting Interoperability performance category.

Response: We thank commenters for their support. As the COVID–19 PHE revealed, public health data is vital in combating PHEs and increasing the points allocated to the objective clearly reflects the importance of this information.

Comment: Some commenters do not support our proposal to increase the points allocated to the Public Health and Clinical Data Exchange objective. One commenter urged CMS to continue working with the CDC to ensure public health agencies are capable of receiving data before changing the existing point distribution. This commenter further stated that funding and implementation schedules have an impact on working with public health agencies that are capable of receiving data, and that these barriers should be resolved before any additional changes are made to the point distribution. One commenter stated that an ''all or nothing'' approach to the Public Health and Clinical Data Exchange objective requirements has a negative impact on MIPS eligible clinicians' success with the Promoting Interoperability performance category.

Response: We will continue to work in close collaboration with the CDC. With regard to the ''all or nothing'' approach, we agree that failure to comply with the objective's requirements could have a potential negative impact on a MIPS eligible

clinician's success. We reiterate that the Public Health and Clinical Data Exchange objective will continue to be an important objective particularly as we may find ourselves having to combat future pandemics. In response to those commenters who have concerns that PHAs are not capable of receiving data, CDC is working with PHAs to ensure that they will be ready to receive data.

After consideration of the public comments, we are finalizing our proposals to reduce the points associated with the Health Information Exchange objective measures from the current 40 points to 30 points beginning with the CY 2023 performance period, increase the points allocated to the Public Health and Clinical Data Exchange objective from 10 to 25 points, and reduce the number of points associated with the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25 points. We note that we are finalizing the proposal to require the Query of PDMP measure, as discussed in section IV.A.6.c.(4)(d)(i) of this final rule, thereby finalizing the point value for the measure at 10 points.

Table 93 reflects the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2023.

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TABLE 93: Scoring Methodology for the Performance Period in CY 2023

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP*	10 points*	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points*	
	-OR-		
	Enabling Exchange under TEFCA*	30 points*	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required
Public Health and Clinical Data Exchange	Report the following two measures*: • Immunization Registry Reporting • Electronic Case Reporting	25 points*	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)*	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review and actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).
*Signifies a final policy adopted in the CY 2023 PFS final rule.

The maximum points available in Table 93 do not include the points that will be redistributed in the event an exclusion is claimed. For ease of reference, Table 94 shows how points will be redistributed among the objectives and measures for the performance period in CY 2023 in the event a MIPS eligible clinician claims an exclusion.

TABLE 94: Exclusion Redistribution for Performance Period in CY 2023

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP*	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA*	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following five measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review and actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).
*Signifies a final policy adopted in the CY 2023 PFS final rule.

For ease of reference, Table 95 lists the objectives and measures for the Promoting Interoperability performance category for the performance period in CY 2023 and the 2015 Edition certification criteria.

TABLE 95: Promoting Interoperability Performance Category Objectives and Measures and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition (CY 2023 Performance Period)
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria, revising and removing existing criteria (85 FR 25667 through 25668). These changes are required beginning with the CY 2023 performance period.

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(h) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) for the performance periods in CY 2017 through 2022 (2019 through 2024 MIPS payment years) under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We analyzed the data submitted for the CY 2017 performance period for the Promoting Interoperability performance category and discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the CY 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the CY 2018 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, we initially found approximately 34 percent submitted data individually for the Promoting Interoperability performance category. However, after further review and the refinement of our analytics, we found that this percentage was 24 percent, not 34 percent. For the CY 2019 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 30 percent submitted data individually for the Promoting Interoperability performance category, a modest increase from 2018. For the CY 2020 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 27.5 percent submitted data individually for the Promoting Interoperability performance category, a modest decrease from 2019. For the CY 2021 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 21.3 percent submitted data individually for the Promoting Interoperability performance category, a decrease from 2020.

Due to the continued relatively low numbers of NPs, PAs, CRNAs, or CNSs that submitted data individually for the Promoting Interoperability performance category for prior performance periods, we did consider proposing to extend the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) for another year (for the CY 2023 performance period/2025 MIPS payment year, CY 2023 PFS proposed rule, 87 FR 46309 through 46310). However, we noted that we believe that incentivizing more of these types of MIPS eligible clinicians to adopt and use CEHRT and submit data for the Promoting Interoperability performance category is important for increased interoperability and data exchange nationwide. We adopted the reweighting policy beginning with the first year of MIPS (the CY 2017 performance period/2019 MIPS payment year), and we believe that there has been sufficient time for NPs, PAs, CRNAs, and CNSs to adopt and implement CEHRT. At this point in the program's maturity, we are concerned that the reweighting policy itself might be serving as a disincentive to these types of MIPS eligible clinicians adopting and using CEHRT, which would be an unintended consequence. We believe it is possible that these clinician types are now able to submit data individually on the measures for the Promoting Interoperability performance category, but they are choosing not to because they would prefer for the performance category to be reweighted and not to contribute to their final score. Further, we believe that there are sufficient measures applicable and available in the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs. The measures that may not apply to these clinician types, such as the e-Prescribing measure, have exclusions that can be claimed if applicable. We considered the impact that not extending the policy may have on MIPS eligible clinicians in small practices, but we believe that the policy we established in the CY 2022 PFS final rule at § 414.1380(c)(2)(i)(A)(*4*)(*ii*)) to automatically assign a weight of zero to the Promoting Interoperability performance category for MIPS eligible clinicians in a small practice will result in very few NPs, PAs, CRNAs, and CNSs being affected. Further, we reminded readers that a MIPS eligible clinician who meets the criteria for a significant hardship may submit a hardship exception application to reweight the Promoting Interoperability performance category based on a significant hardship, such as lack of control over the availability CEHRT and insufficient internet access (81 FR 77240 through 77243, 82 FR 53680 through 53686, 82 FR 53783 through 53785, and 85 FR 84984).

For these reasons, we did not propose to continue the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score for NPs, PAs, CRNAs, or CNSs for the CY 2023 performance period/2025 MIPS payment year. However, we requested public comment on whether we should continue this policy for the CY 2023 performance period/2025 MIPS payment year. We noted particular interest in comments on potential barriers to CEHRT adoption and implementation that may impact one or more of these clinician types, as well as comments on the applicability of the Promoting Interoperability performance category measures to NPs, PAs, CRNAs, or CNSs.

The following is a summary of the public comments received on not continuing the current reweighting policy for NPs, PAs, CRNAs, or CNSs and our responses:

Comment: Many commenters supported our decision not to continue the reweighting policy for NPs, PAs, CRNAs, or CNSs starting with the performance period in CY 2023. One commenter stated that it is critical to expand health care provider participation in the Promoting Interoperability performance category so that data from NPs, PAs, CRNAs, or CNSs is included in public health reporting.

Response: We agree that data from all MIPS eligible clinician types will make

the information available through public health reporting more robust.

Comment: One commenter requested that CMS provide exceptions to small practices and CRNAs in rural areas.

Response: We currently do not have a policy to reweight the Promoting Interoperability performance category for MIPS eligible clinicians in rural areas, though we may consider this feedback in future rulemaking. In the CY 2022 PFS final rule (86 FR 65485 through 65487, § 414.1380(c)(2)(i)(C)(*9*)), we finalized a reweighting policy to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score for MIPS eligible clinicians in small practices.

Comment: Several commenters did not support our choice not to continue the reweighting policy for NPs, PAs, CRNAs, or CNSs. A few of these commenters stated that this is very problematic for those clinicians not reporting as a group because it makes them individually responsible for submitting data for the Promoting Interoperability performance category. A couple commenters stated that this was an unnecessary change during the COVID–19 PHE.

Response: We appreciate the commenters' concerns but believe that the sharing of electronic health information from all MIPS eligible clinicians through CEHRT will improve patient care. MIPS eligible clinicians who do report as a group may be in small practices and eligible for reweighting under the policy at § 414.1380(c)(2)(i)(C)(*9*). While we understand that the COVID–19 PHE has caused stress for many MIPS eligible clinicians, we believe the value of the information in CEHRT will help MIPS eligible clinicians deliver higher quality healthcare. To achieve this, the information from all MIPS eligible clinician types needs to be available for electronic sharing.

After consideration of the public comments, we are not continuing the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score for NPs, PAs, CRNAs, or CNSs for the CY 2023 performance period/2025 MIPS payment year.

(ii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2019 PFS final rule (83 FR 59819 through 59820), we established that we will apply the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are non-physician practitioners (physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the CY 2019 performance period. The reweighting policy for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals is codified at § 414.1380(c)(2)(i)(A)(*4*)(*i*).We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. We extended this policy for the performance periods in CY 2020 (84 FR 63003 through 63004), CY 2021 (85 FR 84895), and CY 2022 (86 FR 65488 through 65489). We analyzed the data from the CY 2019 performance period/2021 MIPS payment year, and approximately 18.4 percent of occupational therapists, 2 percent of physical therapists, and 1 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, approximately 18.8 percent of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category. We analyzed the data from the CY 2020 performance period/2022 MIPS payment year, and approximately 3.3 percent of occupational therapists, 1.4 percent of physical therapists, and 0.6 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, 0 percent (rounded from 16 total clinicians) of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category. We analyzed the data from the CY 2021 performance period/2023 MIPS payment year, and 0 percent of occupational therapists, 0.3 percent of physical therapists, 0.5 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, 6.7 (6.66) percent of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category.

Based on low participation, it is possible that these clinician types may be finding that there are not sufficient measures that are applicable to them. As with NPs, PAs, CRNAs, and CNSs, however, it is also possible that the reweighting policy itself might be serving as a disincentive to these types of MIPS eligible clinicians adopting and using CEHRT, and that they are choosing not to submit data individually on the measures because they would prefer for the performance category to be reweighted and not to contribute to their final score. Because these clinician types were added to the definition of a MIPS eligible clinician under § 414.1305 more recently than NPs, PAs, CRNAs, and CNSs, we believe it would be appropriate to continue the existing reweighting policy for them for one more year. Therefore, we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals only for the CY 2023 performance period/2025 MIPS payment year (CY 2023 PFS proposed rule, 87 FR 46310) and to revise § 414.1380(c)(2)(i)(A)(*4)(i)* to reflect the proposal. We want to continue to encourage these types of MIPS eligible clinicians to adopt and use CEHRT, which would contribute to increased interoperability and data exchange nationwide; therefore, we do not anticipate proposing in future rulemaking to extend the policy for additional years.

We invited comments on this proposal, and the following is a summary of the public comments received on our proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition

professionals for the CY 2023 performance period and our responses:

Comment: The majority of commenters supported our proposal to continue the reweighting policy for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the CY 2023 performance period/2025 MIPS payment year.

Response: We appreciate the support for this proposal.

Comment: Many commenters expressed concern about our statement that we did ''not anticipate proposing in future rulemaking to extend the policy for additional years'' (87 FR 46310). Some stated that these clinician types were not eligible to participate in the Medicare and Medicaid EHR Incentive Programs and do not have the resources to adopt CEHRT. Other commenters recommended that CMS continue to offer hardship exceptions that would result in the reweighting of the Promoting Interoperability performance category. A few commenters asked that we delay the discontinuation of reweighting until CY 2025 to give these MIPS eligible clinicians more time.

Response: We appreciate these concerns and may take this feedback under consideration for future rulemaking. While we do understand that these clinicians were not eligible for EHR incentives, we believe that the value of interoperable electronic health information is great. We will continue to review the number of physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals who submit data for the Promoting Interoperability performance category.

After consideration of the public comments, we are finalizing the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals only for the CY 2023 performance period/2025 MIPS payment year and the corresponding revisions to § 414.1380(c)(2)(i)(A)(*4)(i).*

(iii) Clinical Social Workers

In the CY 2022 PFS final rule (86 FR 65387 through 65389), we added clinical social workers to the definition of a MIPS eligible clinician under § 414.1305, beginning with the CY 2022 performance period/2024 MIPS payment year. This clinician type was not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers also were not eligible for Medicaid EHR incentive payments. We stated that clinical social workers may lack experience with the adoption or use of CEHRT, and that we believed there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to them (86 FR 65489). For the CY 2022 performance period/2024 MIPS payment year, we established that we will apply to clinical social workers the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians who are non-physician practitioners (86 FR 65489). The reweighting policy for clinical social workers is codified at § 414.1380(c)(2)(i)(A)(*4)(iii).*

CY 2022 is the first year that clinical social workers are considered MIPS eligible clinicians, and thus we do not yet have any performance period data that we could use to evaluate whether the Promoting Interoperability performance category measures are applicable and available to this type of MIPS eligible clinician. We proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)(*4)(iii*) to reflect the proposal (CY 2023 PFS proposed rule, 87 FR 46310 through 46311). We noted we would evaluate whether the policy should be continued for future years when we have performance period data available.

We invited comment on this proposal, but we did not receive any comments. For the reasons stated in the CY 2023 proposed rule (87 FR 46310 and 46311) and above, we are finalizing the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year and the corresponding revisions to § 414.1380(c)(2)(i)(A)(*4)(iii*).

(i) Patient Access to Health Information Measure—Request for Information (RFI)

The CY 2023 PFS proposed rule contained an RFI on a measure of patient access to their health information (87 FR 46311 through 46312).

We thank commenters for their responses to this request for information. We may consider this information to inform future rulemaking.

(5) APM Entity Level Participation for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

In the CY 2021 PFS final rule (85 FR 84896), we finalized our policy to terminate the APM scoring standard effective January 1, 2021, and to retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the CY 2021 MIPS performance period. Therefore, we redesignated, in part, the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and titled that section ''APM Entity Groups.''

(b) APM Entity Level Reporting of Promoting Interoperability Performance Category

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to allow APM Entities to report to traditional MIPS using any available MIPS reporting pathway, including the APM Performance Pathway (APP), traditional MIPS and, in the future, MIPS Value Pathways (MVPs).

We finalized that APM Entities that do not report through the APP will continue to have the cost performance category reweighted to zero percent of their MIPS final score, but will be required to report and be scored on the three remaining MIPS performance categories, including quality, IA, and promoting interoperability. We explained in that rule that the PI performance category would continue to be scored for multi-TIN APM Entities using the promoting interoperability roll-up calculation described at § 414.1317(b)(1) (85 FR 84897).

It has come to our attention through feedback from interested parties that many of the workstream modifications, as well as data aggregation and integration tools that are likely to be used by multi-TIN APM Entities, such as use of the FHIR API or hiring vendors to complete the more complex reporting activities required for reporting APM Entity level eCQMs could also be used to collect data and submit for the promoting interoperability performance category at the APM Entity level.

It is also our understanding that it is possible that an APM Entity may

represent only a single practice site or specialty within a larger multi-specialty TIN. We believe that in these circumstances the APM Entity may have both the ability and desire to report on the promoting interoperability performance category at the APM Entity level, thereby excluding data generated by the rest of the larger TIN, in cases where the APM Entity itself performed above average relative to the rest of that TIN.

Therefore, we proposed to introduce a voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the 2023 performance period. Multi-TIN APM Entities that do not choose this proposed new reporting option would continue to be scored using the roll-up calculation described at § 414.1317(b)(1). We sought comment on this proposal.

We did not receive any comments on this proposal. For the reasons stated previously in this section and in the proposed rule (87 FR 46257), we are finalizing as proposed the voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the 2023 performance period.

e. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act provides, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards for a performance period and use such methodology to provide for a composite performance score for each such clinician for each performance period.

For the CY 2023 performance period/2025 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. We believe that this scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. In the CY 2023 PFS proposed rule (87 FR 46313), we proposed to update our scoring policies consistent with this framework. Specifically, we proposed to—

- Amend the benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data.
- Clarify the topped out measure policy and update the topped out measure life cycle for scoring topped out measures in the quality performance category.
- Establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year.

We refer readers to section IV.A.6.c.(4)(g) of this final rule for a discussion of the changes to the scoring methodology for the Promoting Interoperability performance category. We did not propose changes to scoring policies for the improvement activities performance category.

We refer readers to § 414.1380 for our current policies on scoring.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We referred readers to § 414.1380(b)(1) for our current policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913). In the CY 2022 PFS final rule we finalized policies to simplify scoring in MIPS as we transition to MVPs and to incentivize the selection of new, potentially high-value measures (86 FR 65496 through 65507).

(i) Scoring Administrative Claims Measures in the Quality Performance Category Using Performance Period Benchmarks

In the 2023 PFS proposed rule (87 FR 46313), we referred readers to the CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 Quality Payment Program final rules and PFS final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, 84 FR 63014 through 63016, and 85 FR 84901 through 84904, respectively) for our previously established benchmarking policies.

In the CY 2017 Quality Payment Program final rule (81 FR 77276 through 77282), we finalized a rule providing that we will use MIPS eligible clinicians' performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or quality measures where we do not have comparable data from the baseline period. In these cases, we explained that we will calculate benchmarks using data submitted during the applicable performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for the CY 2023 performance period/2025 MIPS payment year, the baseline period two performance periods prior would be the CY 2021 performance period (81 FR 77276 and 77277). Additionally, in the CY 2019 PFS final rule (83 FR 59842), we amended § 414.1380(b)(1)(ii) to align our benchmark policy with concurrently made changes to our data submission terminology. These changes removed references to each individual benchmark and instead stated that benchmarks will be based on measure collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Additionally, in the 2023 PFS proposed rule, we (87 FR 46313) referred readers to the CY 2017 Quality Payment Program final rule and the CY 2021 PFS final rule (81 FR 77130 through 77136 and 85 FR 84871 through 84873 respectively) and § 414.1325(a)(2)(i) for our previously established policies regarding administrative claims measures in the quality performance category.

The policy at § 414.1325 provides that there is no data submission requirement for cost measures or administrative claims measures in the quality performance category as these measures are calculated on behalf of participants by CMS using administrative claims data. In the CY 2017 Quality Payment Program final rule (81 FR 77130), we finalized a policy that clinicians would be scored on applicable administrative claims-based global or population health (henceforth referred to only as population health measures) in addition to the six required submitted measures. Additionally, we established exclusions to the case minimum policy of 20 cases. It was found that the all-cause hospital readmission (ACR) measure was not reliable for cases under 200 and for groups of fewer than ten clinicians. As a result, we established exceptions to the case minimum policy for this measure and others as specified in the MIPS final list of quality measures through rule making

(§ 414.1380(b)(1)(iii)). In the CY 2021 PFS final rule (85 FR 84989 through 84901), we finalized a policy starting in the CY 2021 performance period/2023 MIPS payment year that would allow for performance periods longer than the standard 12-month performance period for administrative claims measures in the cost and quality performance categories as specified through rulemaking.

In the CY 2023 PFS proposed rule (87 FR 46313 and 46314), we proposed that, beginning with the CY 2023 performance period/2025 MIPS payment year, we would score administrative claims measures using benchmarks calculated using performance period benchmarks. We stated that we believe that using a performance period benchmark to score these measures would allow for scores that are more reflective of current performance, while adding no additional burden to clinicians. For the reasons described below, we believe it is more appropriate in certain circumstances to evaluate clinicians against current performance benchmarks. As previously noted, they do not require the submission of data by or on behalf of clinicians and may have a measure-specific performance period to ensure appropriate sample sizes. Additionally, in instances where these measures do not meet the case minimum or benchmark requirements, they are excluded from a MIPS-eligible clinician's quality performance category score.

The use of performance period benchmarks for such measures would help us to improve quality measurement. For example, the Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) has a 3-year performance period (consecutive 36-month timeframe) [540] that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, proceeding with a 3-month numerator assessment period (capturing complication outcomes) followed by a 2-month claims run-out period. For the CY 2023 performance period/2025 MIPS payment year, the 3-year (36 consecutive months) performance period for this measure would span from October 1, 2020 to September 30, 2023 with a 90-day numerator assessment period followed by a 60-day claims run-out period. This means that according to standard scoring policy, the corresponding baseline would include data from October 1, 2018 to September 30, 2021. We believe that comparison to data that precedes that standard 2-year baseline period may limit the usefulness of this measure. By comparing performance to data that was collected 5 years prior, this measure does not account for changes to the healthcare landscape and improvements in care that might have been made in the timeframe.

We noted that we do not believe using performance period benchmarks would increase burden to clinicians. We noted that we believe that clinicians prefer to have historical benchmarks to aid in measure selection and have performance targets. Additionally, population health administrative claims measures in MIPS are not subject to case minimum policies reducing the risk in being scored on these measures.

Accordingly, we proposed to add a paragraph at § 414.1380(b)(1)(ii)(D) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims-based quality measure using the performance on the measure during the current performance period. We noted that we do not intend this proposal to modify our existing policies regarding case minimums and measures for which no benchmark may be calculated. Specifically, measures would remain subject to case minimum requirements described in paragraph (b)(1)(iii) and benchmark requirements in paragraph (b)(1)(ii)(A) of this section. Measures that cannot have a benchmark calculated or meet case minimum requirements would still be deducted from the eligible clinician's total measure achievement points consistent with paragraph (b)(1)(i)(A)(*2*)(*ii*).

We sought public comment on the proposal to score administrative claims measures in the quality performance category using performance period benchmarks.

Comment: Many commenters supported our proposal to score administrative claims measures in the quality performance category using performance period benchmarks, agreeing that the use of performance period benchmarks would allow for scores that are more reflective of current performance and national practice. One commenter further noted that, as demonstrated during the COVID–19 PHE, the collection of administrative claims data can often change year to year and historical data is not always representative of the current environment, and by calculating a measure score based on performance period benchmarks, CMS can better compare performance or cost with more representative data. Another commenter noted that same-year scoring is especially helpful for clinicians in tracking their status, as well as measure stewards in maintaining their measures.

Response: We agree that using performance period benchmarks would be more reflective of current national practices will help clinicians track their progress over years and measure stewards maintain their measures. Through scoring administrative claims measures using performance period benchmarks, clinicians will be scored in a landscape that considers the most up-to-date guidance, practice, environmental effects. As these measures are calculated by CMS on behalf of the clinicians requiring no data submission, providing scores using performance period benchmarks will allow for the calculation of more representative scores that better track clinician performance and progress over time to aid in the quality improvement process.

Comment: A few commenters did not support our proposal to score administrative claims measures using performance period benchmarks based on concerns that using performance period benchmarks would negatively impact clinicians' ability to gauge their performance during the performance period by eliminating their ability to project quality performance category scores. Commenters noted that without historical benchmarks, it would be difficult to estimate scores and determine performance improvement opportunities. One commenter noted that using performance year benchmarks would make it impossible for clinicians to know ahead of time what each measure's performance benchmark is, and therefore, may make it more difficult to improve performance on the measure year after year.

Response: Administrative claims measures are calculated on behalf of clinicians and do not require additional submissions to MIPS to be calculated. We believe clinician efforts to estimate their performance on administrative claims with historical benchmarks are of limited use as the calculation of the measure may require data that is not easily accessible to the clinician. Moving from historical benchmarks to performance period benchmarks will not change this. We believe scoring

[540] Section 414.1320(e)(1) provides in relevant part that, beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures.

these measures using performance period benchmarks can help clinicians track progress over time by providing scores that are representative of current national trends thus aiding in identifying quality improvement opportunities in clinical practice overall and would not hinder in year to year comparisons.

Comment: While some commenters supported our proposal to score administrative claims measures using performance period benchmarks because they agreed the changes to timeframes would likely better represent current clinical care; they also expressed concerns that the proposal did not address their ongoing concerns with using a representative sample of historical data for quality measures of other submission types. In particular, these commenters noted that many of the baseline periods will include data from 2019, 2020, and 2021, all of which are impacted by the COVID–19 pandemic, and urged CMS to avoid using these data for benchmarking purposes. One commenter sought clarity on how much the pandemic impacted the historical information. To account for the impact of COVID–19 PHE on quality measure benchmarks, another commenter suggested that instead of using performance period benchmarks, CMS should instead calculate both historical benchmarks and current period benchmarks, and use the lower benchmark for each quality measure.

Response: We understand the concerns about the appropriateness of using data affected by the COVID–19 PHE to calculate historical benchmarks for quality measures. However, in the CY 2022 PFS final rule (86 FR 65494), we described our analysis of 2019 and 2020 data quality performance data, which found this data are suitable for benchmarking purposes. We maintain that this data is sufficiently representative and we will use this data to calculate benchmarks for Medicare Part B claims measures, eCQMs, MIPS CQMs, and QCDR measures. For this reason, we did not propose any changes to the calculation of benchmarks of quality measures of other submission types and will continue to provide historical benchmarks for such measures in order to aid clinicians in quality improvement efforts using these performance targets.

After consideration of public comments and for the reasons stated above and in the CY 2023 PFS proposed rule (87 FR 46313 and 46314), we are finalizing our proposals to score administrative claims measures in the quality performance category using performance period benchmarks as proposed.

(ii) Assigning Measure Achievement Points for Topped Out Measures

Section 1848(q)(3)(B) of the Act requires that, in establishing performance standards with respect to measures and activities, the Secretary consider, among other things, the opportunity for continued improvement. As part of our implementation of section 1848(q)(3)(B) of the Act, we established our topped out measure policy, which is intended to encourage clinicians to focus on areas where clinical improvement is possible by capping the points received for reporting on MIPS measures where meaningful distinctions in clinical performance are no longer measurable. We refer readers to § 414.1380(b)(1)(iv)(B) for our policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we identify topped out measures in the benchmarks published for each performance year. Under § 414.1380(b)(1)(iv)(B), beginning with the CY 2019 performance period/2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 and 53727).

We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77286) that we would define topped out process measures as those with a median performance rate of 95 percent or higher (§ 414.1305). We defined topped out non-process measures using a definition similar to the definition used in the Hospital Value-Based Purchasing (VBP) Program: a measure where the truncated coefficient of variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors (81 FR 77286). When a measure is topped out, a large majority of clinicians submitting the measure perform at or very near the top of the distribution; therefore, there is little or no room for the majority of MIPS eligible clinicians who submit the measure to improve. We noted that we understand that each measure we have identified as topped out may offer room for improvement for some MIPS eligible clinicians; however, we believe asking clinicians to submit measures that we have identified as topped out and measures for which the vast majority of MIPS eligible clinicians already excel is an unnecessary burden that does not add value or improve beneficiary outcomes.

In the CY 2018 Quality Payment Program final rule, we finalized that, beginning in the CY 2019 performance period/2021 MIPS payment year, each measure (excluding measures in the CMS Web Interface) that is identified as topped out for two or more consecutive years can receive no more than 7 points in the second year that is it identified as topped out and beyond (82 FR 53726 through 53727). A measure is identified as topped out for a given performance period by assessing its historical benchmark. Two consecutive historical benchmarks must be labeled as topped out for the 7-point cap to be applied for a given performance period. For example, for the CY 2023 performance period/2025 MIPS payment year, a measure is considered topped out if the historical benchmark calculated from data submitted in the CY 2021 performance period has a median performance of 95 percent or higher in the case of process measures or the truncated coefficient of variation is less than 0.10 and the 75th and 90th percentiles are within two standard errors in the case of non-process measures. If this same measure is identified as topped out again for the CY 2024 performance period/2026 MIPS payment year from data from the historical baseline period from CY 2022, this measure would be labeled as topped out and have the 7-point cap applied until the historical baseline period shows that the measure is no longer topped out or the measure is removed from the program. We noted that we believe this methodology incentivizes MIPS eligible clinicians to begin submitting non-topped out measures without performing below the median score. The methodology also does not impact scoring for those MIPS eligible clinicians that do not perform near the top of the measure, and therefore, have significant room to improve on the measure.

In the CY 2021 PFS final rule (85 FR 84989 through 84901), we finalized a policy at § 414.1380(b)(1)(vii)(A) that consolidated previously established scoring flexibilities regarding the truncation of a quality measure's performance period to 9-months of data from the CY 2018 Quality Payment Program final rule (82 FR 52714 through 53716) and the measure suppression policy established in the CY 2019 PFS final rule (FR 59845 through 59847). The updated scoring flexibilities policy stated that, beginning with the CY 2021 performance period/2023 MIPS payment year, CMS would truncate the performance period or suppress a

quality measure if CMS determined that revised clinical guidelines, measure specifications, or codes impacted a clinician's ability to submit information on the measure or may lead to potentially misleading results (85 FR 84899 through 84901). We stated that, based on the timing of the changes to clinical guidelines, measure specifications or codes, we will assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we will suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted (85 FR 84899). In the CY 2022 PFS final rule (86 FR 65491 and 65492), the scope of the truncation and suppression policy was expanded to include errors that are outside the control of the clinician, such as an incorrect coding status.

As discussed in the CY 2023 PFS proposed rule (87 FR 46314 and 46315), we clarified the interaction of our topped-out measure policy and our measure truncation and measure suppression policies. First, we noted that not all instances in which a measure lacks a benchmark affect the scoring of the measure equally. For example, when a measure is suppressed in the baseline period for the incorrect inclusion of an inactive status code in the measure specifications, the measure could resume to be scored comparably once the measure specifications are accurate in both the baseline and applicable performance period. Conversely, a measure that was suppressed or had its performance period truncated because it underwent a substantive change could not be comparably scored to past data. In a case like the former, it is not until the suppressed or otherwise affected data is in the baseline period that the topped-out measure lifecycle is affected. A measure that lacks a benchmark for a performance period due to the suppression of data in the measure's baseline period will not have the 7-point cap applied for that performance period. This is because the measure lacks the two topped out historical performance periods necessary for the application of the cap. This does not preclude, however, CMS determining that the measure is topped out for the performance period. In the case of a measure that lacks a baseline period, CMS may base the benchmark on performance during the applicable performance period (see § 414.1380(b)(1)(ii)). Determining the measure was topped out during the performance period would thus require only that MIPS eligible clinician data for the performance period met the topped-out measure standard. In such a case, the 7-point cap could next be applied as soon as the following year.

Where a measure was suppressed or had its performance period truncated because of a substantive change or a change in clinical guidelines, the topped-out measure resets entirely the year following the change as there is no longer a historical benchmark with which to compare the measure for the purpose of determining whether it is topped out.

(c) Cost Performance Category Score

(i) Improvement Scoring Methodology

In the CY 2018 Quality Payment Program final rule, we established policies related to measuring improvement in the cost performance category at the measure level, an improvement scoring methodology for the cost performance category, and a formula for calculating the cost performance category score [541] to include achievement and improvement (82 FR 53748 through 53752). These policies were to apply beginning with the CY 2018 performance period/2020 MIPS payment year. We codified these policies under § 414.1380(b)(2)(iii) and (iv) (82 FR 53748 through 53752, 53957). Subsequent to the publication of that final rule, the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123, enacted February 9, 2018) was enacted. Section 51003(a)(1)(B) of the BBA 18 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take in to account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. In the CY 2019 PFS proposed rule, we stated that we do not believe this statutory change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category score for each of the CY 2020 through 2023 MIPS payment years (83 FR 35956). Therefore, we proposed to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the CY 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points (83 FR 35956). We stated that under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the CY 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under the proposal, the maximum cost improvement score for the CY 2020 MIPS payment year would be zero percentage points (83 FR 35956). We also proposed at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category score will not take in to account improvement until the CY 2024 MIPS payment year (83 FR 35956). In the CY 2019 PFS final rule, we finalized these proposals as proposed (83 FR 59856).

In prior rulemaking, we inadvertently failed to address what the maximum cost improvement score would be under § 414.1380(b)(2)(iv)(E) beginning with the CY 2022 performance period/2024 MIPS payment year. As we stated previously in the CY 2019 PFS proposed and final rules (83 FR 35956 and 83 FR 59856, respectively), we do not believe the changes made to section 1848(q)(5)(D) of the Act by section 51003(a)(1)(B) of the BBA 18 required us to remove our existing methodology for scoring improvement in the cost performance category. Thus, in the CY 2019 PFS final rule, we maintained the methodology we had previously established under § 414.1380(b)(2)(iii) and (iv), while modifying § 414.1380(b)(2)(iv)(E) to reflect the statutory change made by section 51003(a)(1)(B) of the BBA 18. Section 1848(q)(5)(D) of the Act requires us to take in to account the improvement of the MIPS eligible clinician when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year) and for subsequent years. In the CY 2023 PFS proposed rule (87 FR 46315 through 46316), we proposed to establish a maximum cost improvement score of 1 percentage point for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year. A maximum cost improvement score of 1 percentage point was the policy we established previously, before the amendments made by section 51003(a)(1)(B) of the BBA 18 with respect to the second, third, fourth, and fifth years of MIPS. In the CY 2023 PFS proposed rule (87 FR 46316), we stated that we believe that this policy is still appropriate at this time because although there are many

[541] In the CY 2022 PFS final rule, we changed the term ''performance category percentage score'' to ''performance category score'' (86 FR 65490 through 65491). As a result of such terminology change in the CY 2022 PFS final rule, this final rule uses the term ''performance category score'' in all descriptions of the cost improvement scoring proposal and finalized policy.

opportunities for clinicians to actively work on improving their performance on cost measures, such as through more active care management or reductions in certain services, we recognize that many clinicians are still learning about cost measurement under MIPS. We aim to continue to educate clinicians about cost measurement and develop opportunities for robust feedback and measures that better recognize the role of clinicians. Clinicians are navigating and overcoming the obstacles of the COVID–19 public health emergency while having to familiarize themselves with new policies we have adopted for MIPS, such as the establishment of MVPs as a voluntary means for participation starting with the CY 2023 performance period that could become a mandatory means of participation, the opportunity for subgroup participation and reporting, the sunset of the CMS Web Interface as a collection/submission type and transition to other collection and submission types for CMS Web Interface users starting with the CY 2023 performance period, and the implementation of new cost measures. As the CY 2022 performance period/2024 MIPS payment year is the first program year we will be measuring improvement for the cost performance category, we stated that we believe it would be appropriate to begin gradually with a maximum cost improvement score of 1 percentage point—a policy clinicians already would be familiar with from prior rulemaking. In a future year, we may consider and assess the possibility of increasing the maximum cost improvement score.

As we stated in the CY 2023 PFS proposed rule, to the extent that the proposed change constitutes a change to the MIPS scoring or payment methodology for the CY 2024 MIPS payment adjustment after the start of the CY 2022 performance period, we believe that, consistent with section 1871(e)(1)(A)(i) of the Act, it is necessary to comply with the requirement of section 1848(q)(5)(D) of the Act that we take in to account the improvement of the MIPS eligible clinician when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year) (87 FR 46316). Also, we stated that we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to fill the gap in our existing methodology for scoring improvement in the cost performance category for the CY 2022 performance period/2024 MIPS payment year (87 FR 46316). Currently, the improvement scoring methodology for the cost performance category under § 414.1380(b)(2)(iv)(E) does not include a maximum cost improvement score for the CY 2022 performance period/2024 MIPS payment year. We stated (87 FR 46316) that the proposal would correct this deficiency by establishing a maximum cost improvement score of 1 percentage point beginning with the CY 2022 performance period/2024 MIPS payment year. In addition, we stated that it would be contrary to the public interest not to comply the statutory requirement of section 1848(q)(5)(D) of the Act to take in to account improvement when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year).

In the CY 2023 PFS proposed rule, we proposed corresponding changes to § 414.1380(b)(2)(iv)(E) to reflect the proposal (87 FR 46316). We solicited public comment on the proposal to establish a maximum cost improvement score of 1 percentage point for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year. The following is a summary of the public comments received.

Comment: Several commenters supported the proposal to establish a maximum cost improvement score of 1 percentage point for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year to satisfy statutory requirements. Commenters stated that the proposal would clarify improvement scoring policy and appreciated the recognition from CMS that many physicians continue to adapt to cost measurement under MIPS.

Response: We appreciate the support from commenters.

Comment: One commenter expressed support for the proposal, but encouraged CMS to delay increasing the maximum cost improvement score in future years in order to allow clinicians further flexibility while they become accustomed to the cost measures and continue to navigate practicing throughout the ongoing COVID–19 pandemic.

Response: We appreciate the support from the commenter. We recognize that the COVID–19 PHE may have continued to impact some MIPS eligible clinicians, groups, and virtual groups more than others during the CY 2022 performance period/2024 MIPS payment year. We will consider whether to increase the maximum cost improvement score above 1 percentage point in future rulemaking.

Comment: One commenter expressed appreciation for the ongoing refinement of the cost performance category, but requested that CMS elaborate on how the maximum cost improvement score of 1 percentage point would be implemented under MIPS.

Response: In the CY 2018 Quality Payment Program final rule, we noted that we will calculate a cost improvement score only when data sufficient to measure improvement is available (82 FR 53749 and 53750). We consider sufficient data to be available when a MIPS eligible clinician participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods (82 FR 53749 and 53750) (for example, in the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year). If the cost improvement score cannot be calculated due to sufficient data not being available, we assign a cost improvement score of zero percentage points (82 FR 53749 and 53750). We quantify improvement in the cost performance category by comparing the number of cost measures with a significant improvement in performance (statistically significant change) and the number of cost measures with a significant decline in performance (statistically significant change) (82 FR 53750 through 53752). To determine whether there was a significant improvement or decline in performance between the two performance periods, we apply a common standard statistical test, a t-test (82 FR 53750 through 53752). To determine the cost improvement score, we subtract the number of cost measures with a significant decline from the number of cost measures with a significant improvement, then divide the result by the number of cost measures for which the MIPS eligible clinician or group was scored for 2 consecutive performance periods, and then multiply the result by the maximum improvement score (82 FR 53750 through 53752). The cost improvement score cannot be lower than zero percentage points (82 FR 53750 through 53752).

Under our proposal, the maximum cost improvement score available in the cost performance category would be 1 percentage point out of 100 percentage points available for the cost performance category score. If a clinician is measured on only one cost measure consistently from one performance period to the next and met the requirements for improvement (statistically significant levels of

change), the clinician would receive one improvement percentage point in the cost performance category score. If a clinician were measured on 2 cost measures consistently, improved significantly on one cost measure, and did not demonstrate significant improvement on the other cost measure (as measured by a t-test), the clinician would receive 0.5 improvement percentage points (82 FR 53751).

We calculate the overall cost performance category score with the assessment of achievement and improvement based on the following formula.

- (Cost Achievement Points/Available Cost Achievement Points) + (Cost Improvement Score) = (Cost Performance Category Score).

In Table 96, we provide an example of cost performance category scores along with the determination of improvement or decline (82 FR 53752). The example pertains to group-level reporting where a group is measured on both the Total Per Capita Cost measure and the Medicare Spending Per Beneficiary (MSPB) Clinician [542] measure for 2 consecutive performance periods.

TABLE 96: Example of Assessing Achievement and Improvement in the Cost Performance Category

Measure	Measure Achievement Points Earned by the Group	Total Possible Measure Achievement Points	Significant Improvement from Prior Performance Period	Significant Decline from Prior Performance Period
Total Per Capita Cost (TPCC) Measure	8.2	10	Yes	No
Medicare Spending Per Beneficiary (MSPB) Clinician Measure	6.4	10	No	No
Total	**14.6**	**20**	**N/A**	**N/A**

In the example, there are 20 total possible measure achievement points and 14.6 measure achievement points earned by the group, and the group improved on one measure but not the other, with both measures being scored in each performance period. The first part of the formula is calculating (Cost Achievement Points/Available Cost Achievement Points) which is 14.6/20, which equals 0.730 and can be represented as 73.0 percent. The cost improvement score will be determined as follows: ((1 measure with significant improvement—zero measures with significant decline)/2 measures) * 1 percentage point = 0.5 percentage points. Under the formula, the cost performance category score will be (14.6/20 or 73.0 percent) + 0.5 percent = 73.5 percent. To determine how many points the cost performance category contributes to the final score, we will multiply the performance category score (73.5 percent) by the weight of the cost performance category (10 percent of the final score) and by 100 to determine the points to the final score. The group would have 73.5 percent × 10 percent × 100 = 7.35 points for the cost performance category contributed towards the final score.

Comment: One commenter did not support the proposal to establish a maximum cost improvement score of 1 percentage point for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year. The commenter requested that CMS increase the maximum cost improvement score to at least 5 percentage points due to the cost performance category's significant impact on a clinician's total MIPS final score.

Response: The cost performance category composes 10 percent of the MIPS final score.

As individual MIPS eligible clinicians, groups, and virtual groups continue to become acquainted with the cost measures and gain experience in understanding their cost performance, we believe that establishing a maximum cost improvement score of 1 percentage point for the cost performance category is appropriate at this juncture. In a future year, we may consider and assess the possibility of increasing the maximum cost improvement score.

After consideration of public comments, we are finalizing our proposal to establish a maximum cost improvement score of 1 percentage point for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year as well as the corresponding revisions to § 414.1380(b)(2)(iv)(E).

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for each MIPS eligible clinician, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, respectively) on final score calculations, performance category weights, reweighting the performance categories, and the complex patient bonus.

As described in more detail in the following sections, in the CY 2023 PFS proposed rule (87 FR 46316 through 46319), we:

- Proposed that a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus.
- Requested information on which additional risk indicators and data sources we should consider for use within the complex patient bonus formula to better assess the social and medical complexity for the patients of MIPS eligible clinicians.
- Proposed that virtual groups would be eligible for facility-based measurement.

[542] In the CY 2020 PFS final rule, the name of this cost measure was changed from ''Medicare Spending Per Beneficiary (MSPB)'' to ''Medicare Spending Per Beneficiary (MSPB) Clinician'' (84 FR 62974 through 62977). The example outlined in this final rule was previously outlined in the CY 2018 Quality Payment Program final rule (82 FR 53572); however, the name of this cost measure in this final rule reflects the name change as outlined in the CY 2020 PFS final rule (84 FR 62974 through 62977).

• Proposed changes to the definition of a facility-based MIPS eligible clinician.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the CY 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the CY 2021, 2022, and 2023 MIPS payment years (83 FR 59870, 84 FR 63023, and 85 FR 84910, respectively). Additionally, we finalized for the CY 2022 and 2023 MIPS payment years at § 414.1380(c)(3)(iv) that the complex patient bonus will be calculated under the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2, but cannot exceed 10.0 (85 FR 84911 through 84913 and 86 FR 65510 and 65511, respectively). Finally, beginning with the CY 2022 performance period/2024 MIPS payment year, we revised the complex patient bonus by: (1) limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (Hierarchical Condition Category (HCC)and dual proportion); (2) standardizing the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients; and (3) providing one overall complex patient bonus cap at 10 bonus points (86 FR 65511 through 65519). We refer readers to the final rules cited above for additional details on the background, statutory authority, policy rationale, and calculation of the complex patient bonus.

(ii) Eligibility for the Complex Patient Bonus

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1380(c)(3) a complex patient bonus for MIPS eligible clinicians, groups, APM Entities, and virtual groups that submit data for at least one MIPS performance category during the applicable performance period, which will be added to the final score (82 FR 53771 through 53776). In the CY 2018 Quality Payment Program proposed rule, we proposed that a MIPS eligible clinician, group, virtual group or APM Entity must submit data on at least one measure or activity in a performance category during the performance period to receive the complex patient bonus (82 FR 30138). We stated that under this proposal, MIPS eligible clinicians would not need to meet submission requirements for the quality performance category to receive the bonus (they could instead submit improvement activities or Promoting Interoperability performance category measures only or submit fewer than the required number of measures for the quality performance category). In the CY 2018 Quality Payment Program final rule, we also established facility-based measurement for certain MIPS eligible clinicians under the authority in section 1848(q)(2)(C)(ii) of the Act, which provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories (82 FR 53752 through 53767). We did not address whether facility-based MIPS eligible clinicians would be eligible to receive the complex patient bonus. Under the scoring methodology for facility-based measurement under § 414.1380(e), there are no data submission requirements for individual clinicians to be scored under facility-based measurement (§ 414.1380(e)(4)). In the CY 2023 PFS proposed rule (87 FR 46317), we stated that although individual facility-based MIPS eligible clinicians are not required to submit data for at least one MIPS performance category, and it is possible they may choose not to submit data voluntarily, we believe they should be eligible to receive the complex patient bonus. As with other MIPS eligible clinicians who submit data for the quality performance category, we are able to score this performance category for facility-based MIPS eligible clinicians based on quality measure data available to us pursuant to the methodology described under § 414.1380(e). Thus, we proposed that beginning with the CY 2023 performance period/2025 MIPS payment year, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category (87 FR 46317). We proposed corresponding revisions to § 414.1380(c)(3). We sought comments on the proposal.

The following is a summary of the public comments received on the proposal that a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category and our responses:

Comment: Many commenters supported our proposal that, beginning with the CY 2023 performance period/2025 MIPS payment year, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if the clinician does not submit data for at least one MIPS performance category. A few commenters specifically supported this policy proposal because they stated that policies such as this can help to reduce access to care issues, advance health equity by recognizing physicians who work harder to treat more complex patients, and ultimately improve patient care. One commenter encouraged CMS to continue to identify additional opportunities to reward care that is provided to complex patients.

Response: We agree with the noted benefits of the policy and note that CMS continues to identify additional opportunities to reward care that is provided to complex patients. We refer readers to CY 2023 PFS proposed rule in which we have a request for information on risk indicators within the complex patient bonus formula to continue to align with CMS's approach to operationalizing health equity (87 FR 46317 through 46319).

After consideration of public comments, we are finalizing our proposal that beginning with the CY 2023 performance period/2025 MIPS payment year, a facility-based MIPS eligible clinician is eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category, and the corresponding revisions to at § 414.1380(c)(3).

(iii) Request for Information on Risk Indicators for the Complex Patient Bonus Formula

The CY 2023 PFS proposed rule contained a request for information on risk indicators within the complex patient bonus formula to continue to align with CMS's approach to operationalizing health equity (87 FR 46317 through 46319).

We thank commenters for their responses to this request for information. We may consider this information to inform future rulemaking.

(b) Facility-Based Measurement

(i) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767), we established facility-based measurement under the authority in section 1848(q)(2)(C)(ii) of the Act for certain MIPS eligible clinicians. We established facility-based measurement to better align incentives between facilities and the MIPS eligible clinicians who provide services there (82 FR 53753). Scoring under facility-based measurement was available for clinicians beginning with the CY 2019 performance period/2021 MIPS payment year. In the CY 2022 PFS final rule, we finalized at § 414.1380(e)(6)(vi)(B) that for clinicians and groups eligible for facility-based measurement, beginning with the CY 2022 performance period/2024 MIPS payment year, the MIPS quality and cost performance category scores for such clinicians and groups will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission (86 FR 65526 and 65527). For more background on facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767), the CY 2019 PFS final rule (83 FR 59856 and 59867), the CY 2020 PFS final rule (84 FR 63018 through 63020), and the CY 2022 PFS final rule (86 FR 65526 and 65527).

(A) Eligibility for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53756 and 53757), we finalized individual eligibility criteria for facility-based measurement at § 414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service (POS) codes used in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS is eligible as an individual for facility-based measurement. We specified that we would use the definition of professional services provided in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). In the CY 2019 PFS final rule, we added the on-campus outpatient hospital (POS code 22) to the list of sites of service we consider when determining eligibility for facility-based measurement (83 FR 59857 through 59860). Additionally, we required that clinicians bill at least one covered professional service in a site of service identified by the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement. We codified these standards in § 414.1380(e)(2)(i)(A) and (B). We also finalized that we must be able to attribute a clinician to a particular facility that has a value-based purchasing score under the methodology specified in § 414.1380(e)(5) in order for the clinician to be eligible for facility-based measurement (§ 414.1380(e)(2)(i)(C)).

Separately, in the CY 2018 Quality Payment Program final rule (82 FR 53759), we defined a facility-based group as a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements described above.

As we clarified and expanded our definition of a facility-based MIPS eligible clinician, we intended to allow MIPS eligible clinicians participating in virtual groups to be eligible for facility-based measurement using the same standards applicable to individual MIPS eligible clinicians and groups. We intended this because, just like individual clinicians and groups, some virtual groups may predominantly practice within a hospital setting and their MIPS eligible clinicians may otherwise be eligible for facility-based measurement based on the eligibility standards established at § 414.1380(e)(2)(i)(A) through (C) were they to participate in MIPS individually or as a group. However, we did not specify at § 414.1380(e)(2) that virtual groups may be eligible for facility-based measurement. Therefore, we proposed in the CY 2023 PFS proposed rule to revise § 414.1380(e)(2) to permit facility-based measurement of a virtual group so long as it meets the specified eligibility standards beginning with the CY 2023 performance period/CY 2025 MIPS payment year (87 FR 46319). Additionally, we also proposed to revise § 414.1380(e)(2) to specify, consistent with our prior discussion of the matter (82 FR 53757), that a MIPS eligible clinician is eligible for facility-based measurement only if CMS determines it eligible to be facility-based. We sought comments on these proposals.

The following is a summary of the public comments received on the proposals regarding eligibility for facility-based measurement and our responses:

Comment: A few commenters supported our proposal to permit facility-based measurement of a virtual group so long as it meets the specified eligibility standards beginning with the CY 2023 performance period/2025 MIPS payment year.

Response: We thank the commenters for their support.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46319), we are finalizing our proposal to revise § 414.1380(e)(2) to permit facility-based measurement of a virtual group beginning with the CY 2023 performance period/2025 MIPS payment year as proposed. Additionally, we are also finalizing our proposal to revise § 414.1380(e)(2) to specify that a MIPS eligible clinician is eligible for facility-based measurement only if CMS determines it eligible to be facility-based as proposed.

(B) Definition of Facility-Based MIPS Eligible Clinician

In the CY 2018 Quality Payment Program final rule, we finalized the definition of a facility-based MIPS eligible clinician at § 414.1305 (82 FR 53578). In the CY 2019 PFS final rule, we finalized additions to the determination of eligibility for facility-based measurement as reflected in the regulation text at § 414.1380(e)(2)(i)(A), (B), and (C) (83 FR 59856 through 59860); however, we inadvertently did not update the definition of a facility-based MIPS eligible clinician at § 414.1305 to reflect these additions. Therefore, we proposed in the CY 2023 PFS proposed rule (87 FR 46320) to revise the facility-based MIPS eligible clinician definition at § 414.1305 to align with the current policies at § 414.1380(e)(2)(i)(A), (B), and (C). We also proposed to revise the terminology within § 414.1380(e) to align with the

terminology used in the definition of a facility-based MIPS eligible clinician at § 414.1305. We sought comments on the proposals.

We did not receive any comments on our proposal to revise the terminology within § 414.1305 to align with the current policies at § 414.1380(e)(2)(i)(A), (B), and (C). We also did not receive any comments on our proposal to revise the terminology within § 414.1380(e) to align with the terminology used in the definition of a facility-based MIPS eligible clinician at § 414.1305 and for the reasons stated above and in the proposed rule (87 FR 46319), we are finalizing the revisions as proposed.

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used to determine MIPS payment adjustments, we refer readers to the CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In the CY 2023 PFS proposed rule (87 FR 46319 through 46323), we proposed to establish the performance threshold for the CY 2025 MIPS payment year using CY 2019 MIPS payment year data. In addition, we included information about our timing for providing MIPS performance feedback to clinicians for the performance period in 2021.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which required the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the CY 2021 through CY 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the CY 2024 MIPS payment year) to which the MIPS applies.

We applied these special rules for the first 5 years of MIPS to provide for a gradual and incremental transition to the performance we estimated for the sixth year of MIPS (the CY 2024 MIPS payment year). In the CY 2022 PFS final rule, we set the performance threshold at 75 points for the CY 2024 MIPS payment year (86 FR 65532). For further information on the performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53794), CY 2019 PFS final rule (83 FR 59880 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), and CY 2022 PFS final rule (86 FR 65527 through 65532). We codified the performance thresholds for each of the first 6 years of MIPS at § 414.1405(b)(4) through (9), as shown in Table 97.

TABLE 97: Performance Thresholds for the CY 2019 MIPS Payment Year through CY 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year
Performance Threshold	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
	3 points	15 points	30 points	45 points	60 points	75 points
Difference in Performance Threshold (Year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points	15 points

Beginning with the CY 2024 MIPS payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every 3 years. In the CY 2022 PFS final rule (86 FR 65527 through 65532), we

selected the mean as the methodology for determining the performance threshold for each of the CY 2024, 2025, and 2026 MIPS payment years. We intend to reassess and establish the methodology (mean or median) that we will use to determine the performance threshold for each of the next 3 years (CY 2027 MIPS payment year, CY 2028 MIPS payment year, and CY 2029 MIPS payment year) in future rulemaking.

In the CY 2023 PFS proposed rule (87 FR 46320), we stated that while we identified the mean as our methodology for determining the performance threshold for MIPS payment years CY 2024 through 2026, we have not specified which prior period's mean final score we would use for the CY 2025 MIPS payment year's performance threshold. We stated that from our review of the data available to us, we identified the mean final scores for each of the CY 2019 through 2022 MIPS payment years, as shown in Table 98. We stated that these four values represent the mean final scores for all MIPS eligible clinicians from prior periods that are available for consideration for the CY 2025 MIPS payment year performance threshold. We stated that the final scores for the CY 2021 performance period/2023 MIPS payment year were not finalized in time for the CY 2023 PFS proposed rule; thus, the mean final score for the CY 2023 MIPS payment year was not listed and considered as a potential performance threshold value for the CY 2025 MIPS payment year.

TABLE 98: Possible Values for the CY 2025 MIPS Payment Year Performance Threshold

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year
Mean	74.65 Points	87 Points	85.63 Points	89.47

As shown in Table 98, the mean final scores available for consideration for the CY 2025 MIPS payment year performance threshold cover a range of values from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). In the CY 2023 PFS proposed rule (87 FR 46321), we proposed to use the CY 2019 MIPS payment year as the prior period for the purpose of determining the performance threshold for the CY 2025 MIPS payment year for several reasons. We noted that we expect the mean final score for the CY 2023 performance period/2025 MIPS payment year to be lower than the mean final scores from the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. In the CY 2022 PFS final rule (86 FR 65491 through 65507), we removed transition policies such as quality bonus points that had been established for scoring the quality performance category for the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. Additionally, for the CY 2019 through 2021 performance periods/CY 2021 through 2023 MIPS payment years, we applied certain extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 Public Health Emergency (PHE), which resulted in the reweighting of some performance categories if data were not submitted for a MIPS eligible clinician. In setting the performance threshold for the CY 2025 MIPS payment year, we stated that we believe we should consider the elimination of those transition policies, as well as the possibility that the performance categories will not be reweighted for as many MIPS eligible clinicians for the CY 2023 performance period/2025 MIPS payment year. Further, we stated that continuing to use the mean final score from the CY 2019 MIPS payment year to determine the performance threshold for the CY 2025 MIPS payment year would maintain stability in the program. We stated that we believe continuing to use the mean final score from the CY 2019 MIPS payment year would provide predictability to MIPS eligible clinicians during a program year in which they might be affected by those prior policy changes, as well as potentially scored on performance categories that were previously reweighted due to the PHE.

In the CY 2023 PFS proposed rule (87 FR 46321), we stated that the Regulatory Impact Analysis (RIA) estimates that approximately a third of MIPS eligible clinicians who engage in MIPS would receive a negative payment adjustment for the CY 2023 performance period/2025 MIPS payment year if the proposed policies are finalized and the performance threshold is equal to 75 points. However, we stated that we estimated that final scores for many clinicians for the CY 2023 performance period/2025 MIPS payment year would be close to the proposed performance threshold of 75 points; therefore, the actual observed percentage of clinicians receiving negative payment adjustments may slightly differ from the RIA estimates. We referred readers to the alternatives considered in the proposed rule RIA (87 FR 46428). The RIA of this final rule as described in section VII.E.16. estimates the impact of the policies finalized in this rule, including finalizing the proposed performance threshold of 75 points, and incorporates updated data sources. The estimate that approximately a third of MIPS eligible clinicians would receive a negative payment adjustment remains unchanged. We refer readers to the alternatives considered in the RIA in section VII.F.6. of this final rule where we present the impact of using data from alternative years to determine the performance threshold for the CY 2025 MIPS payment year. We intend to revisit in future rulemaking whether we should use a different prior period to establish the performance threshold for future MIPS payment years.

Under our proposal to use the CY 2019 MIPS payment year as the prior period for the purpose of determining the performance threshold for the CY 2025 MIPS payment year (87 FR 46321), as well as the methodology we established previously at § 414.1405(g), the performance threshold for the CY 2025 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2019 MIPS payment year, which is 75 points (rounded from 74.65 points). We proposed corresponding changes to § 414.1405(b)(9) to reflect this proposal (87 FR 46321). We requested public comments on this proposal, as well as whether we should use data from alternative years to set the performance threshold for the CY 2025 MIPS payment year, which we considered and discussed in the RIA of the CY 2023 PFS proposed rule (87 FR 46428). The

following is a summary of the comments received and our responses.

Comment: Many commenters supported the proposal to use the mean from the CY 2019 MIPS payment year and to set the performance threshold at 75 points for the CY 2025 MIPS payment year. Several commenters stated that maintaining the performance threshold at 75 points is needed due to the challenges of the PHE, which made prioritizing MIPS performance and reporting for clinicians difficult, especially for small practices. A few commenters expressed that sustaining the 75-point performance threshold would motivate eligible clinicians and groups to report for MIPS because the commenters believed there would likely be more funds available for redistribution. One commenter stated that a prospective increase in MIPS reporting would help to close any gaps in data quality due to the observed decline in reporting from the PHE. Another commenter stated that this may be the first time since the PHE that many clinicians will be reporting for MIPS and therefore maintaining the performance threshold at 75 points is appropriate.

Response: We agree that setting the performance threshold to the lowest of the available possible values (75 points), using the CY 2019 MIPS payment year final score mean, would alleviate performance burden and promote stability as clinicians handle the demands of the COVID–19 PHE. We appreciate the commenters' observations regarding the expected increase in participation and hope our policies encourage MIPS eligible clinicians to submit data for MIPS.

Comment: Several commenters indicated that using data from prior to the PHE is important and would provide stability and predictability for MIPS eligible clinicians, allowing time for recovery from the PHE before increased minimum thresholds are introduced. While supportive of the proposed performance threshold, one commenter stated that data from the CY 2019 through CY 2021 MIPS performance periods would be inappropriate for CMS to use to determine future performance thresholds due to the application of the extreme and uncontrollable circumstances policies for those years, which the commenter believed caused fewer clinicians to submit MIPS data. The commenter asserted that many clinicians who might have received a score below the performance threshold for those years did not submit data due to the automatic extreme and uncontrollable circumstances policy, and therefore, the commenter asserted that the mean and median values for those years are artificially high. The commenter recommended CMS take action to lessen the impact of a high performance threshold, especially given the removal of transition policies, such as the additional positive adjustment for exceptional performance and bonuses within the quality performance category.

Response: We acknowledge the commenter's concern with using the CY 2019 through CY 2021 performance period data and the possible implications of the application of the extreme and uncontrollable circumstances policies under § 414.1380(c)(2)(i)(A)(*8*) and (c)(2)(i)(C)(*3*), and § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*). The application of these policies meant that the performance categories could be reweighted for many MIPS eligible clinicians, and we agree that this may have caused some clinicians to not report data for MIPS. As we explained in the CY 2023 PFS proposed rule (87 FR 46321), this was one reason why we proposed to use the mean final score from the CY 2017 MIPS performance period/2019 MIPS payment year. We may take the commenter's concerns into consideration as we continue to reassess yearly which prior period to use to determine the performance threshold.

Comment: A few commenters suggested that CMS continue monitoring yearly changes in mean and median final scores as future performance thresholds are determined and requested more detailed information on how different specialties and practices would be impacted by any change in the performance threshold. The commenters also requested that CMS provide the latest performance period data for determining future performance thresholds as early as possible and continue using the lowest available mean or median final score given that the commenters believed that MIPS is a constantly evolving program and scores will likely be lower than the early years.

Response: We understand the importance of examining how different specialties are performing in MIPS relative to the established performance threshold. We expect to continue to regularly report the performance period data used to determine the performance threshold value for future years. Information on a prior year's final scores can be found in the corresponding Quality Payment Program Experience Report while specialty-specific information can be found in the Public Use File in the QPP resource library (*https://qpp.cms.gov/resources/resource-library*).

Comment: One commenter suggested CMS develop a strategy for providing support for re-entry into MIPS after the conclusion of the extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) that were applied to MIPS eligible clinicians nationwide due to the COVID–19 PHE. In addition, the commenter recommended CMS require groups to supply sufficient documentation to support their significant hardship application for the Promoting Interoperability performance category and their application for extreme and uncontrollable circumstances for other MIPS performance categories; noting that although automatic extreme and uncontrollable circumstances policies may provide widespread burden relief, they discourage quality improvement at the local and national level.

Response: We appreciate the commenter's suggestions to develop a strategy for providing support for re-entry into MIPS and to require groups to provide sufficient documentation of hardship. Although documentation is not required to be submitted with the extreme and uncontrollable circumstance application, we do review clinicians' ability to collect and submit data for each performance category, considering the event circumstances and the length of time the clinicians were impacted. We detail the criteria and circumstances for the extreme and uncontrollable circumstances policies and Promoting Interoperability performance category hardship policies at *https://qpp.cms.gov/mips/exception-applications?py=2022#extremeCircumstancesException-2022*. We will continue to ensure the appropriate education and resources are available to help guide clinicians and practices through the application process and through the resumption of data reporting.

Comment: Several commenters did not support the proposal to set the performance threshold to 75 points for the CY 2025 MIPS payment year and asked CMS to explore ways to use its authority to lower the performance threshold starting in the CY 2023 performance period and to extend the $500 million of funding available under section 1848(q)(6)(F)(iv) of the Act. One commenter requested CMS apply the automatic extreme and uncontrollable circumstances policy for the CY 2022 performance period and conduct targeted outreach and education to assist clinicians and group practices due to the belief that clinicians continue to face challenges stemming from the

impacts of the COVID–19 public health emergency.

Response: As previously discussed, the statute requires us to set the performance threshold at the mean or median of a prior period's final scores. The mean final score from the CY 2017 performance period/2019 MIPS payment year is the lowest of the available possible values for setting the performance threshold for the CY 2025 MIPS payment year. As stated in the CY 2023 PFS proposed rule (87 FR 46321), we proposed to use the mean final score from the CY 2017 performance period/ 2019 MIPS payment year to provide predictability to MIPS eligible clinicians during a program year in which they might be affected by the removal of transition policies for the first time and potentially scored on performance categories that were previously reweighted due to the COVID–19 PHE. We do not have the statutory authority to extend the $500 million of funding under section 1848(q)(6)(F)(iv) of the Act. To the commenter who suggested that we apply the automatic extreme and uncontrollable circumstances policy for the CY 2022 performance, we note that MIPS eligible clinicians may request reweighting for any or all performance categories due to an extreme and uncontrollable circumstance or public health emergency through the MIPS application based extreme and uncontrollable exception and further guidance on how to apply may be found at *https://qpp.cms.gov/mips/exception-applications?py=2022#extremeCircumstancesException-2022*. We refer readers to § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*) where we detail the extreme and uncontrollable circumstances policies.

Comment: Several commenters stated that the proposed performance threshold of 75 points is a significant increase from the previous performance threshold of 30 points for the CY 2019 performance period/2021 MIPS payment, the year prior to the COVID–19 PHE. The commenters urged CMS to reduce the performance threshold to avert more clinicians receiving negative payment adjustments, assist small practices reporting data, foster a better re-entry into MIPS, and encourage more participation by clinicians and/or practices that may not have submitted data due to the automatic and application-based extreme and uncontrollable circumstances policies. A few commenters stated that the 75-point threshold is unfairly punitive and may place disproportionate undue burden on small practices and/or clinicians who continue to struggle because of the PHE.

Response: As noted in the CY 2023 PFS proposed rule (87 FR 46320), section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. We proposed to use the CY 2019 MIPS payment year as the prior period for determining the performance threshold for the CY 2025 MIPS payment year for multiple reasons (87 FR 46321), such as the fact that MIPS eligible clinicians may be scored on performance categories that were reweighted during the COVID–19 PHE and the performance threshold of 75 points offers predictability. The CY 2019 MIPS payment year final score mean is also the lowest final score mean compared to the other prior periods available for the purpose of determining the performance threshold for the CY 2025 MIPS payment year.

We encourage the commenters to look at our estimates of how our finalized policies will affect the payment adjustments, broken down by practice size, for the CY 2025 MIPS payment year in our regulatory impact analysis (see section VII.E.16. of this final rule). As shown in the impact analysis, we expect approximately a third of clinicians who submit data for MIPS will receive a negative payment adjustment, and we do not observe a large discrepancy in payment adjustments between large and small practices as a cumulative result of our policies. The regulatory impact analysis for the CY 2022 performance period (86 FR 65637 through 65647) reported similar results. For these reasons, we believe maintaining the performance threshold at 75 points is reasonable.

Comment: A few commenters requested that CMS consider how this threshold may affect new Medicare providers and suggested that CMS allow new clinicians a trial-run after their grace period year, such as providing a mock score (rather than penalizing them) and additional resources on how to improve performance.

Response: We appreciate the commenters' suggestions for onboarding new clinicians into the program. As noted, under our existing grace period policy, new Medicare-enrolled eligible clinicians, as defined at § 414.1305, are not to be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year. During that period, these clinicians have the option to voluntarily report measures and activities for MIPS prior to being treated as MIPS eligible clinicians. A MIPS payment adjustment factor will not be applied to payments for items and services furnished by an eligible clinician who voluntarily reports on applicable measures and activities under MIPS. We believe that a one-year grace period with the opportunity to voluntarily report provides clinicians with opportunity to receive a score without penalty while still ensuring participation in future years. We will continue to provide resources to support new clinicians in navigating the MIPS program at *https://qpp.cms.gov/*.

Comment: A few commenters opposed the proposal to set the performance threshold at 75 points because they believe that the data from the past few years may be unreliable. They stated that only high performers may have chosen to submit data for MIPS and the data may no longer be representative of MIPS eligible clinicians. One commenter questioned whether CMS could remove points that clinicians may have received due to transition policies or the COVID–19 PHE, in previous year's data when evaluating the mean and median final scores from prior years since it may be unrealistic for clinicians to meet the same standard after those policies end. Another commenter recommended using the mean or median final score from the CY 2021 performance period when it becomes available since it may provide a more accurate representation of MIPS eligible clinicians' performance.

Response: We acknowledge the commenters' concern that the data from the past several years may not be representative of true performance in MIPS if only a certain portion of MIPS eligible clinicians (specifically MIPS eligible clinicians who expect to receive high final scores) may have submitted data for MIPS. If only MIPS eligible clinicians who expected high final scores submitted data for MIPS, then the expected mean final scores may be higher than when a larger proportion of MIPS eligible clinicians submitted data for MIPS. This was one reason that we proposed to use the data from a year prior to the PHE (the CY 2017 performance period, which corresponds to the CY 2019 MIPS payment year) to set the performance threshold for the CY 2023 MIPS performance period/CY 2025 MIPS payment year. We appreciate the commenters' suggestion to remove points that clinicians may have received due to transition policies or the COVID–19 PHE when calculating the mean or median final scores to set the performance threshold. Section

1848(q)(6)(D)(i) of the Act requires the performance threshold for a year to be the mean or median (as selected by the Secretary) of the composite performance scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. We refer to the composite performance score as the final score as defined under § 414.1305 (81 FR 77319 through 77320). We do not believe that we have discretion under the statute to alter the final scores from a prior period for the purpose of establishing the performance threshold. We plan to consider the CY 2021 performance period data for determining the performance threshold for future rulemaking once it is available for consideration.

Comment: Several commenters expressed concern about the reasonableness of the proposed performance threshold due to the lack of specialist-specific measures or MVPs and that some clinicians who may qualify for reweighting of performance categories may only have topped-out measures to report. A few commenters further expressed concern about the magnitude of positive payment adjustments and the impact on clinicians who do not meet the proposed performance threshold, with one commenter expressing concern about other economic pressures like inflation.

Response: We understand different specialties sometimes face challenges with not being able to report measures and activities for every performance category. We agree the final scores of these clinicians may be based on fewer categories than they would be for a clinician reporting all 4 performance categories. However, we remind clinicians that even if their final score is based on fewer than 4 performance categories, they still can score anywhere from 0 to 100 points for their final score, just as a clinician reporting all 4 performance categories would, due to our reweighting policies. In this way, we do not believe a performance threshold of 75 points is disadvantageous to clinicians reporting fewer than 4 performance categories. Regarding the commenter's concerns on the specialty measures available, we identify specialty measurement gaps through the annual publication of the CMS Quality Measure Development Plan (MDP) and the MDP Annual Report (*https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development*). In addition, we solicit interested party recommendations for new specialty measure sets and revisions to existing specialty sets on an annual basis. We urge interested parties to work with their specialty societies to provide recommendations during the specialty measure set solicitation process (for more information please see the QPP resource library at *http://www.qpp.cms.gov*). We are also developing MIPS Value Pathways (MVPs) to provide clinicians with a simplified method to report measures that are relevant to their practice, and we encourage them to report an MVP when one that is relevant to their scope of practice is available. We remind the commenters who were concerned about the magnitude or distribution of the positive payments adjustments that MIPS is a budget neutral program by statute. Generally stated, it is designed to balance the positive payment adjustments of clinicians who score above the performance threshold against the negative payment adjustments of clinicians whose scores are below the performance threshold. Therefore, a larger proportion of clinicians receiving a negative payment adjustment generally would result in larger positive payment adjustments for those above the performance threshold. We encourage the commenters to look at our estimates of how our finalized policies will affect the payment adjustments, broken down by practice size, for the CY 2025 MIPS payment year in our regulatory impact analysis (see section VII.E.16. of this final rule). We present the expected size of the budget neutral pool available for redistribution and the expected maximum positive payment adjustment for clinicians with a final score of 100 for the CY 2023 performance period/2025 MIPS payment year.

Comment: A few commenters stated their belief that the proposed 75-point performance threshold may be unachievable for some clinicians, and paired with other impending Medicare payments cuts, clinicians might opt-out of Medicare entirely, thereby creating a gap in access to care for an already stressed system and a vulnerable patient population.

Response: We appreciate commenters' concerns that some clinicians may not be able to achieve a 75-point performance threshold and note that we are setting the performance threshold to the lowest of the available possible values by using the CY 2019 MIPS payment year final score mean. The RIA of this final rule as described in section VII.E.16. estimates approximately a third of MIPS eligible clinicians would receive a negative payment adjustment if the proposed policies are finalized after updating the data sources. Because many clinicians' scores are close to the performance threshold, many of these clinician's payment adjustments are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. In the RIA of this final rule as described in section VII.E.16. the average positive payment adjustment among MIPS eligible clinicians who submit data for MIPS is 3.71 percent and the average negative payment adjustment among MIPS eligible clinicians who submit data for MIPS is −1.84 percent. Only 8.46 percent of MIPS eligible clinicians receive a final score less than 50 points and therefore a negative payment adjustment of more than −3 percent.

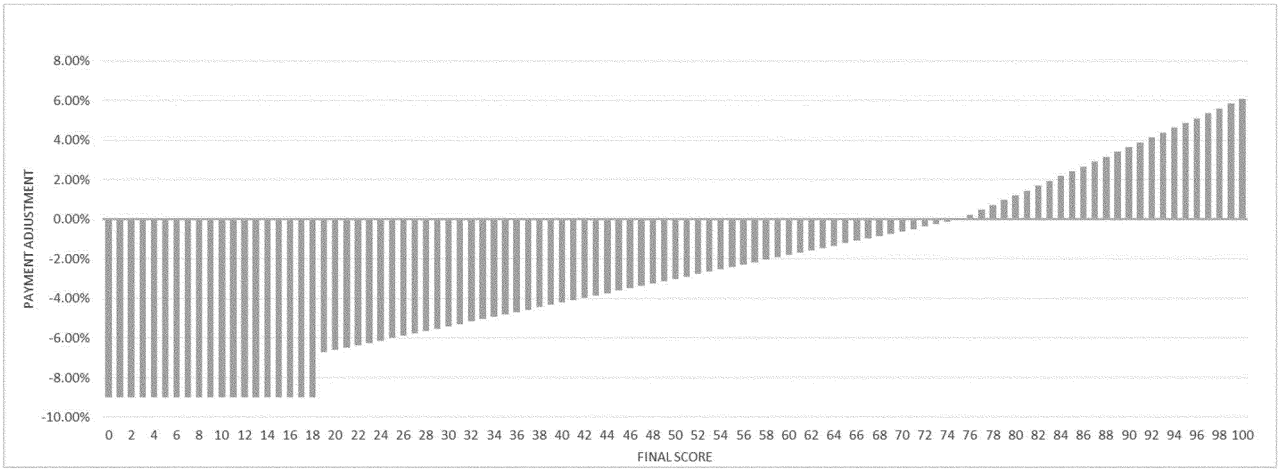
After consideration of public comments, we are finalizing our proposal to use the CY 2019 MIPS payment year as the prior period for the purpose of determining the performance threshold for the CY 2025 MIPS payment year and to set the performance threshold at 75 points, as well as the proposed corresponding changes to § 414.1405(b)(9).

(3) Example of Adjustment Factors

Figure 4 provides an illustrative example of how various final scores will be converted to a MIPS payment adjustment factor using the statutory formula and based on our finalized policies for the CY 2025 MIPS payment year. In Figure 4, the performance threshold is set at 75 points. The applicable percentage is 9 percent for the CY 2025 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the CY 2025 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the performance threshold of 75 points for the CY 2025 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive the lowest negative applicable percentage (negative 9 percent for the CY 2025 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (which is the finalized performance threshold for the CY 2025 MIPS payment year) will receive a neutral MIPS payment adjustment. Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act will no longer be available. For this reason, Figure 4 no longer illustrates an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 4: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2025 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 99 illustrates the changes in payment adjustment based on the final policies from the CY 2022 PFS final rule (86 FR 65527 through 65536) for the CY 2024 MIPS payment year and the finalized policies for the CY 2025 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

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TABLE 99: Illustration of Point System and Associated Adjustments Comparison between the CY 2024 MIPS Payment Year and the CY 2025 MIPS Payment Year

2024 MIPS Payment Year		2025 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.0	0% adjustment	75.0	0% adjustment
75.01-88.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.
89.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 89.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance		

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f. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

As we explained previously, we aim to provide performance feedback on or around July 1 of each year, but due to the PHE and COVID–19, it is possible that we might provide performance feedback later (85 FR 50321). We made performance feedback available for the CY 2019 performance period on August 5, 2020; for the CY 2020 performance period on August 2 and September 27, 2021; and for the CY 2021 performance period on August 22, 2022. We direct readers to *qpp.cms.gov* for more information.

g. Third Party Intermediaries General Requirements

(1) General Requirements

(a) Background

Flexible reporting options will provide eligible clinicians with options to accommodate different practices and make measurement meaningful. We believe that allowing eligible clinicians to participate in MIPS through the use of third party intermediaries that will collect or submit data on their behalf, will help us accomplish our goal of implementing a flexible program (82 FR 53806).

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), and the CY 2022 PFS final rule (86 FR 65538 through 65550) for our previously established policies regarding third party intermediaries.

In the CY 2023 PFS proposed rule (87 FR 46324), we proposed to update the definition of a third party intermediary at § 414.1305 and to make other minor conforming technical edits to the regulation text governing third party intermediaries set forth in § 414.1400. We also proposed to revise Qualified Clinical Data Registry (QCDR) measure self-nomination and measure approval requirements, including to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year (87 FR 46324 and 46325). We also proposed to revise remedial action and termination of third party intermediaries' policies (87 FR 46325 through 46328). Finally, we included two RFIs on third party intermediary support of MIPS value pathways (MVPs) and national Continuing Medical Education (CME) organizations becoming a new type of third party intermediary (87 FR 46327 through 46329).

(b) Definition of a Third Party Intermediary

In the CY 2022 PFS final rule (86 FR 65542 through 65545), we finalized at § 414.1400(a)(1) that MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or Alternative Payment Model (APM) Entity by any of the following third party intermediaries: QCDR; qualified registry; health IT vendor; or CMS approved survey vendor. In that rule, we added APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third party intermediaries reporting MIPS on behalf of APM Entities (86 FR 65542). We also revised § 414.1400(a)(1) to allow for QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, a recently adopted option for MIPS eligible clinicians reporting MIPS Value Pathways (86 FR 65544 through 65545). One of our strategic goals in developing MIPS included developing a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians. We discussed that one way we believe this could be accomplished is through flexible reporting options, including allowing MIPS eligible clinicians the flexibility of using third party intermediaries to collect or submit data on their behalf. In the CY 2019 PFS final rule (83 FR 59894) we finalized at § 414.1305 to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

In the CY 2023 PFS proposed rule (87 FR 46324), we proposed to update the definition of a third party intermediary at § 414.1305 to include subgroups and APM Entities and to make minor edits for technical clarity. We proposed the revised definition would state that a third party intermediary means an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. We requested comments on the proposal.

The following is a summary of the comments we received on our proposal and our responses.

Comment: One commenter opposed the requirement that third party intermediaries be required to support subgroup reporting, expressing concern that frequent transitions among clinicians in practices could be difficult to track year to year for third party intermediaries.

Response: We note that while we proposed a change in the definition of third party intermediary to include subgroups, we did not propose a new requirement for third party intermediaries to support subgroup reporting. We previously finalized in the CY 2022 PFS rule (See § 414.1400(a)(1); 86 FR 65544) a requirement that third party intermediaries support subgroup reporting beginning with the CY 2023 performance period. We note that we separately finalized the definition of the term subgroup (86 FR 65398 through 65400), as well as the requirements for subgroup registration (86 FR 65417 and 65418). In the requirements for subgroup registration, we finalized that at the time of registration, a subgroup identifier will be established by CMS. We also clarify that the same subgroup identifier will be used year to year, unless the composition of the group changes, in which case a new identifier would be issued.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46324), we are finalizing our proposal to revise the definition a third party intermediary as proposed and are revising § 414.1305.

(2) Requirements Specific to QCDRs

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(B)(ii) of the Act provides, that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of certified EHR technology and qualified clinical data registries.

We believe QCDRs and QCDR measures further health equity through the expansion of data collection, reporting, and analysis. QCDR measures data can be used not only to identify gaps in the standard of care, but also to determine solutions to disparate impacts on different populations. We anticipate growth in the number of QCDR measures that address health equity in upcoming performance years. We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944) and the CY 2022 PFS final rule (86 FR 65540 through 65550) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

(b) QCDR Measure Self-Nomination Requirements

As part of QCDR measure self-nomination, § 414.1400(b)(4)(i) and (b)(4)(i)(B) require the nominating QCDR to publicly post the QCDR measure specifications (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted no later than 15 calendar days following CMS approval. We typically notify a QCDR of its measure's approval prior to our posting

of the approved measure specifications. While we require QCDRs to post their approved measure specifications, as their websites are an important source for clinicians, we want to limit the chance of discrepancies between CMS's posting and QCDRs' postings.

To avoid confusion, in the CY 2023 PFS proposed rule we proposed to revise § 414.1400(b)(4)(i)(B) to clarify requirements for publicly posting the approved measure specifications (87 FR 46324 and 46325). Specifically, we proposed to revise the language such that entities must publicly post measure specifications no later than 15 calendar days following CMS's posting of approved QCDR measure specifications on a CMS website and that QCDRs need to confirm that the measure specifications they post align with the measure specifications posted by CMS. We proposed to revise § 414.1400(b)(4)(i)(B) to state that, for a QCDR measure, the entity must submit for CMS approval measure specifications including the Name/title of measure, National Quality Forum (NQF) number (if NQF- endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. We requested comments on this proposal.

The following is a summary of the comments we received on our proposal and our responses.

Comment: A few commenters supported the clarifications outlined in the QCDR measure self-nomination proposal.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern regarding the timing of the approved measure specifications posting that CMS requires of QCDRs. One commenter expressed concern that QCDRs are only given 15 calendar days to post their measure specifications following CMS's posting of the approved measure specifications. Given that the timing of the posting often falls around the end of the year and the holidays, the commenter suggested allowing QCDRs 21 calendar days to ensure that their posting follows requirements. One commenter suggested that QCDRs should not be required to post measure specifications until the PFS final rule has been released and the previous program year has ended.

Response: QCDRs are required to post approved measure specifications no later than 15 days following our posting because measure specifications need to be posted by January 1st of the performance period. This provides clinicians who start collecting data for that year with important information on relevant measures as most clinicians view their vendor's website and may not specifically view the CMS posting. Additionally, we believe that 15 days offers sufficient time to post given that QCDRs are notified after their specifications are approved and, therefore, already have the final version of the measure specifications ready.

Comment: One commenter stated their belief that QCDRs should not have to publicly post risk adjustment algorithms. The commenter explained that it often creates confusion for those who have not worked directly with the measure development team.

Response: If a measure is going to be used as part of a public program such as the Quality Payment Program, those clinicians who are to be measured must have the opportunity to fully review and understand the measure specifications, which include any risk adjustment algorithms included in the measure.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46324), we are finalizing our proposal to clarify the requirements for publicly posting the approved measure specifications as proposed and are revising § 414.1400(b)(4)(i)(B).

(c) QCDR Measure Approval Criteria

We refer readers to § 414.1400(b)(4)(iii), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84942), and the CY 2022 PFS final rule (86 FR 65540 through 65542) for previously finalized standards and criteria for QCDRs, specifically QCDR measure requirements.

We refer readers to the CY 2020 PFS final rule where we finalized requirements for QCDR measure testing (84 FR 63065 through 63067). Based on our goal that all measures available in MIPS are reliable and valid, we finalized in the CY 2020 PFS final rule a requirement for all QCDR measures to be fully developed and tested with complete testing results at the clinician level beginning with the CY 2021 performance period/2023 MIPS payment year (84 FR 63065 through 63067).[543] In consideration of the burden of collecting data as part of QCDR measure testing on clinicians and hospitals on the front lines of the COVID–19 pandemic, in the May 8th COVID–19 IFC and CY 2021 PFS final rule, we delayed the requirement for fully developed and tested QCDR measures by a year, to begin with the CY 2022 performance year (85 FR 27594 and 85 FR 84938 through 84939). Separately, to incorporate feedback from interested parties into the CY 2021 PFS final rule, we finalized an incremental approach to the QCDR measure testing requirements beginning with the CY 2022 performance year. Specifically, we finalized a policy that a QCDR measure must be face valid prior to being self-nominated for the CY 2022 performance year (85 FR 84939). For new QCDR measures to be approved, we must verify they are face valid for the initial performance year and fully tested for any subsequent performance year (85 FR 84939). Thus, a QCDR measure that we approve for the CY 2022 performance year; does not have to be fully tested until the CY 2023 performance year (85 FR 84939).

We recognized concerns expressed by interested parties regarding the burden of full measure testing and the continuing impact of the COVID–19 PHE (86 FR 65540 and 65541). Data collection efforts pose a challenge given the myriad disruptions to the health care system caused by the PHE, including clinicians' need to prioritize care for COVID–19 patients (and deprioritize data collection), and lost data due to the delay and cancelation of elective procedures. In particular, the COVID–19 extreme and uncontrollable circumstances exception decreased the number of groups reporting to MIPS through QCDRs. Without data from clinicians, QCDRs cannot complete their measure assessments, and delaying for one year will reduce the burden placed on QCDRs and clinicians. Despite these challenges, we believe QCDRs will soon be able to work with clinicians on full measure testing. Fully developed and tested measures improve measure reliability and validity thereby increasing clinician usability. Full

[543] We refer readers to the Blueprint for the CMS Measures Management System for additional details and guidance on QCDR measure testing. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

measure testing also prevents instances where QCDRs may discover that a measure is not feasible part way through data collection (84 FR 63066). Therefore, we proposed in the CY 2023 PFS proposed rule to revise our QCDR measure approval requirements again by delaying the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year (87 FR 46325). As proposed, a QCDR measure approved for the CY 2023 performance year or earlier would not need to be fully developed and tested until the CY 2024 performance year. A new QCDR measure proposed for the CY 2024 performance year would be required to meet face validity. We would require full testing at the clinician level before the QCDR measure can continue in the program beyond the first year. We proposed to amend § 414.1400(b)(4)(iii)(A)(*3*) to state that beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination. We requested comments on this proposal.

The following is a summary of the comments we received on our proposal and our responses.

Comment: Several commenters supported the proposed delay in the requirement for full measure testing citing the continuing impacts of the PHE. These commenters stated that resources required to complete full measure testing have been challenged by budget cuts, staffing shortages, and lower QCDR participation rates resulting from the PHE and stated that they appreciated the additional time to implement full measure testing.

Response: We thank the commenters for their support.

Comment: A few commenters suggested that it would be beneficial for CMS to provide clearer guidance for measure testing requirements. They suggested that there was confusion about the guidance for reliability and validity testing thresholds, as well as what it means to be ''fully tested at the clinician level.'' One commenter suggested that CMS develop a publicized process for evaluating testing measures including how insufficient data is determined, providing feedback to QCDRs, and allowing appeals. Additionally, a few commenters suggested that it would be helpful for QCDRs to review testing protocols with CMS prior to testing to clarify the amount of thoroughness expected by CMS and to avoid preventable mistakes and expenses.

Response: As discussed in the proposed rule (87 FR 46325), we referred readers to the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*) for tools regarding measure testing guidance. The website provides information on the full measure testing process and specific evaluation criteria. Additionally, the Measure Evaluation Criteria Guidance document (available at *https://mmshub.cms.gov/measure-lifecycle/measure-testing/overview*) provides a detailed outline for evaluating reliability and validity.

We regularly host training and support sessions throughout the year that address issues relevant to QCDRs and QRs. A repository of past webinars is available at *https://qpp.cms.gov/resources/webinars*. It is mandatory for QCDRs to attend the annual QCDR Measure Workgroup as well as the annual QCDR/QR Kickoff where we review all testing requirements. Webinars are followed by a question and answer session where attendees may ask questions and receive feedback from our subject matter experts regarding measure testing. Additionally, QCDRs/QRs can schedule a measure concept preview call where we will preview measure concepts and provide feedback prior to self-nomination.

Comment: A few commenters suggested that the delay should apply not only to MIPS, but also to measures included in an MVP to maintain consistency between MIPS and MVPs. They stated their belief that without a comparable delay, the number of quality measures available in MVPs will decrease and thus increase the burden for MVP participants who need more measures to report on which could ultimately lead to an overall reduction in MVP reporting.

Response: As we have previously discussed (85 FR 84937 through 84943), precisely because there may be a smaller number of measures available in MVPs, which tend to be focused on specific clinical topics, we believe that those QCDR measures available in MVPs should be of the highest quality and can be relied upon to support quality reporting on behalf of MVP Participants. We also believe that despite the delay for full measure testing for MIPS, there are some QCDRs that have been testing their measures and those fully tested QCDR measures may be ready to be considered for inclusion within an MVP.

Comment: A few commenters expressed concerns about the burden of CMS's measure testing requirements. These commenters stated their belief that the measure testing requirements place a significant burden on physicians and QCDRs and that the cost associated with the requirements will decrease measure development or even force QCDRs to stop all measure development and leave the program entirely. These commenters suggested that the burden of these standards disproportionately affects small QCDRs and specialty-specific measures which will likely play an important role as MVP and sub-group reporting increases. A few commenters suggested changes in CMS's measure testing requirements to reduce these burdens. One suggested allowing QCDR statisticians who are familiar with sample sizes and population to determine the appropriate level of testing (clinician, facility, or group). One commenter suggested that we allow measure stewards to determine their own testing plan to meet CMS's data standards.

Response: Over multiple years, we have expressed our intention to improve the quality and reliability of QCDR measures that are available for reporting within the MIPS program. In the CY 2018 Quality Payment Program proposed rule (82 FR 30160), we described our goal and sought comment on having fully tested QCDR measures. In the CY 2019 PFS final rule, we gave notice that we were considering requiring reliability and feasibility testing as an additional criterion for QCDR measures (83 FR 59901 through 59902). Ultimately, in the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. As described in the CY 2020 PFS final rule (84 FR 63066), while we understand the increased time and cost burdens associated with measure testing for the QCDR, we believe the benefits of full measure testing outweigh the burdens. However, in recognition of those burdens and the PHE, the implementation of this policy was delayed by 1 year, until the 2022 performance period, in the May 8th COVID–19 IFC (85 FR 27594 through 27595). Most recently, in the CY 2023 PFS proposed rule, we proposed to

further delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year (87 FR 46325). Given our longstanding objectives and our efforts to accommodate the disruption placed on the healthcare system caused by the COVID–19 PHE, we believe that interested parties have now had sufficient time and notice to prepare for full measure testing by CY 2024.

Additionally, we believe that implementing full measure testing will help reduce the burden on clinicians rather than increase it. In past performance years, there have been several instances where QCDRs have had issues with a measure mid performance period, and thus could not support the reporting of the impacted QCDR measure. This has forced clinicians to quickly find alternative measures to report to satisfy the quality reporting requirements of the MIPS program. Many of these issues could be avoided if the measures had gone through reliability and feasibility testing.

We note in response to the suggestions for changes in our testing requirements that we believe we offer flexibility in measure testing to demonstrate reliability and validity but require testing at the clinician level because the Quality Payment Program measures clinicians at the individual level in addition to the group and other levels. More broadly, we require uniform testing standards to help ensure that clinicians and groups are able to select from an array of measures that are consistently reliable, feasible, and provide meaningful measurement.

Comment: A few commenters expressed concern with the timing of the announcement of the delay for the full measure testing requirement. The commenters noted that the CY 2023 PFS final rule would not be posted until a few months after the self-nomination deadline, so commenters are unclear about whether QCDR measures need to be fully tested for CY 2023. Some commenters suggested that this confusion has led some QCDRs and registries to consider leaving the program and would negatively impact MVPs since QCDR measures must be fully tested prior to inclusion in an MVP. A few commenters asked CMS to release guidance and expectations through another medium regarding full measure testing.

Response: We understand the potential for confusion, however, our effort to change the timeline for the full measure testing requirement required proposing the change in the CY 2023 PFS proposed rule. However, we are delaying all QCDR measure decisions until after the publication of the final rule. Additionally, QCDRs that have been fully testing measures will be well prepared and practiced in completing the requirements for self-nomination for the CY 2024 performance period.

Comment: A few commenters suggested extending the delay for the measure testing requirement more than one year given that the PHE has led to decreased participation in MIPS and less reported data, which makes it more difficult to establish benchmarks. One commenter recommended that CMS extend the delay until 2 years after the end of the PHE. Other commenters proposed that new measures could have 2 years before full measure testing requirements instead of one.

Response: The full measure testing requirement was already delayed due to the PHE in the May 8th COVID–19 IFC (85 FR 27594 through 27595). In the CY 2021 PFS final rule, we finalized further changes, such that QCDR measures must be face valid prior to being self-nominated for the CY 2022 performance year (85 FR 84939) and does not have to be fully tested until the CY 2023 performance year (85 FR 84939). Given previous delays and the implementation of a gradual approach to requiring full measure testing, we believe that QCDRs will have had a reasonable amount of time in advance of the CY 2024 performance period requirement to prepare.

Comment: One commenter expressed concern about the delay of the full measure testing requirement and recommended implementing the full measure testing requirement sooner. The commenter noted that the delay in the requirement for MIPS will limit the availability of QCDR measures for inclusion in an MVP given that QCDR measures must be fully tested prior to inclusion in an MVP. Another commenter supported the requirement that all QCDR measures be fully tested before inclusion in an MVP.

Response: We have been balancing the need to have fully tested, valid, and reliable measures in the MIPS program with the challenges posed by the PHE and the general time and resources required to fully test QCDR measures. Based on the feedback from interested parties, we proposed delaying the requirement for full measure testing for 1 more year; however, we do not intend to further delay the implementation of this requirement (87 FR 46325). We strongly believe that all measures in a pay-for-performance quality program such as MIPS should be reliable, feasible, valid, and implementable as they impact performance determinations and thusly, payment adjustments.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46325), we are finalizing our proposal to delay QCDR measure approval requirements by delaying the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year and are revising § 414.1400(b)(4)(iii)(A)(*3*) as proposed.

(3) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77389), the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), and the CY 2022 PFS final rule (86 FR 65542 and 65550) for previously finalized policies for remedial action and termination of third party intermediaries.

In the CY 2023 PFS proposed rule (87 FR 46325 and 46326), we proposed a few changes to the regulations relating to remedial actions and terminations set forth in § 414.1400(e). These included one revised and one new requirement for Corrective Action Plans (CAPs), and proposed termination of certain approved QCDRs and Qualified Registries that continue to fail to submit performance data.

Section 414.1400(e)(1) provides that, after providing written notice, CMS may take remedial action if CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised. As described in § 414.1400(e)(1)(i) and (ii), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP) and publicly disclosing an entity's data error rate on the CMS website until the data error rate falls below 3 percent.

As described in § 414.1400(e)(2), CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action;

CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

Therefore, we proposed a technical correction in § 414.1400(e)(3), to include the missing introductory text of, ''A data submission that,'' which we inadvertently failed to include when finalizing our proposal to revise and redesignate existing language from former § 414.1400(f)(3)(ii) to paragraph (e)(3) in the CY 2022 PFS final rule (86 FR 65550) (87 FR 46325 and 46326). As proposed, the technical correction to the provision at § 414.1400(e)(3) would read, ''A data submission that contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.''

The following is a summary of the comments we received on our proposal and our responses.

Comment: In the context of determining whether a corrective action plan would be required, one commenter asked whether qualified registries are responsible for reviewing or validating data submitted to them and for additional operational details.

Response: Qualified registries are required to have data validation plans. We finalized our policy for the requirements for a data validation audit in the CY 2021 PFS rule (85 FR 84930 through 84937). We direct the reader to that section for a further discussion of the requirements and the rationale. We also direct readers to the self-nomination toolkit for QCDRs and registries that is available at *qpp.cms.gov/resources/resource-library* in which we offer more guidance for the data validation audit.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46325 and 46326), we are finalizing our proposal to revise § 414.1400(e)(3) to begin ''A data submission that'' as proposed.

(a) Revised Corrective Action Plan (CAP) Requirements

As described in § 414.1400(e)(1)(i), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP). As finalized in the CY 2021 PFS final rule and specified at §§ 414.1400(e)(1)(i)(A) through (D), unless different or additional information is specified by CMS, the CAP must address the following issues: (A) the issues that contributed to the non-compliance; (B) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (C) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future; and (D) a detailed timeline for achieving compliance with the applicable requirements.

In the CY 2023 PFS proposed rule, we proposed to revise the scope of affected parties impacted by the second CAP requirement at § 414.1400(e)(1)(i)(B) (87 FR 46326). As finalized in the CY 2021 PFS final rule at § 414.1400(e)(1)(i)(B), we explained that, depending on the circumstances, non-compliance by a third party intermediary may affect an uncertain number of clinicians and groups and has the potential to implicate substantial program dollars. We noted our belief that the information regarding the scope of harms was necessary for the agency to assess the full program impact of the non-compliance, as well as our belief that it was important for the CAP to include this impact information regardless of the clinician's participation status, because non-compliance may have programmatic implications even if it does not affect payment, such as for data posted on the Physician Compare website (now Care Compare) (85 FR 84947).

We discussed in the CY 2023 PFS proposed rule that we have become aware that in some cases, QCDRs granted licenses to the measures of another QCDR upon which a CAP has been imposed may be directly impacted by the issues that led to the CAP. We proposed to broaden the scope of affected parties under the CAP requirement at § 414.1400(e)(1)(i)(B) to also identify impacts to any QCDRs that were granted licenses to the measures of the affected QCDR, rather than limit the identification of impacts to clinicians only (87 FR 46326). We also proposed a technical correction in § 414.1400(e)(1)(i)(B) to correct the word ''voluntary'' to ''voluntarily.'' Accordingly, we proposed to revise the CAP requirement at § 414.1400(e)(1)(i)(B) to require the third party intermediary to address in its CAP the impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

We also proposed to add a new CAP requirement to require the third party intermediary to notify the parties identified in proposed § 414.1400(e)(1)(i)(B) of the impact to these parties by submitting a communication plan. We noted that the intent of this proposal is to enable affected parties to better understand and prepare for any operational and other challenges as needed. We noted our belief that having third party intermediaries submit a communication plan as part of their CAP would ensure third party intermediaries directly communicate the situation and its impact to these parties in a timely and consistent manner. Accordingly, we proposed to add § 414.1400(e)(1)(i)(E) to require the third party intermediary to develop a communication plan for communicating the impact to the parties identified in proposed § 414.1400(e)(1)(i)(B). Specifically, as proposed, this would include individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed. We requested comments on the proposals.

We did not receive any public comments on our proposals to revise § 414.1400(e)(1)(i)(B). For the reasons stated above and in the PFS proposed rule (87 FR 46326), we are finalizing our proposed revisions to § 414.1400(e)(1)(i)(B) and to add new paragraph (e)(1)(i)(E) as proposed.

(b) Termination of Approved QCDRs and Qualified Registries That Have Not Submitted Performance Data

In the CY 2022 PFS final rule, we noted that we had identified a number of QCDRs and qualified registries that had continued to self-nominate to become a third party intermediary for the MIPS program but had not submitted clinician, group, or virtual group data to CMS (86 FR 65545). We further noted as the MIPS program continues to mature, we wished to reduce the number of vendors that self-nominate to become a qualified vendor but do not actively participate in the MIPS program (*Id.*). We also noted that our goal was to decrease the operational

burden on CMS and those vendors that do not submit MIPS data to CMS (86 FR 65546). Accordingly, we finalized requirements for approved QCDRs and qualified registries that have not submitted performance data to submit a participation plan as part of their self-nomination process (*Id.*). We finalized an incremental approach to addressing this issue. First, we established a participation plan requirement, which requires a QCDR or qualified registry that was approved but did not submit data for any of the CY 2019 through 2023 payment years to submit a participation plan in order to be approved for the CY 2023 performance period/2025 MIPS payment year (§ 414.1400(b)(3)(vii)). Second, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan in order for it to be approved for the CY 2024 performance period/2026 MIPS payment year or for a future performance period/payment year (§ 414.1400(b)(3)(viii)).

Even with the participation requirements in place, we noted that we remained concerned about the administrative burden created by QCDRs and qualified registries that submit the required participation plans during the self-nomination process and continue as an approved QCDR or qualified registry yet continue not to submit MIPS data to CMS. Maintaining these vendors that do not actively participate does not provide a benefit to the MIPS program, rather it creates confusion for interested parties by including these vendors in our qualified postings (86 FR 65545).

Our goal is also to decrease the operational burden on CMS and interested parties. CMS would decrease its operational burden by eliminating the need to screen these entities. Removing QCDRs and qualified registries who do not actively participate from our qualified postings would also decrease the administrative burden for clinicians trying to identify an active participating QCDR or qualified registry.

Accordingly, we proposed in the CY 2023 PFS proposed rule that, beginning with the CY 2024 performance period, in the we would terminate those QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period (87 FR 46327). For example, if a QCDR or qualified registry is required to submit a participation plan during the self-nomination process for the CY 2024 performance period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for the CY 2022 and 2023 performance periods, and CMS approves their participation plan, but the QCDR or qualified registry continues to not submit MIPS data for the CY 2024 performance period (CY 2024 performance data is submitted by March 2025), then under our proposed policy, that QCDR or qualified registry would be terminated.

Specifically, we proposed to add a new ground for termination at § 414.1400(e)(5) stating that, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under § 414.1400(b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under § 414.1400(b)(3)(viii), will be terminated (87 FR 46327). We requested comments on the proposal.

Finally, in conjunction with the proposal to amend the definition of ''third party intermediary'' to refer to subgroups and APM Entities (87 FR 46327), we proposed a conforming change to § 414.1400(e)(2), which currently stated that CMS may immediately or with advance notice terminate ''the ability of a third party intermediary to submit MIPS data on behalf of MIPS eligible clinician, group or virtual group'' under certain circumstances. Rather than amend this provision to add references to subgroups and APM Entities, we proposed to revise § 414.1400(e)(2) by removing the previously quoted phrase to read that CMS may immediately or with advance notice ''terminate a third party intermediary'' under the specified circumstances. We requested comments on this proposal.

The following is a summary of the comments we received on our proposals and our responses.

Comment: A few commenters opposed our proposal to terminate QCDRs and qualified registries that do not submit any MIPS data, noting that recent years have been affected by flexibilities in MIPS participation related to the PHE that reduced the likelihood of clinicians using these QCDRs or qualified registries to report data. One commenter recommended that termination not be considered until there is more traction in MVP reporting.

Response: While we acknowledge that the PHE has had many effects on how clinicians have participated in MIPS, we note that our proposal does not include a termination of a QCDR or qualified registry until the CY 2024 performance period, for which data may be submitted in 2025. We believe that there is ample time for a registry or QCDR to gather participants and submit data in the coming years. We also believe that waiting until such time that MVPs are more available would not be appropriate because clinicians need the tools to participate in MVPs when they first become available.

Comment: One commenter opposed our proposal to terminate QCDRs and qualified registries that do not report data because they noted that QCDR status allows them access to Medicare claims data and to serve as a vetting tool for their own data.

Response: While we hope that QCDRs and qualified registries can be used to support broader quality improvement efforts, we maintain the requirements for QCDRs for the purpose of participation in the Quality Payment Program. As stated in the proposed rule, we believe that having a vendor on a list that does not actively submit data offers confusion to clinicians and other interested parties.

Comment: One commenter noted that they did not oppose the proposal but recommended that terminated qualified registries and QCDRs be given the opportunity to reapply for participation in the future.

Response: A third party intermediary that has been terminated may apply again in the future.

After consideration of the public comments and for the reasons stated above and in the proposed rule (87 FR 46327), we are finalizing our proposals as proposed to terminate those QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period and are revising § 414.1400(e)(2).

(4) Auditing of Entities Submitting MIPS Data

(a) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77389 through 77390), we finalized that third party intermediaries submitting MIPS data must comply with auditing procedures as a condition of qualification and approval to participate in MIPS, including the requirement to make

available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data (§ 414.1400(f)(1)).

(b) Revisions to the Requirement To Make Contact Information Available

In conjunction with our proposal to revise the definition of a third party intermediary to update the definition of a third party intermediary include subgroups and APM Entities (87 FR 46324), we proposed to revise the requirements codified at § 414.1400(f)(1) to account for third party intermediaries reporting on behalf of subgroups and APM Entities (87 FR 46327). Additionally, we also proposed to update the requirement to apply to third party intermediaries submitting data on behalf of virtual groups. Therefore, we proposed to update § 414.1400(f)(1) to require that the entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email. We invited public comment on the proposal.

We did not receive any public comments on these proposals. For the reasons stated above and in the proposed rule (87 FR 46327), we are finalizing the proposed revisions to § 414.1400(f)(1) as proposed.

(5) Requests for Information

(a) Request for Information on Third Party Intermediary Support of MVPs

We requested input on aspects of how third party intermediaries could support MVPs in the CY 2023 PFS proposed rule (87 FR 46327). We requested input on flexibility in measure selection in MVPs for third party intermediaries, barriers/burdens for third party intermediaries in supporting all measures, and whether there were technical resources CMS could provide that would be helpful for these third party intermediaries.

We thank the commenters for their input on these questions and will use the information gathered in consideration for future rulemaking.

(b) Request for Information on National Continuing Medical Education (CME) Accreditation Organizations Submitting Improvement Activities

In the CY 2023 PFS proposed rule (87 FR 46327 and 46328) we sought feedback on the value to clinicians of adding CME accreditation organizations as third party intermediaries. We requested input on the general value of adding such organizations, as well as input on the criteria we should use in evaluating such organizations. We thank the commenters for their input on these issues and will use the information gathered in consideration for future rulemaking.

h. Public Reporting on the Compare Tools Hosted by HHS

In the CY 2023 PFS proposed rule (87 FR 46329 through 46330), we proposed to add a telehealth indicator to clinician and group profile pages, as technically feasible. Along with the indicator, we proposed to include a statement caveating, in a user-friendly way based on consumer testing, that the clinician or group only provides some, not all, services via telehealth. We proposed using Place of Service (POS) Code 02 (indicating telehealth) on paid physician & ancillary service (that is, carrier) claims, or modifier 95 appended on paid claims to identify telehealth services rendered. To keep the indicator current, we proposed using a 6-month lookback period and refresh the telehealth indicator on clinician profile pages bi-monthly.

Additionally, we proposed to publicly report Medicare procedural utilization data on the Compare tool clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions (87 FR 46330 through 46331). Specifically, we proposed to: collapse Healthcare Common Procedure Coding System (HCPCS) codes using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System into procedural categories; use a 12-month lookback period and refresh data bi-monthly, as technically feasible. We also proposed publicly reporting this information no earlier than CY 2023.

For previous discussions on public reporting, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2022 PFS final rule (86 FR 65550 through 65554) and the Care Compare: Doctors and Clinicians Initiative Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC*. We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as ''compare tool'' throughout the final rule (86 FR 39466).

(1) Telehealth Indicator

Prior to the start of the COVID–19 public health emergency (PHE) in March 2020, Medicare paid for telehealth under limited circumstances, with telemedicine services restricted to rural or health professional shortage areas, established patients, or certain types of health care providers. In response to the ongoing PHE, we expanded Medicare payment for telemedicine services to increase access to care. According to the September 2021 Medicare Telemedicine Snapshot,[544] telehealth services have increased more than 30-fold since the start of the PHE and have been utilized by more than half of the Medicare population. With the increase in patients seeking telehealth due to the ongoing PHE, and CMS finalizing and expanding coverage of certain more permanent Category 1 and time-limited Category 3 telehealth services codes, adding an indicator to clinician and group profile pages would clarify for website users which clinicians offer telehealth services.

The Compare tool includes information on how beneficiaries may access care. Our research suggests that the addition of a telehealth indicator would meet a gap in the current information we provide on access to care and that such an indicator would be well understood by users. Keyword searches from the legacy Physician Compare website showed that, historically, website users search for telehealth information. Additionally, user testing we conducted with Medicare beneficiaries and caregivers showed that users accurately understood the meaning of a telehealth indicator and some even expressed an interest in knowing which services, specifically, might be offered via telehealth. Most users found the telehealth indicator to be important and useful when selecting a clinician. Telehealth is also one of beneficiaries' primary service requests the Medicare Call Center receives on a monthly basis.

[544] CMS, *Medicare Telemedicine Snapshot: March 2020–Feb. 2021* (2021), *https://www.cms.gov/files/document/medicare-telemedicine-snapshot.pdf. See also Medicare Telemedicine Snapshot Data File, https://www.cms.gov/files/zip/medicare-telemedicine-snapshot-data-file.zip.*

We also believe that publicly reporting a telehealth indicator on clinician and group profile pages would further CMS's health equity goals. According to the aforementioned Medicare Telemedicine Snapshot, more than half of the Medicare population in almost every racial/ethnic group regardless of sex or Medicare and Medicaid status are utilizing telehealth services. Given the exponential increase in Medicare telehealth usage by Medicare users over the past 2 years, particularly by those in areas with limited healthcare access, and those who cannot physically access a clinician's office, publicly reporting information on which clinicians furnish services via telehealth would aid in more widely applicable health care provider selection across the Medicare and dually eligible Medicare and Medicaid populations, since some beneficiaries have preferences for, or limitations preventing them from seeing a clinician in-person. For these reasons, we proposed adding a telehealth indicator to clinician and group profile pages, as technically feasible. Along with the indicator, we proposed including a statement on the profile page caveating, in a user-friendly way based on consumer testing, that the clinician or group only provides some, not all, services via telehealth.

To develop the indicator that would display on the Compare tool clinician and group profile pages, we proposed to identify clinicians who perform telehealth services using POS Code 02 (indicating telehealth) on paid physician & ancillary service (that is, carrier) claims, or modifier 95 appended on paid claims. To keep the indicator current and address concerns that some telehealth codes are time-limited, we proposed using a 6-month lookback period and refresh the telehealth indicator on clinician profile pages bi-monthly, which is the same cadence in which we update other clinician directory information. Frequently updating the telehealth indicator information would ensure that when a time-limited Category 3 codes expires, a clinician who only bills telehealth services under that code would no longer have a telehealth indicator on their profile page.

We sought comment on all aspects of the proposals to add a telehealth indicator to clinician and group profile pages, as technically feasible, including the proposed approach to identifying clinicians and groups furnishing telehealth services and the proposed 6-month lookback period and bi-monthly data refresh frequency. The following is a summary of the public comments received on the proposed Telehealth Indicator provisions and our responses:

Comment: All comments received on this proposal supported adding a telehealth indicator to clinician profile pages. The commenters noted the importance of the growth in the provision and usage of telehealth services throughout the PHE and that adding a telehealth indicator to profile pages would increase transparency and help patients, especially those who live in rural areas or are unable travel, find clinicians who may meet their needs. Two of the commenters noted the importance of a telehealth indicator for clinician types providing such services, even though some specialties, such as anesthesiology or emergency medicine, may not provide as many other telehealth services as others.

One of the commenters also supported our proposal to add a user-friendly statement, based on consumer testing, alongside the telehealth indicator, that not all services provided may be rendered via telehealth. This commenter also suggested adding an acknowledgment that individual patient access to telehealth services may be restricted due to limitations relating to interstate licensure.

Two commenters specifically supported the proposed approach for identifying clinicians and groups furnishing telehealth services using POS Code 02 (indicating telehealth) or modifier 95 appended on paid physician and ancillary service (that is, carrier) claims. One of these commenters also recommended using newly added POS Code 10. One commenter supported the proposed 6-month lookback period for identifying telehealth services and bi-monthly data refresh frequency for updating profile pages.

Response: We appreciate commenters' support and recommendations for the telehealth indicator and process for identifying and updating telehealth service information on clinician profile pages. We agree that knowing whether a clinician offers services via telehealth would be useful to patients and caregivers generally, beyond the PHE, particularly for those who have access to care barriers. We also agree that not all services may be provided via telehealth, sometimes due to interstate licensure restrictions, and will conduct consumer testing of such statements for inclusion on profile pages.

Additionally, we appreciate the suggestion to use the newly available POS Code 10 in addition to the proposed POS Code 02 and modifier 95 appended on paid physician and ancillary service claims to identify telehealth services. Upon review, we agree with the recommendation. We had proposed to use POS Code 02 to broadly capture the provision of services via telehealth, including in the patient's home. At the time of the proposed rule, we were not aware of a recent update made to POS Code 02 revising the description from ''telehealth'' to ''telehealth provided other than in patient's home'' for locations in which telehealth services were furnished. In connection with this change to POS Code 02, newly added POS Code 10, telehealth provided in patient's home, was adopted by Medicare to more specifically identify the provision of telehealth in the patient's home. Since many telehealth visits occur in patients' homes, we believe it is appropriate and consistent with the intent of our proposal to use POS 10 in addition to POS 02 to identify clinicians providing telehealth services.

Regarding the comment that the telehealth indicator may not apply to all specialties, we proposed that the telehealth indicator would only show on profile pages for clinicians in which we identify telehealth services using the appropriate POS codes or modifier 95 on paid physician and ancillary claims (see 87 FR 46329 and 46330). That is, no telehealth indicator will show on a clinician's profile page if we do not identify telehealth services rendered using these criteria.

After consideration of the public comments, as well as coding review and operational updates since the time of the proposed rule, we are finalizing these Telehealth Indicator proposals with several modifications. We proposed publicly reporting a telehealth indicator on clinician and group profile pages, however we are finalizing publicly reporting the indicator on clinician profile pages only. While we recognize that publishing telehealth indicators on both clinician and group profile pages may be helpful to consumers, it is not operationally feasible at this time to publish telehealth indicators on group profile pages with accuracy, given clinician turnover at group practices and resulting data implications. We believe that including the telehealth indicator on clinician profile pages only will provide the most accurate and current information for consumers.

Upon review of the changes to POS 02 to include telehealth furnished in locations other than a patient's home and Medicare's adoption of the newly added POS Code 10 for telehealth services rendered on patients receiving such services from home, we are finalizing use of POS 10 in addition to

using POS Code 02 or modifier 95 appended on paid physician and ancillary service claims.

We are also finalizing our proposals to use a 6-month lookback period and bi-monthly update frequency, as technically feasible.

(2) Publicly Reporting Utilization Data on Profile Pages

Section 104(a) of MACRA provides that, beginning with 2015, the Secretary shall make publicly available on an annual basis, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals, on items and services furnished to Medicare beneficiaries. The information made available must be similar to the physician and other supplier utilization data we have historically made available and shall include information on the number of services furnished by the physician or other eligible professional under Medicare, which may include information on the most frequent services furnished or groupings of services. Section 104(e) of MACRA requires that we integrate this data into the Compare tool.

To satisfy section 104(e), we implemented a policy of including utilization data in a downloadable format from late 2017 using the most currently available data and that the specific codes to be included were determined using data analysis and reported at the eligible clinician level (80 FR 71130). We also finalized a policy of continuing to include utilization data in the downloadable database (81 FR 77398). This information continues to be available today in the Medicare Provider Data Catalog (PDC) available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*. Separately, we have reported on the Compare tool clinician training information as well as a clinician's primary and secondary specialties.[545]

In the CY 2022 PFS proposed rule, we solicited comments on publicly reporting utilization data on clinician and group profile pages (86 FR 39466 through 39469). We received four responses, none of which directly addressed our Request for Information (RFI) questions. We stated in the CY 2023 PFS proposed rule (87 FR 46330 through 46331) that we believe it would be useful to patients and their caregivers, when making healthcare decisions, if a subset of procedures performed were publicly reported on clinician profile pages in an understandable and meaningful way. To date, we have gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the public use file (PUF) file entitled ''Physician and Other Supplier Data.'' These data are useful to the healthcare industry, healthcare researchers, and other interested parties who have the expertise to accurately interpret these data and use them in meaningful analyses. However, this information is presented in a technical manner that is not easily accessible or usable by patients, who do not frequently visit *data.cms.gov* or understand medical procedure coding. Additionally, the amount of information available in the PUF may overwhelm patients and caregivers.

As explained in the proposed rule, we envision that reporting utilization data on patient-facing clinician profile pages would provide two main areas of benefit. The first is to allow for more granular clinician searches. Patients would not only be able to find specific types of clinicians but also those clinicians who have performed specific types of procedures. The second is to provide categories of utilization data in a plain language display that is more usable to patients and their caregivers than what is available in the PDC.

In order to publicly report procedural utilization data in a meaningful way to patients and caregivers, rather than showing thousands of rows of individual HCPCS data, as we do for the research community in the PDC, we proposed to collapse HCPCS codes using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System into procedural categories. Restructured BETOS is a taxonomy that allows for the grouping of health care services codes for Medicare Part B into clinically meaningful categories and subcategories. Additional Restructured BETOS information is available at *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system*.

For example, applying categories would enable us to list that a clinician performs knee arthroplasties, which we could further simplify to knee replacements for understandability instead listing each of nine unique procedure codes indicating the specifics of exactly which bones and implants were utilized. We explained that we would exclude non-specific procedure codes, such as evaluation and management (E&M) codes for office visits which do not provide context about the care provided and low complexity procedures such as basic wound care or administering a vaccine because these codes encompass many types of care and are not specific enough about the services covered. For procedures in which no Restructured BETOS categories are available, we proposed to utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures.

Prior to publishing this data, we explained that we would conduct user testing with patients and caregivers to determine which procedures are of most importance, as well as how to best display and plain language utilization data on profile pages. User testing would also inform the appropriate context necessary to display utilization data in a meaningful way that ensures it is interpreted accurately. We noted that the utilization data shown on profile pages would only reflect Medicare claims data. Though this would provide information to patients and caregivers about which procedures are covered by Medicare, the utilization data would not include procedures performed for patients who have other types of insurance. For this reason, we noted that we would include a disclaimer on profile pages that the utilization data only represents the care that has been provided to Medicare beneficiaries and does not include those of patients with other forms of insurance.

In summary, we proposed publicly reporting Medicare procedural utilization data on the Compare tool clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions. We proposed publicly reporting procedural utilization data no earlier than CY 2023 and using a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. We sought comment on all aspects of the proposal, including the proposed approaches to identifying the most relevant and understandable procedural categories.

The following is a summary of the public comments received on the proposed Publicly Reporting Utilization Data on Profile Pages provisions and our responses:

Comment: Some commenters supported the utilization data proposal, noting that publicly reporting this information promotes greater

[545] CMS, *Physician Compare Report to Congress* 36 (2014), available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Downloads/Physician-Compare-Report-to-Congress.pdf*.

transparency and will help patients find the right clinicians for specific procedures.

Response: We agree that publicly reporting utilization data on clinician profile pages will promote transparency and help patients find clinicians who can better serve their needs, while also fulfilling sections 104(a) and (e) of the MACRA.

Comment: Many commenters opposed publicly reporting utilization data on procedures performed on clinician profile pages. These commenters' concern related to patient understanding of the information, including incorrectly equating higher volume of procedures to higher quality of care and better outcomes, especially for more complex, rare procedures. One of these commenters suggested adding a disclaimer that the volume of procedures performed does not always indicate higher quality of care. Commenters also expressed concern that patients could misinterpret that the clinician only performs the procedures shown on the profile page or not understand the coding data in its entirety. One commenter thought these data may be too confusing for patients to understand even with a disclaimer stating that listed information only includes Medicare data and therefore may not be reflective of the physician's total volume of a specified procedure. Even with these concerns, most emphasized the need for rigorous consumer testing to ensure accurate understanding of the information, if CMS moves forward with finalizing this policy. Another commenter suggested conducting clinician pilot testing.

Response: To clarify, we intend to start the reporting of utilization data on patient-facing clinician profile pages on a rolling basis (no sooner than CY 2023) and to expand the reporting of procedure categories over time. When we referred to conducting user testing to determine which ''procedures are of most importance'' to users (87 FR 46331), we meant that we would prioritize the publication of such procedures as public reporting begins. We appreciate and understand the concern that a higher volume of procedures does not always correlate to better quality of care and successful outcomes. Therefore, we are modifying the criteria that we will use to prioritize the publication of commonly performed procedures to better take this into account. Such procedures will meet one or more of the following criteria: have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research; are affiliated with existing MIPS measures indicating importance to CMS; represent care that a patient might shop for a clinician to provide; and/or is a U.S. Department of Health and Human Services (HHS) priority. We will not initially prioritize complex, rare procedures.

Regarding concerns that utilization data may confuse or mislead patients, we note that we will not display individual procedure codes on clinician profile pages, rather we will group them using Restructured BETOS categories, as discussed in this section. Furthermore, since the time of the proposed rule, we have started comprehensive user testing of plain language descriptions for several procedure categories as well as for other statements, some of which are based on public comments received, to help patients accurately understand the information, including explanations that: the data do not reflect all procedures the clinicians perform; the information shown only reflects procedures performed on patients with Medicare; and that the utilization data on their own are not the only indicator of quality. Preliminary findings show that patients and caregivers: understand this language; would not select a provider based on this information alone; and find the information helpful but would like the procedure volume to also reflect patients with other insurance if possible. We plan to continue testing including plain language regarding how to interpret the utilization information in the context of quality, rural vs. non-rural locations, and other information available on the profile page. We will explore, based on user testing, adding procedures for patients with other insurance, such as Medicare Advantage (MA) and Medicaid, in the future.

We have never conducted clinician pilot testing of information publicly reported on clinician and group profile pages, since the primary users are patients and caregivers, such as family members of patients looking for a provider. However, we appreciate the suggestion and may consider ways of engaging with clinicians in the future.

Comment: Two commenters recommended having a clinician review and correction process that would allow clinicians to update and correct procedural and other information listed on their profiles if needed.

Response: Since claims are the data source for identifying procedures performed, we encourage clinicians to first look into any billing errors. However, as with any other questions or concerns regarding the information on clinician and group profile pages on the Compare tool, interested parties may contact the Quality Payment Program at 1–866–288–8292 or by email at *QPP@cms.hhs.gov*. Those who are hard of hearing can dial 711 to be connected to a Telecommunications Relay Service (TRS) Communications Assistant. We also encourage clinicians to ensure their information is current in the Provider Enrollment, Chain, and Ownership System (PECOS) and to visit the Doctors and Clinicians initiative page for more information *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Care-Compare-DAC-Initiative*.

Comment: One commenter suggested using longer than a 12-month lookback period, since it may disadvantage clinicians who perform a particular procedure infrequently but have years of practice. The commenter did not suggest a specific length of time to use instead of 12-months.

Response: We understand there are a number of reasons a clinician may not have performed a certain procedure within the previous year. However, we believe the 12-month lookback period is appropriate for three main reasons. First, based on preliminary user testing conducted since the time of the proposed rule, early findings show that most patients and caregivers believe 12 months is an appropriate timeframe, since they want to make decisions based on clinicians' recent experience. Second, although the 12-month timeframe would capture some procedures a clinician hasn't performed recently (for instance if there is a seasonality component related to the number of procedures performed), showing procedural experience over a longer timeframe may mislead patients. For example, if we displayed coronary artery bypass graft (CABG) procedures over the last five years on a clinician profile page, it may be less desirable to the patient if most were from three years ago, prior to the PHE. Third, the procedure information in the PUF reflects a calendar year (that is, a 12-month period), which provides operational efficiency in keeping utilization data consistent on both the Compare tool and in the PDC.

With these considerations in mind, and as discussed earlier in this section, we will continue conducting comprehensive and robust user testing of all utilization data, including the lookback period, to ensure appropriate interpretation of the information.

Comment: Two commenters expressed concern that BETOS is outdated, has broad categories and, as a result, may lead to errors that mislead patients. Furthermore, one of these commenters stated there is no standard

or systematic way to group procedures by Common Procedural Terminology (CPT) or HCPCS codes beyond the BETOS system. One of these commenters also expressed concern that Restructured BETOS does not contain all procedure codes.

Response: In response to the concern that BETOS is outdated, we note that we proposed using Restructured BETOS, not original BETOS (87 FR 46330 and 46331). Restructured BETOS data are updated annually first released in 2020, the most recent of which are from 2021. As stated on the website, available at *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system*, Restructured BETOS provides ''information that allows researchers to group Medicare Part B healthcare service codes into clinically meaningful categories and subcategories.'' While we did consider the Clinical Classifications Software (CCS) classification system, Restructured BETOS categories represented the most appropriate level of detail to reflect patient and caregiver needs. We are not aware of any other more recent or available sources of this type of categorization and did not receive any recommendations of other sources in response to our proposal. We also did not receive any source suggestions in response to the Utilization Data RFI in the CY 2022 PFS Proposed Rule (86 FR 39468 and 39469).

Regarding the concern about Restructured BETOS not containing all procedures, we acknowledge that while the system classifies many commonly performed procedures, it does not classify all of them. For this reason, we proposed that we would utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures, for procedures in which no Restructured BETOS categories are available (87 FR 46331). For these reasons, we believe Restructured BETOS is the most appropriate procedure code categorization system available at this time. We will also use plain language to describe each category on profile pages in an effort to prevent confusion about which procedures are included and excluded.

Comment: One commenter noted that ''incident to'' billing may limit procedure attribution for certain clinicians, such as nurse practitioners (NPs) and physician assistants (PAs).

Response: We agree that if a clinician, such as a NP or PA, bills Medicare incident to a physician, then we would attribute a procedure billed in this way to the physician listed on the claim. However, we believe such attribution is appropriate, since the billing physician supervised and is accountable for the procedure billed. Additionally, we note that the attribution concern is a non-issue for clinicians who only bill Medicare incident to a supervising physician, since these clinicians would not have a Compare tool profile page upon which we could display utilization data. Only clinicians who bill Medicare directly have Compare tool profile pages.

Moreover, a number of NPs and PAs do bill Medicare directly and therefore, have profile pages. As a result, we expect that some of these types of clinicians may have procedural data available to show on profile pages. Data analyses and consumer testing will evaluate procedural information for a range of clinician types, so we will include this type of information on profile pages, including for non-physician clinicians, as appropriate and technically feasible. We also note that some utilization data for NPs and PAs is already available in the PDC, available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*.

We did not receive any comments on our proposal to exclude non-specific procedure codes, such as evaluation and management (E&M) codes and low-complexity services. We also did not receive comments on our proposal to utilize procedure code sources used in MIPS cost or quality measures for procedures in which no Restructured BETOS categories are available.

After consideration of the public comments and operational updates since the time of the proposed rule, we are finalizing these proposals with one modification. We proposed publicly reporting utilization data on clinician and group profile pages, however we are finalizing publicly reporting this information on clinician profile pages only. While we recognize that publishing utilization data on both clinician and group profile pages may be helpful to consumers, it is not operationally feasible at this time to publish utilization data on group profile pages with accuracy, given clinician turnover at group practices and resulting data implications. We believe that including utilization data on clinician profile pages will provide the most accurate and current information for consumers.

We are finalizing our proposals to publicly report Medicare procedural utilization data on the Compare tool clinician profile pages in a way that is meaningful to patients and caregivers, based on user testing. We are finalizing using Restructured BETOS to categorize procedures in an understandable way and that, for procedures in which no Restructured BETOS categories are available, we will utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures. We are also finalizing publicly reporting procedural utilization data no earlier than CY 2023 and using a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. Specifically, prior to each data refresh, we will use the preceding 12 months with a 3-month claims runout period. For example, we would use claims received between January 1, 2023 and March 31, 2024 for dates of service between January 1, 2023 and December 31, 2023 for a spring 2024 data refresh.

To address concerns raised related to patient understanding of publicly reported procedure categories, we are modifying the criteria we will use to prioritize the publication of commonly performed procedures. Priority procedures will meet one or more of the following criteria: have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research; are affiliated with existing MIPS measures indicating importance to CMS; represent care that a patient might shop for a clinician to provide; and/or are an HHS priority. We will not initially prioritize complex, rare procedures. Patients and caregivers have displayed understanding of plain language procedure category descriptions in recent testing. We will continue conducting comprehensive and robust consumer testing to better ensure this information is both interpreted correctly and meaningful to patients and their caregivers when making healthcare decisions.

11. Overview of the APM Incentive

a. Overview

Under the Quality Payment Program, an eligible clinician who is a Qualifying APM Participant (QP) for a performance year earns an APM Incentive Payment, which is made in the corresponding payment year for payment years 2019 through 2024. As provided in our regulation at § 414.1450(d), this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2022 APM Incentive Payment will correspond to the 2020 performance year), and at § 414.1450(b)(1) the APM Incentive Payment is equal to 5 percent of the eligible clinician's estimated aggregate payments for covered professional services in the base period (the year

between the QP performance and payment years).

b. APM Incentive Payment Recipient

In the CY 2017 Quality Payment Program final rule (81 FR 77008, 77487), we initially finalized a policy that the APM Incentive Payment is made to the TIN associated with the APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. In the CY 2021 PFS final rule (85 FR 84472, 84949 through 84950), we revised our approach to identifying the TIN or TINs to which we make the APM Incentive Payment at § 414.1450(c) to use a stepwise hierarchy to identify an appropriate payee TIN or TINs.

c. Public Notice

As specified in § 414.1450(c)(8), we notify QPs for whom we are unable to identify an appropriate TIN to which to make the APM Incentive Payment through a notice published annually in the **Federal Register**. In that notice, we include information on how the QP can update their information to enable CMS to make the APM Incentive Payment. Under our current policy, the deadline for providing CMS with updated information is the later of November 1 of each payment year or 60 days from the date on which we make the initial round of APM Incentive Payments for such year.

Section 414.1450(d) specifies that we make APM Incentive Payments as soon as practicable following calculation and validation of the APM Incentive Payment amount, but in no event later than 1 year after the incentive payment base period, defined in § 414.1305 as the calendar year prior to the year in which CMS disburses the APM Incentive Payment. Based on our experience and lessons learned in disbursing APM Incentive Payments, we have determined that the November 1 cutoff date for QPs to provide us with updated information does not leave sufficient time for us to process the information provided and make payments within the timeframe established in § 414.1450(d). In addition, we made operational adjustments beginning in the 2021 payment year that allowed us to make the initial round of APM Incentive Payments earlier in the calendar year than was possible in the first 2 payment years. Because we are now able to notify QPs for whom we have not identified a TIN to which to make the APM Incentive Payment through the **Federal Register** notice earlier in the payment year, and because we have found that we need additional time to process the updated information we receive in response to the notice, we proposed to change the specified cutoff date from November 1 to September 1 of the payment year, or 60 days from the date on which we make the initial round of payments, whichever is later. As is the case under the current policy, after the specified cutoff date, we will no longer accept updated information from QPs or their representatives, and any claims to an APM Incentive Payment for such QPs for the payment year will be forfeited.

As discussed in the proposed rule, we believe this change to the cutoff date for response to the public notice would allow us to disburse APM Incentive Payments more efficiently and effectively, reducing the time within which we make the remaining APM Incentive Payments for the payment year. This change would also improve our ability to make all APM Incentive Payments within the timeframe established under § 414.1450(d), and therefore, affected QPs would not have to wait as long to receive their payments.

We sought comment on the proposal to amend § 414.1450(c)(8) to change the cutoff date for response to the public notice from November 1 to September 1 of each payment year, or 60 days from the date on which we make the initial round of APM Incentive Payments, whichever is later.

We did not receive any comments on the proposed revisions to the public notice provisions. For reasons stated previously in this section and in the proposed rule (87 FR 46332), we are finalizing theses revisions to the public notices provisions as proposed.

d. Request for Information on Quality Payment Program Incentives Beginning in Performance Year 2023

Section 1833(z)(1) of the Act provides for APM Incentive Payments in each year for eligible clinicians who are QPs with respect to a year from 2019 through 2024. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is a QP for such year, there is an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year. Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act.

In the CY 2017 Quality Payment Program final rule (81 FR 77445), we established a policy that, beginning with the 2017 QP Performance Period, the QP Performance Period would be the calendar year that is 2 calendar years before the payment year for the APM Incentive Payment. Thus, we established that the first QP Performance Period would begin on January 1, 2017, the first ''base year'' (established at 81 FR 77481 and 77482) for which we would use claims for professional services to calculate the 5 percent APM Incentive Payment amount would be in 2018, and the first payment year for the APM Incentive Payment would be in 2019 as required by the statute. The QP Performance Period, base year, and payment year continue in this fashion through payment year 2024, which is the final year for which the statute authorizes an APM Incentive Payment.

After performance year 2022, which correlates with payment year 2024, there is no further statutory authority for a 5 percent APM Incentive Payment for eligible clinicians who become QPs for a year. In performance year 2023, which correlates with payment year 2025, the statute does not provide for any type of incentive for eligible clinicians who become QPs. Beginning with performance year 2024, which correlates with payment year 2026, section 1848(d)(1) of the Act provides for the application of two different PFS conversion factors depending on whether the services are furnished by an eligible clinician who is a QP for the year. The PFS conversion factor is the fixed-dollar constant, updated each year in accordance with statute, that is used to convert the RVUs (relative value units) for a service, after application of geographic practice cost indices to adjust for cost variations, into PFS payment amounts. Section 1848(d)(20) of the Act specifies that, beginning in CY 2026 (which is the payment year that correlates with the 2024 QP Performance Period under the Quality Payment Program), the update to the ''qualifying APM conversion factor'' (hereafter, ''QP conversion factor'') that applies for eligible clinicians who are QPs with respect to the payment year is 0.75 percent, and the update to the ''non-qualifying APM conversion factor'' (hereafter, ''general conversion factor'') that applies for eligible clinicians who are not QPs with respect to the year (as well as other types of

suppliers that are not eligible clinicians under the Quality Payment Program) is 0.25 percent. With the differentially higher 0.75 percent update to the QP conversion factor compounding each year beginning with CY 2026, compared to the 0.25 percent update to the general conversion factor in each year, the two PFS conversion factors will continue to diverge with each year, as illustrated in Figure 5.

Beginning in payment year 2025, the statutory incentive structure under the Quality Payment Program for eligible clinicians who participate in Advanced APMs stands in contrast to the incentives for MIPS eligible clinicians. Specifically, as described in 87 FR 46333 of the proposed rule, we anticipate that the maximum potential positive payment adjustment that could be applied under MIPS for payment years beginning in 2025 will be at or above 6.9 percent, and the corresponding maximum negative payment adjustment will be 9 percent. While only some MIPS eligible clinicians could earn the maximum positive payment adjustment, there is nonetheless a significant range of potential positive payment adjustments under MIPS that would exceed the differentially higher QP conversion factor beginning in payment year 2026 and for many years to come. As illustrated in Figure 5, the QP conversion factor, with the compounded differentially higher 0.75 percent update in each year, is not expected to equate to the anticipated maximum available positive payment adjustment under MIPS until after CY 2035.

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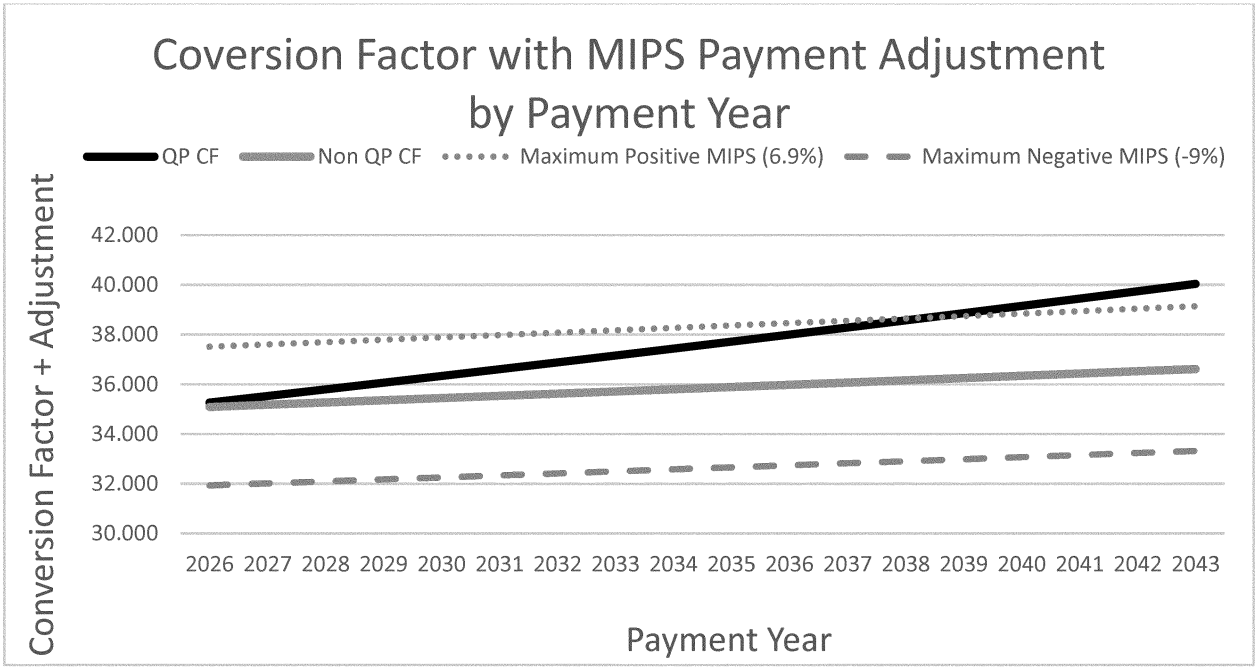
FIGURE 5: PFS Conversion Factors vs. Maximum MIPS Payment Adjustments*



*This graph depicts the PFS conversion factors that would apply for each year given the annual updates as specified in current statute, and does not otherwise depict an estimate of PFS payment rates for future years.

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We note again that the statute does not provide for any financial incentives for eligible clinicians who achieve QP status in QP Performance Period 2023/payment year 2025. Because section 1848(q)(1)(C)(ii)(I) of the Act explicitly excludes eligible clinicians who are QPs for a year from being considered as MIPS eligible clinicians, eligible clinicians who are QPs for a year are not subject to MIPS for that year, and thus, cannot receive MIPS payment adjustments. As such, eligible clinicians who are determined to be QPs in performance year 2023 will be paid under the PFS in payment year 2025 at the same rate as any other eligible clinicians who are not subject to MIPS and suppliers that are not subject to the Quality Payment Program at all.

We recognize that the lack of any available financial incentive under the Quality Payment Program for QPs for the 2025 payment year could affect the willingness of some eligible clinicians to participate in Advanced APMs in performance year 2023. Moreover, we recognize that the substantial difference between the QP conversion factor that will apply for QPs beginning in CY 2026 and maximum positive payment adjustment available under MIPS might affect the willingness of eligible clinicians to participate in Advanced APMs for several years to come. We recognize that there are other factors that affect an eligible clinician's decision whether to participate in an Advanced APM, including the avoidance of MIPS reporting requirements and the availability of shared savings and other incentives within the various Advanced APMs.

However, as explained in the proposed rule (87 FR 46333), we are concerned that the statutory incentive structure under the Quality Payment Program beginning in the 2023 performance year and corresponding 2025 payment year could potentially lead to a drop in Advanced APM

participation, and a corresponding increase in MIPS participation as eligible clinicians may believe their payments would be higher if they receive the MIPS payment adjustment. While it has been CMS's goal to increase MIPS participation, we continue to believe MIPS should be a first step on a glide path towards Advanced APM participation. Furthermore, we are concerned that a significant reduction in Advanced APM participation stemming from changes in financial incentives under the Quality Payment Program could potentially bias the CMS Innovation Center's model tests of voluntary Advanced APMs by leading clinicians who have performed well in Advanced APMs on both cost and quality metrics, to leave participation in the Advanced APM in which they currently participate, or decide not to apply for and participate in Advanced APMs, thereby interfering with the evaluation of current model tests and interfering with potential participation in future models.

We explained in the proposed rule that we also are concerned that a shift of eligible clinicians into MIPS and out of Advanced APMs would be likely to affect the availability and distribution of funds in the budget-neutral MIPS payment pool. The average MIPS final score for MIPS eligible clinicians who were participants in MIPS APMs in 2020 was 96.24 points while the average MIPS final score for all other MIPS eligible clinicians was 84.42 points. Given these statistics, we can reasonably anticipate that eligible clinicians who would shift away from participation in Advanced APMs and into MIPS would increase the relative number of high-performing MIPS eligible clinicians likely to earn a positive MIPS payment adjustment. As a result of more MIPS eligible clinicians earning a positive MIPS payment adjustment, we would expect to see a corresponding reduction in the average and maximum positive MIPS payment adjustment due to the statutory requirement under section 1848(q)(6)(F)(ii) of the Act to maintain budget neutrality in MIPS.

We have considered a range of potential administrative actions within our authority that might address these concerns. For example, we explored options for modifying the Advanced APM criteria or the requirements for current and future Advanced APMs to permit some degree of flexibility for eligible clinicians to choose whether to be considered under either the MIPS or the Advanced APM track of the Quality Payment Program. We have found it difficult to conceive of potential administrative options that would increase flexibility for eligible clinicians without drastically modifying characteristics of Advanced APMs, including CEHRT use, quality-based payment, and financial risk. After further consideration, we have concluded that it would be more prudent to forego administrative action for the 2023 performance period and 2025 payment year, and instead sought public input that we will consider in identifying potential options for the 2024 performance period and 2026 payment year of the Quality Payment Program (and potentially beyond). Specifically, we sought public comment on whether administrative action is needed beginning in the 2024 performance period and 2026 payment year, and if so, what would be the best approach to address the multi-faceted issues that arise with the end of statutory authority for an APM Incentive Payment for QPs and the transition to the differential QP and general conversion factors beginning in payment year 2026, which correlates to the 2024 performance year.

Taking into account that the current statute: (1) requires us to make QP determinations for eligible clinicians participating in Advanced APMs; (2) defines Advanced APMs as those APMs that require CEHRT use, sets payment based on MIPS-comparable quality measures, and assumption of more than nominal financial risk, as described at § 414.1415; and (3) specifically excludes QPs from being MIPS eligible clinicians, we are seeking input on what, if any, administrative actions eligible clinicians and APM Entities would potentially find helpful to better balance the payment incentives within the Quality Payment Program going forward, while continuing to encourage eligible clinicians and APM Entities to participate in APMs that align with the broader goals of CMS.

We noted that we are particularly interested in public comments in response to the questions asked in the proposed rule, which will help us to gauge options going forward. We also noted that we considered holding a public listening session in the near future to gather additional feedback on these questions and ideas.

We thank commenters for providing feedback on this topic through this RFI and for participation in our public listening session. We will continue monitoring this issue and we will continue to engage with the public on this topic.

e. Advanced APMs

(1) Advanced APM Criteria

(a) General Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

In this section, we address policies regarding several aspects of the Advanced APM criteria. We provide a clarification around payment based on quality measures and a proposal to modify the period of applicability for the generally applicable nominal amount standard.

(b) Payment Based on Quality Measures

In the CY 2017 Quality Payment Program final rule, we finalized the requirement for Advanced APMs that payment be based on quality measures at § 414.1415(b). In the CY 2019 PFS final rule (83 FR 59915 through 59938), we revised § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid. We also revised the requirement at § 414.1415(b)(3) that the quality measures upon which an Advanced APM bases payment must include at least one outcome measure (unless there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period) to provide, effective January 1, 2020, that at least one such outcome measure must either be finalized on the MIPS final list of measures as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

It has come to our attention that it may not be clear whether the two criteria at § 414.1415(b) require different quality measures. That is, interested parties have questioned whether two separate measures are required with one to meet each criterion, or whether it is sufficient that a single quality measure meets both of the criteria. Therefore, we proposed to revise the regulation at § 414.1415(b)(3) and proposed to add paragraph (b)(4) to clarify that the requirement for Advanced APMs that payment must be based on quality measures as specified at § 414.1415(b)(1) can be met through the use of a single quality measure that meets the criteria under both § 414.1415(b)(2) and (b)(3). Likewise, consistent with our practice of aligning Advanced APM and Other Payer Advanced APM policies to the extent feasible and appropriate, we also proposed to revise § 414.1420(c)(3)(ii) and to add paragraph (c)(4) to clarify that the requirement for Other Payer Advanced APMs that payment must be based on quality measures as specified at § 414.1420(c)(1) can be met through the use of a single quality measure that meets the criteria at § 414.1420(c)(2) and (c)(3). We sought public comment on the proposals. We did not receive any comments on the proposed revisions to payment based on quality measures. For the reasons stated previously in this section and in the proposed rule (87 FR 46335), we are finalizing these revisions to the payment based on quality measures provisions as proposed.

(c) Generally Applicable Nominal Amount Standard

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on setting the revenue-based standard: (1) for 2019 and later at up to 15 percent of revenue; or (2) at 10 percent so long as risk is equal to at least 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1415(c)(3)(i)(A) our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods. We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we would address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

In the CY 2019 PFS final rule (83 FR 59922 through 59923), we revised § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

At the same time, we established the generally applicable revenue-based nominal amount standard for Other Payer Advanced APMs at § 414.1420(d)(3)(i) to reflect the same 8 percent standard for QP Performance Periods for years 2021 through 2024, but based on the total combined revenues from the payer to providers and other entities under the payment arrangement.

We proposed to amend § 414.1415(c)(3)(i)(A) to permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the QP Performance Period. We proposed this change because the nominal amount standard of 8 percent has worked well and we noted that we are making the change permanent to provide continuity in policy into the future.

We also proposed to amend § 414.1420(d)(3)(i) to permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement, consistent with our longstanding practice of aligning Advanced APM policies with Other Payer Advanced APM policies to the extent feasible and appropriate. We proposed to amend these regulations to remove the specified end date of the 2024 QP Performance Period, such that the 8 percent standard would apply for all future performance years beginning with the 2023 QP Performance Period. The proposal would not change the current generally applicable revenue-based nominal amount standard. While we will continue to evaluate the generally applicable revenue-based nominal amount standard going forward and may determine at some point that it would be appropriate to propose to change the generally applicable revenue-based nominal amount standard, we noted that we believe that the current standard of 8 percent continues to be appropriate at this time for both the Advanced APM and Other Payer Advanced APM financial risk criteria.

We sought public comment on the proposals to amend § 414.1415(c)(3)(i)(A) and 414.1420(d)(3)(i) to make permanent the 8 percent level of the generally applicable revenue-based nominal amount standard such that it would apply to all future QP Performance Periods beginning January 1, 2023.

The following is a summary of the public comments received on the proposed revisions to Generally applicable nominal amount standard and our responses:

Comment: Some commenters suggested that rather than freeze the generally applicable revenue-based nominal amount standard at 8 percent, we should reduce that risk threshold to a figure closer to the financial risk standard used for Medical Home Models. Some commenters indicated that such a change would be likely to induce more participation in these models.

Response: We understand that some eligible clinicians and practices may be hesitant to join an Advanced APMs in part because of the financial risk involved. However, section 1833(z)(2)(iii)(II)(cc) of the Act generally requires that, to be an Advanced APM, to the APM require participants to take on more than nominal financial risk. Reducing that financial risk standard to a point where participants are no longer concerned about the financial implications of poor performance under the model is, by definition, nominal. We believe that the 8 percent standard that was set in the initial years of the program should not be increased at present because there are still some geographic regions and specialties that have not yet had the opportunity to join an Advanced APM under the current, relatively low, risk standard. and we continue to believe that maintaining the current standard is appropriate.

Comment: Several commenters expressed support for continuing the 8 percent generally applicable revenue-based nominal amount standard for all future years.

Response: We thank commenters for their support.

After considering public comments, we are finalizing the policy as proposed.

(d) Medical Home Model 50 Eligible Clinician Limit

In the 2017 Quality Payment Program final rule (81 FR 77428), we finalized a policy for the Medical Home Model

nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates in an Advanced APM through a Medical Home Model.

At that time, we described the way in which we would identify APM Entities that meet this standard as looking for ''APM Entities that participate in Medical Home Models and that have 50 or fewer eligible clinicians in the organization through which the entity is owned and operated.'' We defined organizational size as measured based on the size of the ''parent organization'' rather than the size of the APM Entity itself. We recognized that there would be ''additional but [. . .] achievable'' burden to correctly identify parent organizations and their size (81 FR 77428).

In the 2017 Quality Payment Program final rule, we responded to the many comments we had received in opposition to the proposal (81 FR 77429), where commenters expressed opinions that identifying eligible entities in this way was arbitrary, or that it would unfairly discriminate between similarly situated organizations. We finalized the proposal despite these concerns because we believed we could identify organizations that were or were not reasonably capable of taking on the generally applicable level of financial risk by identifying the ultimate size of the parent organization, and in so doing, identify organizations that should be excluded from the Medical Home Model financial risk standard.

After several years of implementation and upon closer analysis of our results under the Medical Home Model standard, we have gained experience about the composition of parent organizations and that there is a wide variation in how practices are organized and proposed a change in our policy. These changes are based on a re-evaluation of two assumptions we used in finalizing the 50 eligible clinician limit, codified at § 414.1415(c)(7), have not borne out in practice.

Our belief that we could easily gather accurate data about the size and composition of ''parent organizations'' through disclosures from the APM Entities affiliated with them was misplaced. To accurately understand the numerous and varied ways in which a parent organization (itself a complex concept) may enter into contractual relationships with other subsidiary entities that have Taxpayer Identification Numbers (TINs), which otherwise might have no apparent relationship with one another, would require insight and access to private contracts do not have. The administration of QPP is not the same as the administration of an individual APM and we are not party to the contracts between those private entities. Based on the information about these relationships, we are unable to confidently say that, under the parent organization approach we had finalized, all similarly situated organizations are being treated in the same manner. On the other hand, we believe we have a good understanding of APM Entities and how they will manage financial risk from our time implementing the QPP and various APMs.

Based on this insight and experience implementing the 50 eligible clinician limit for the Medical Home Model financial risk standard, we proposed to amend our methodology for identifying which eligible clinicians are to be included under the 50 eligible clinician limit.

Specifically, we proposed to amend § 414.1415(c)(7) to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity. We would identify the eligible clinicians in the APM Entity by using the TIN/NPIs on the participation list of the APM Entity on each of the three QP determination dates (March 31, June 30, and August 31). As discussed in the proposed rule, the proposal, if finalized, would become effective beginning in Performance Year 2023. We noted that we believe the change would address the challenges we have faced in implementing this policy, as discussed in the proposed rule.

We also proposed to amend § 414.1420(d)(8) to apply the 50 eligible clinician limit directly to the APM Entity participating in Aligned Other Payer Medical Home Model and Medicaid Medical Home Model, and to no longer look to the parent organization for the APM Entity, consistent with our longstanding practice of aligning Advanced APM policies with Other Payer Advanced APM policies to the extent feasible and appropriate.

In order to continue to achieve our aim of reducing the possibility for an APM Entity to potentially manipulate their numbers of eligible clinicians to inappropriately take advantage of participation in an Advanced APM that is a Medical Home Model, we proposed that the Medical Home Model financial risk and nominal amount standards under § 414.1415(c)(2) and (c)(4) would apply only if the APM Entity remains below the 50 eligible clinician limit on all three QP determination dates during the QP Performance Period. If the number of eligible clinicians in the APM Entity is above 50 on any of the three QP determination dates, the Medical Home Model financial risk and nominal amount standards will not apply for that APM Entity for the QP Performance Period. Should an APM Entity exceed the 50 eligible clinician limit on any of the three snapshot dates, no eligible clinicians would achieve or retain QP status through that APM Entity for the QP Performance Period and corresponding payment year, regardless of the outcome of QP determinations made at another QP determination date. We proposed to amend the regulation text to says that an APM Entity's Participation List will be used to determine if the 50 eligible clinician limit requirement has been met three times a year, for each of the three QP determination dates (March 31, June 30, and August 31).

In addition, we proposed to amend § 414.1440(e)(2) to require APM Entities or eligible clinician requesting a QP determination under the All-Payer Combination Option through participation in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model to supply information and certify that the 50 eligible clinician limit is being met for any Aligned Other Payer Medical Home Model or Medicaid Medical Home Model in which they participate and for the applicable time period in which the APM Entity or eligible clinician QP determination is made under the All-Payer Combination Option, as specified in the proposed revised § 414.1420(d)(8). Note, a practice exceeding the 50 eligible clinician limit under the Medicare Option would not preclude an eligible clinician or APM Entity from seeking a QP determination based on an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model.

We explained that we believe the modification to the methodology used to apply the 50 eligible clinician limit would better identify the eligible clinicians and APM Entities that should be included in QP determinations for participation in Advanced APMs under the Medical Home Model financial risk standard, and therefore continue to encourage movement into value based payment arrangements. The methodology would not attempt the complex task of gathering information on parent organizations, and we believe it would treat similarly situated entities similarly.

We sought public comment on these proposals.

The following is a summary of the public comments received on the

proposed revisions to the Medical Home Model 50 Eligible Clinician Limit and our responses:

Comment: Several commenters suggested that we should eliminate the 50 eligible clinician Limit entirely, rather than simply modifying the methodology used to identify clinicians to be counted.

Response: While we understand that the 50clinician limit may have the effect of limiting QP status for participants in larger practices under the Medical Home Model standard, we believe that this limitation is necessary to ensure that the benefits of the Medical Home Model financial risk standard are being made available only to those APM Entities and groups for whom a higher degree of risk is a less viable option. Specifically, we believe that a group practice that contains 50 or more eligible clinicians is of a sufficient size to bear the more significant financial risk under the generally applicable financial risk standard, and so should not be receiving the benefits of QP status for participation in an Advanced APM through which they took on a lower amount of risk as permitted for Medical Home Models.

Comment: Some commenters supported our proposed methodology to better identify the participants within the APM Entity who are taking on the financial risk under the Medical Home Model financial risk standard and using the size of that practice to determine whether the 50 Eligible Clinician Limit has been exceeded.

Response: We thank commenters for their support of this proposal.

After considering public comments, we are finalizing this policy as proposed.

(2) Qualifying APM Participant Determination

(a) General Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77448), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates of that year. An eligible clinician can be determined to be a QP only if they appear on the Participation List on a snapshot date that we use to identify the APM Entity group and to calculate Threshold Scores and make QP determinations at the APM Entity level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List with more than one APM Entity, but do not to achieve QP status based on any APM Entity group-level determinations, we make most QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians who appear on an Affiliated Practitioner list for an Advanced APM we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

(b) Request for Information: Potential Transition to Individual QP Determinations Only

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we discussed our reasons for establishing a policy to calculate Threshold Scores and make most QP determinations at the APM Entity group level, rather than at the individual eligible clinician level. At that time, we believed that this policy promoted administrative simplicity and collaboration among group members instead of imposing barriers or burden. We recognized that while many beneficiaries are attributed to an APM Entity based on the services rendered by one eligible clinician, many of the eligible clinicians participating in the APM Entity play a role in the actual diagnosis, treatment, and management of the many beneficiaries in the APM Entity's patient population. Each of these individual eligible clinicians can potentially be viewed as being instrumental to providing quality care to the beneficiary in alignment with the objectives of the APM, regardless of whether the specific services they furnish are used for purposes of APM-specific attribution methods. We noted that an APM Entity faces the risks and rewards of participation in an Advanced APM as a single unit and generally is responsible for performance metrics that are aggregated to the level of that APM Entity. The policy is based on the premise that entire organizations commit to participating in an Advanced APM and focusing on the attendant cost and quality goals as a whole.

Under the current policy at § 414.1425(b), for most eligible clinicians participating in Advanced APMs, QP determinations are made at the APM Entity level. As described in § 414.1435, the Threshold Score for an APM Entity or eligible clinician is calculated in one of two ways, either the payment amount method or patient count method. The threshold score using the payment count method is calculated by dividing: (1) the aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period; by (2) aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the QP Performance Period. The Threshold Score using the patient count method is calculated by dividing: (1) the number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services; by (2) the number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services. Attributed beneficiaries are generally determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology.

The current policy for QP determinations under the All-Payer Combination Option at § 414.1440(d) establishes a process that is similar to the QP determination participating in Advanced APMs, but accounts for participation in Other Payer Advanced APMs. Under the All-Payer Combination Option, an eligible clinician may request the QP determination be made at the individual or APM Entity level, and an APM Entity may request that the QP determination made at the individual, TIN or APM Entity level. Further, § 414.1440(d) specifies that CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold Score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations

using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

We requested public comment on the idea of transitioning away from an APM Entity level QP determination and instead calculating Threshold Scores and making QP determinations at the individual eligible clinician level for all eligible clinicians in Advanced APMs and Other Payer Advanced APMs. We explained that we believe making QP determinations at the individual eligible clinician level may have several benefits over the current policy. First, as explained in the proposed rule, we believe that making all QP determinations at the individual eligible clinician level would substantially reduce the practice of APM Entities removing specialists from their participation lists. Second, the change to make all QP determinations at the individual eligible clinician level would increase the number of eligible clinicians who are determined to be QPs for whom their individual participation would qualify them, but whose APM Entities did not qualify because other eligible clinicians in the APM Entity reduced its Threshold Score. Third, if we were to begin making all QP determinations at the individual eligible clinician level, that approach would eliminate the number of eligible clinicians who become QPs for a year, but whose individual participation in their Advanced APM(s) is well below the Threshold Score. Under our current policy to make most QP determinations at the APM Entity level, many eligible clinicians who would not meet the Threshold Score individually but whose APM Entities met the Threshold Score are able to gain QP status. For at least some of those eligible clinicians, a significant portion of the covered professional services they furnish may occur outside of the Advanced APM. When such eligible clinicians receive QP status, they may receive a financial windfall because their APM Incentive Payments are calculated based on all of the covered professional services they furnish during the base year, not just the services they furnish as part of the APM Entity in the Advanced APM.

We noted that this potential for receiving a financial windfall is possible through the 2022 QP Performance Period (which correlates to payment year 2024), but this will change beginning in the 2023 QP Performance Period (which correlates to payment year 2025) because the current statute does not provide for any APM Incentive Payment for that year. As such, there will be no further potential windfall in the form of the APM Incentive Payment.

However, there could be a similar windfall beginning in CY 2026 (which corresponds to the 2024 QP Performance Period) because eligible clinicians who achieve QP status beginning in that year will be paid under the PFS using the differentially higher QP conversion factor for the year, which will apply to all the covered professional services the eligible clinician furnishes in the year. In addition, beginning in payment year 2025 there are competing incentives under the QPP between the MIPS and APM track which are discussed in detail 87 FR 46332 of the proposed rule.

Because the APM Entity Threshold Scores (using the payment amount and patient count methods) that are used to make APM Entity-level QP determinations are based on an aggregate calculation across all eligible clinicians participating in the APM Entity group, eligible clinicians in the APM Entity group who furnish proportionally fewer services that lead to attribution of patients or payment amounts to the APM Entity are likely to lower the APM Entity's Threshold Score. For example, primary care physicians may furnish proportionally more evaluation and management (office visit) services which are frequently the basis for attribution of patients and payment amounts to the numerator of the APM Entity's Threshold Score; whereas specialist physicians may furnish proportionally more diagnostic tests and surgical procedures which are not usually part of the attribution basis to the APM Entity.

We noted that we have received reports from Advanced APM participants that some APM Entities have taken steps to reduce the number of such eligible clinicians on their Participation Lists. Specifically, to achieve higher QP Threshold Scores, some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating threshold scores for APM Entity-level QP determinations. There are important reasons that it is not beneficial for an APM Entity to exclude specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. In both the Medicare Shared Savings Program and in models tested by the Innovation Center that the meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is essential for achieving this goal. For example, a comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.[546] The methodology used in beneficiary assignment for the Shared Savings Program is deliberately constructed such that assignment is largely based on primary care, rather than specialty care, which results in specialists contributing proportionately less in terms of payment amounts and patient counts to the ACO's QP numerator.

Similarly, it was not our intent to create a policy wherein eligible clinicians who are seeing most or all of their Medicare patients through an Advanced APM may remain unable to achieve QP status because the APM Entity with which they participate in the Advanced APM includes eligible clinicians who furnish very few services through the Advanced APM. It has always been one of the goals of the APM track of the Quality Payment Program for the availability of QP status to incentivize eligible clinicians to join Advanced APMs. But, as discussed in the proposed rule, under our current policy to make most QP determinations at the APM Entity level, there is the potential that eligible clinicians who are fully engaged in an Advanced APM may still be unable to earn QP status.

We carefully considered our policy to make most QP determinations at the APM Entity level, and believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and their full participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care.

Finally, we noted concern that, under our current policy to make most QP determinations a the APM Entity level, some eligible clinicians who furnish relatively fewer of their services through an APM Entity may receive a disproportionate financial benefit because they achieve QP status as a result of the care furnished by other eligible clinicians in the APM Entity, while their APM Incentive Payment is calculated based on all of the covered professional services they furnish

[546] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.*

during the base year—both as part of the APM Entity and elsewhere. Our policy to make most QP determinations at the APM Entity level allows these windfall financial rewards because we calculate the Threshold Scores using the aggregate of payment amounts or patient counts for attributed patients based on Medicare Part B covered professional services furnished by all the eligible clinicians in the APM Entity, whether they furnished a few or many of such services. Once an eligible clinician receives QP status for a year, the APM Incentive Payment is calculated based on paid claims for that individual QP's covered professional services across all their TINs in the base year. This can allow an eligible clinician with minimal Advanced APM participation to receive a large APM Incentive Payment, which we do not believe aligns with the intent of the Quality Payment Program. Though, as we note above, QPs for payment year 2025 (QP Performance Period 2023) will not, by statute, receive a financial incentive for achieving such status, beginning in payment 2026 (QP Performance Period 2024) financial incentives once again will apply in the form of the enhanced QP conversion factor, which in turn compounds each year after that, and therefore, increases over time.

We requested input from interested parties on the possibility of discontinuing our policy to calculate Threshold Scores and make most QP determinations at the APM Entity level, and instead to make all QP determinations at the individual eligible clinician level. We noted that we believe this would avoid the potential incentive for APM Entities to limit or exclude specialists and other eligible clinicians who furnish services that are an important part of the health care spectrum, but less likely to be attributed to the APM Entity for purposes of calculating Threshold Scores for QP determinations. While the exclusion from an APM Entity of such specialists and other eligible clinicians can serve to improve the Threshold Scores for an APM Entity, it would not necessarily serve the central goals of many of our Advanced APMs, such as the statutory charge to Medicare Shared Savings Program ACOs to encourage groups of doctors, hospitals, and other health care providers to work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO.

In light of this potential conflict between Advanced APM goals and the existing QP Threshold Score calculation methodology, we considered whether it would be better to make all QP determinations at the individual eligible clinician level using the unique National Provider Identifier (NPI) associated with an eligible clinician participating in an Advanced APM. Under that approach, we would calculate a Threshold Score for each eligible clinician, identified by their NPI, based on all the covered professional services furnished by that individual eligible clinician, including services billed across all of the TINs to which the individual has reassigned their Medicare billing rights. This Threshold Score calculated at the individual eligible clinician level would provide a more specific measurement of each such eligible clinician's level of participation in one or more Advanced APMs. This methodology to calculate Threshold Scores and make QP determinations at the individual eligible clinician level would ensure that only those eligible clinicians (NPIs) who individually meet or exceed the applicable Threshold Score would receive QP status. At the same time, it would allow APM Entities to make decisions about which eligible clinicians to include on their Participation Lists based on the scope of eligible clinicians needed to furnish services to their patient populations under the Advanced APM, and to include those eligible clinicians who furnish proportionally fewer services that lead to patient attribution to the APM Entity under the current QP determination policy, without potentially affecting the QP status of other eligible clinicians in the APM Entity group. Because APM Entities no longer would have a need to consider how each eligible clinician may affect their aggregate Threshold Score for the APM Entity group, they would be able to include any eligible clinician who they believe can help them meet the patient-centered care goals of the Advanced APM(s) they are participating in. Therefore, we considered whether a change to make QP determinations at the individual eligible clinician level would have a positive health equity impact by ensuring that incentives under the Quality Payment Program would hold ACOs ''accountable for the quality, cost, and experience of care of an assigned Medicare fee-for-service (FFS) beneficiary population.'' [547]

Additionally, an analysis conducted by CMS found that many eligible clinicians do in fact frequently provide covered professional services to beneficiaries attributed to other APM Entities. These types of services and relationships are not necessarily accounted for or rewarded under the current methodology that makes QP determinations predominantly at the APM Entity level because they are outside the APM Entity participating in the Advanced APM, but would be if QP determinations were made at the individual eligible clinician level because all of the relevant covered professional services furnished by that eligible clinician would be counted in the QP determination. While our initial decision to calculate Threshold Scores and make most QP determinations at the APM Entity level was appropriate and, at the time, preferable to achieve the policy goals as stated in the CY 2017 proposed rule and reiterated above, for the reasons we identify here, we also believe that a change to calculate Threshold Scores and make QP determinations at the individual eligible clinician level may be preferable.

We requested public feedback on whether an individual level QP determination approach is an avenue we should continue exploring in future years to better identify and reward individual eligible clinicians with substantial engagement in Advanced APMs.

We received several comments on this RFI which provided us with meaningful insight into how the changes described could impact participation in Advanced APMs and QPP. We thank commenters for submitting these comments and we will keep them in mind as we continue to consider future changes to QPP.

(c) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019. The All-Payer Combination Option, which uses the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning in the payment year 2021. In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

In the CY 2022 PFS final rule (86 FR 65557 through 65558), we finalized policies to implement section 114(a) of Subtitle B of Title I of Division CC of the

[547] Ibid.

CAA (referred to herein as section 114(a) of Division CC of the CAA), which amended section 1833(z)(2)(B) of the Act with regard to payment years 2023 and 2024 (which correspond respectively to performance years 2021 and 2022), by freezing for such years the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. However, we neglected to fully amend our regulations at § 414.1430(a) and (b) to reflect these changes, and therefore, we proposed conforming changes to § 414.1430(a) and (b) in the proposed rule.

Specifically, section 114(a) of Division CC of the CAA amended section 1833(z)(2)(B) of the Act to continue the QP payment amount thresholds that apply in payment years 2021 and 2022 for payment years 2023 and 2024. Additionally, section 114(a) of Division CC of the CAA amended section 1833(z)(2)(D) of the Act to require that, for payment years 2023 and 2024, the Secretary must use the same percentage criteria for the QP patient count threshold that are applied in payment year 2022. As such, the Medicare Option QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. Section 114(b) of Division CC of the CAA amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2024 the Partial QP thresholds that are established for payment years 2021 and 2022. Therefore, the Partial QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 40 percent for the payment amount method and 25 percent for the patient count method. For performance years beginning with 2023 (corresponding to payment years beginning with 2025) the statute prescribes the QP thresholds for the payment amount method, and the QP thresholds we established for the patient count method at § 414.1430 will take effect. Specifically, for performance years beginning with 2023, the Medicare Option QP Thresholds will be 75 percent for the payment amount method and 50 percent for the patient count method. The Partial QP Thresholds under the Medicare Option will be 50 percent for the payment amount method and 35 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 40 percent for the payment amount method and 25 percent for the patient count method. The Partial QP thresholds for performance year 2023 and later (corresponding to payment years 2025 and later) will be 50 percent for the payment amount method and 35 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain threshold percentages under the Medicare Option. For performance years 2021 and later (corresponding to payment year 2023 and later), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent under the patient count method.

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TABLE 100: QP Threshold Score Updates

Medicare Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50		50		75	
Partial QP Payment Amount Threshold	40		40		50	
Medicare Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35		35		50	
Partial QP Patient Count Threshold	25		25		35	
All-Payer Combination Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50	25	50	25	75	25
Partial QP Payment Amount Threshold	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

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We did not receive any comments on the proposed revisions to the QP Thresholds and Partial QP Thresholds. For the reasons stated previously in this section and in the proposed rule (87 FR 46337), we are finalizing these revisions to the QP Threshold and Partial QP Threshold regulations as proposed.

V. Finalizing Provisions From Interim Final Rules

A. Finalizing the CY 2022 Methadone Payment Exception for Opioid Treatment Programs

1. Background

CMS issued an interim final rule with comment period (IFC) regarding the payment rate for methadone under the Medicare OTP benefit for CY 2022, titled ''Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception'' (hereafter referred to as ''Methadone IFC''), which appeared in the November 19, 2021 **Federal Register** (86 FR 66031). In the Methadone IFC, we froze the payment rate to Opioid Treatment Programs (OTPs) for methadone in CY 2022 at the CY 2021 rate because we believed would not have been appropriate to implement a decrease to the payment rate when substance use and overdoses had increased during the Coronavirus Disease 2019 (COVID–19) pandemic. In this final rule, we are responding to the comments received in response to the request for public comments in the Methadone IFC and establishing final policies with respect to payment to OTPs for methadone during CY 2022.

a. Methadone

The Food and Drug Administration (FDA) has approved three medications for the treatment of opioid use disorder (OUD): methadone, buprenorphine, and naltrexone. These are referred to as medications for opioid use disorder (MOUD). The combination of MOUD with counseling and behavioral therapies to provide a ''whole-patient'' approach to OUD care is referred to as medication-assisted treatment (MAT). OTPs are clinically driven and tailored to meet each patient's needs.[548] MOUD are also used to prevent or reduce opioid overdose. These medications are safe to use for months, years, or even a lifetime.[549]

As discussed in the CY 2020 PFS final rule (84 FR 62630), when used to treat those with a confirmed diagnosis of OUD, methadone cannot be dispensed by a pharmacy like certain other MOUD treatments (that is buprenorphine, buprenorphine-naloxone combination products, or naltrexone products) and therefore is not covered under Medicare Part D. Methadone is a schedule II controlled substance that is highly regulated because it has a potential for misuse and serious adverse effects if taken by opioid-naïve individuals. Methadone is also used as an analgesic to treat chronic pain. When used for the treatment of OUD, methadone is taken daily and is available in tablet, tablet for suspension, and solution forms and can only be dispensed and administered by an OTP as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. In the CY 2020 PFS final rule, we noted that approximately 74 percent of

[548] *https://www.samhsa.gov/medication-assisted-treatment.*

[549] *https://www.samhsa.gov/medication-assisted-treatment.*

patients receiving services from OTPs receive methadone for OUD treatment, with the vast majority of the remaining patients receiving buprenorphine (84 FR 62631).[550] In monitoring utilization of OTP services furnished under the new Medicare benefit, we have observed the percentage of Medicare beneficiaries receiving methadone to be closer to 95 percent.

According to SAMHSA's website, MAT has been shown to improve patient survival and increase retention in treatment.[551] Several studies indicate that retention in MAT is associated with lower mortality rates. One study stated that ''Retention in MAT of over one year was associated with a lower mortality rate than that with retention of less than one year. Improved coverage and adherence to MAT and post-treatment follow-up are crucial to reduce the mortality.'' [552]

b. Effects of the COVID–19 Pandemic on the Opioid Crisis

During the development of the final OTP payment rates for CY 2022, CMS became concerned that a reduction in the payment to Opioid Treatment Programs for methadone in CY 2022 would limit access to MOUD for Medicare beneficiaries amidst a worsening opioid crisis further exacerbated by social and economic stressors stemming from the COVID–19 pandemic. In the Methadone IFC, we explained that the United States is now facing a fourth wave of the overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 96,000 for the 12-month period to March 2021,[553] with overdose death rates surging among Black and Latino Americans.[554] While overdose deaths were already increasing in the months preceding the COVID–19 pandemic, the latest numbers available at the time of the Methadone IFC suggested that overdose deaths had accelerated during the pandemic, particularly among racial and ethnic health inequities. Public comments received in response to the CY 2022 PFS proposed rule highlighted the recent increases in overdose deaths. One commenter stated that drug overdose deaths have reached historic highs in this country. According to the commenter, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID–19 pandemic, but they also reflect the longstanding inadequacy of our medical infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, tobacco, cannabis, opioids). We also noted in the IFC that even before the COVID–19 pandemic began, more than 21 million Americans aged 12 or over in 2019 needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[555] The concerns described in these public comments and additional evidence showing an increased rate of overdose deaths and rising disparities in access to treatment for OUD strongly informed the policies in the Methadone IFC.

c. Opioid Use Disorders (OUDs) in the Medicare Population

In addition to the adverse effects of the COVID–19 pandemic on the worsening opioid crisis, the rising incidence of OUD among the Medicare population further informed CMS's decision to issue the Methadone IFC. As stated in the Methadone IFC, nearly one million adults aged 65 and older live with a SUD, as reported in 2018 data.[556] According to a Data Highlight published by CMS' Office of Minority Health, Medicare beneficiaries represent a growing proportion of individuals with OUD. Overall, 2.8 percent of Medicare Fee-for-Service (FFS) beneficiaries had an opioid use disorder (OUD) in 2018 out of a total of 38,665,082 Medicare FFS beneficiaries.[557] The problems associated with OUD in the Medicare population are compounded by chronic pain-associated conditions more common in later life, as well as the increased prevalence of multiple comorbidities and polypharmacy risks that exist among older adults.[558] Before issuing the Methadone IFC, CMS received a public comment in response to the CY 2022 PFS proposed rule that referred to increases in overdose deaths in individuals over age 65, stating that data from the CDC indicates that drug overdose deaths are increasing across all age groups, including those over age 65. Additionally, as we noted in the Methadone IFC (86 FR 66032), a recent Office of Inspector General (OIG) analysis of Medicare data reports that opioid overdoses have resulted in more than 200,000 deaths among Medicare beneficiaries nationwide since 2015. From 2016 to 2019, Medicare Part D saw a steady decline in opioid use, along with an increased use of drugs for treatment of OUD. OIG also noted that COVID–19 poses specific dangers for people using opioids, as respiratory diseases like COVID–19 can increase the risk of fatal overdose among those taking opioids and those with OUD are more likely to contract COVID–19 and suffer complications. With the onset of COVID–19 and the new dangers it poses for beneficiaries taking opioids, the OIG report states that it is imperative that HHS closely monitor opioid use during this unprecedented time. We also noted that during the first 8 months of 2020, about 5,000 Medicare Part D beneficiaries per month had an opioid overdose.[559] For these reasons, we concluded that implementing a reduction in methadone payments to OTPs would not have been appropriate given the growing proportion of the Medicare population diagnosed with OUD who also faced various challenges as a result of the COVID–19 pandemic.

2. Methadone Pricing

As discussed in the Methadone IFC, in the CY 2020 PFS final rule (84 FR 62667), we finalized a policy in § 410.67(d)(2)(i) under which the payment for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. Under the policy finalized at § 410.67(d)(2)(i)(B),

[550] *https://www.cdc.gov/drugoverdose/deaths/index.html.*

[551] *https://www.samhsa.gov/medication-assisted-treatment.*

[552] Ma, J., Bao, YP., Wang, RJ. *et al.* Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Mol Psychiatry* 24, 1868–1883 (2019). *https://doi.org/10.1038/s41380-018-0094-5.*

[553] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[554] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428.

[555] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/.*

[556] *https://www.drugabuse.gov/publications/substance-use-in-older-adults-drugfacts.*

[557] *https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-enrollment-section.*

[558] *https://www.cms.gov/files/document/oud-disparities-prevalence-2018-medicare-ffs-dh-002.pdf.*

[559] Opioid Use in Medicare Part D During the Onset of the COVID–19 Pandemic. U.S. Department of Health and Human Services Office of Inspector General. Data Snapshot, OEI–02–20–00400. Published February 2021.

for oral medications, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart J and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. We indicated that the payment amount for methadone furnished by OTPs during an episode of care in CY 2021 was $37.38,[560] which was 100 percent of ASP, as determined based on voluntarily submitted ASP data for the methadone.

We explained that quarterly ASP pricing files are typically posted on the CMS website prior to the beginning of the quarter in which Medicare payments will be effective, which allows drug manufacturers that are required to submit their sales data to review and identify any issues. Due to the timing of CY PFS rulemaking and because ASP drug pricing file data is updated on a quarterly basis, the most recent ASP drug pricing file data available for the CY 2022 PFS final rule was the October 2021 update, which was posted on September 9, 2021.

In the Methadone IFC (86 FR 66033), we noted that in early September 2021, while gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to the rate used for CY 2021, from $37.38 to $17.64.[561] This reduction was due to inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. We explained that the ASP is volume-weighted; however, ASP reporting is not required for oral methadone and only a small subset of methadone manufacturers voluntarily submit ASP data. Of the nearly 50 available NDCs for oral methadone preparations with available pricing in the Red Book® compendia, voluntarily submitted ASP data was available for only three of these NDCs. We noted that pricing for oral methadone is distinct from most other drug pricing based on ASP because oral methadone is not separately payable as a drug or biological under Medicare Part B, and manufacturers are not subject to ASP reporting requirements under section 1927(b)(3)(A)(iii) of the Act for those NDCs. Additionally, we noted that we did not, at the time of the Methadone IFC, have utilization data on the different forms of methadone that can be dispensed or administered at OTPs. That is, at that time, we did not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally. When we researched OTP practice patterns as we were preparing to implement the new benefit for OUD treatment services furnished in OTPs, we received anecdotal reports that several OTPs used the oral concentrate exclusively.

For these reasons, we had questions as to whether the ASP data available at the time of the CY 2022 rulemaking, which reflects voluntarily reported data from only a very small subset of methadone manufacturers, is representative of utilization of the two forms of oral methadone by the Medicare beneficiaries receiving OUD treatment services in OTPs.

We stated that given recent reports regarding the effects of the public health emergency (PHE) for COVID–19 on individuals with SUD, including OUD, and the questions we had related to whether the available ASP data for methadone is reflective of OTP utilization due to the distinct nature of methadone pricing, as described above, we believed it would be in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. We noted that section 1834(w)(2) of the Act allows for flexibility to consider the scope of services furnished, the characteristics of the individuals receiving services, and such other factors as the Secretary determines appropriate, in determining the rates paid to OTPs under Medicare.

Therefore, in the Methadone IFC (86 FR 66031 through 66036), we established a limited exception to the existing methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021. We also revised the regulation at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception and to make a conforming change to the reference to 42 CFR part 414, subpart J.

Under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) was maintained at the CY 2021 rate of $37.38 for the duration of CY 2022. We applied the annual update to the non-drug component of HCPCS G2067 for CY 2022 as required under § 410.67(d)(4)(iii). We noted that we believed maintaining the payment amount for methadone at the CY 2021 rate during CY 2022 would allow time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for CY 2023.

We solicited comment on the exception to the payment methodology for the drug component of an episode of care that we were adopting in the Methadone IFC in order to maintain the payment rate for methadone at the CY 2021 payment amount during CY 2022.

We received public comments on the exception to the payment methodology to freeze the payment rate for methadone at the CY 2021 payment amount for the duration of CY 2022. The following is a summary of the comments we received and our responses.

Comment: We received several comments from individual commenters, medical associations, and national associations representing OTPs. The majority of commenters expressed support for the exception to the payment methodology for the drug component of an episode of care to maintain the payment rate for methadone at the CY 2021 payment amount for the duration of CY 2022.

[560] *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.*

[561] The TRICARE rate for the drug portion of its weekly bundled payment for methadone treatment is $24.04 for 2022, which would also be a decrease from the CY 2021 payment rate under Medicare and cannot be used to set the Medicare payment rate for methadone in CY 2022 under § 410.67(d)(2)(i)(B) because ASP data is available for methadone.

Some commenters reiterated that this payment exception was important during a time of increased opioid-related overdose deaths that have accelerated during the COVID–19 pandemic. In this regard, commenters noted that reducing the payment amount for methadone to providers who specialize in treatment of OUD could impact access to methadone and adequate retention of providers administering these services and other related OUD treatment services. One commenter also cited data showing that a large majority of treatment services furnished in conjunction with methadone are offered through telemedicine, including medication management and psychosocial therapy. The commenter stated that if methadone reimbursement is reduced, beneficiary access to telemedicine may be limited. Additionally, another commenter expressed support for the methadone payment exception adopted in the Methadone IFC, stating that it would provide CMS additional time to consider utilization of different methadone formulations, which may inform alternative reimbursement methodologies that better reflect methadone utilization.

Response: We thank the commenters for the support expressed in their comments. We agree that this payment exception was important in order to promote treatment accessibility for MOUD during a worsening opioid crisis and to allow for the additional time needed to evaluate utilization of different forms of methadone for purposes of informing the payment rate for methadone furnished in OTPs for CY 2023 and future years.

Comment: Although the majority of commenters expressed support for freezing the payment rates for methadone furnished by OTPs in CY 2022, a few commenters noted concerns that freezing the payment rate for methadone at the CY 2021 level may still result in unanticipated negative outcomes. One commenter indicated that supply chain and other logistical issues have driven up global drug prices alongside widespread inflation, such that an increase in payment rates may be necessary. Another commenter noted that if Medicare reimbursement for methadone falls well below OTPs' costs of acquiring and administering the medication, OTPs may have no choice but to prescribe a much more expensive medication (buprenorphine or naloxone) as part of MOUD. The commenter noted this might increase costs for the Medicare program and taxpayers, while not necessarily improving care due to different clinical and situational indications for other types of medications utilized in MOUD.

Response: We acknowledge and continue to track commenters' concerns about the payment rate for methadone furnished in OTPs. We believe these comments further demonstrate the importance of the payment freeze adopted in the Methadone IFC in order to allow CMS time to investigate methadone payment rates further and to seek feedback from the public in order to inform potential future payment methodologies that better capture costs of furnishing methadone. We took the feedback received in response to the Methadone IFC into consideration in developing and proposing a new methodology for methadone pricing that would stabilize payment to OTPs for methadone and maintain access to OUD treatment services. Under the proposed methodology, which we are finalizing in this final rule, we will base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription). For a detailed discussion of the final policy for methadone pricing for CY 2023 and subsequent years, see section III.F.2. of this final rule.

In the Methadone IFC (86 FR 66033), we also solicited comment on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic. We noted that because the OTP benefit is still fairly new under Medicare, we have not yet had the opportunity to fully understand how changes in the payment rates may affect OTP operations and beneficiary access to treatment. However, we stated our intent to continue to refine our payment policies in order to best meet the needs of Medicare beneficiaries.

We received public comments on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided input on the frequency of utilization for methadone oral concentrate compared to methadone tablets. One commenter reported surveying dozens of OTPs in their region and found that the majority of OTPs utilized oral concentrate exclusively and none utilized methadone tablets exclusively. The same commenter identified that among OTPs that distributed both formulations of methadone to a single patient, the tablet formulation was preferable in situations in which accommodation of a patient's travel is necessary. Moreover, another commenter reported that almost all of its patients receive oral concentrate because it has shown to lead to better clinical outcomes, thus the oral concentrate is the preferred formulation amongst both practitioners and patients.

Response: We thank the commenters for their comments regarding the higher frequency of utilization for methadone oral concentrate compared to methadone tablets. We note that the 2021 payment amount for methadone which we also used for 2022, and which forms the basis for the payment rate for methadone for CY 2023 and subsequent years is based on average sales price data for methadone oral concentrate. We will consider the information on methadone utilization shared by the commenters as we continue to evaluate the drug pricing methodology for methadone going forward.

Comment: One commenter noted that the National Association of State Alcohol and Drug Abuse Directors (NASADAD), in conjunction with the State Opioid Treatment Authorities (SOTAs), conducted a survey that was distributed to the 1,800 OTPs throughout the United States. As of December 31, 2021, NASADAD and the SOTAs had collected data from 1,550 OTPs. These data include the number of patients being treated at OTPs as of January 1, 2021, including the number of patients using one of the three FDA-approved medications to treat opioid use disorder (methadone, buprenorphine, and extended-release naltrexone) and the specific forms of the medication being used. The commenter further noted that the data is currently being analyzed by NASADAD staff.

Response: We thank the commenter for this information and are looking forward to seeing the survey results.

In the Methadone IFC, we indicated that we would consider the comments received in response to the IFC in deciding how best to determine the payment rate for methadone in CY 2023, including whether we should propose changes in future rulemaking to the structure of OTP coding and payment in order to account for differences in pricing and utilization for the different formulations of methadone. The following is a summary of the comments we received on these issues and our responses.

Comment: Several commenters stated that oral concentrate methadone is more costly to provide to patients than methadone tablets. Commenters raised various cost considerations for administering oral concentrate that they believe should be reflected in pricing for methadone. For example, commenters noted that extra effort is required from nurses in administering doses that require more complex technology and precision in measurement to ensure patient safety. Additionally, commenters noted that some states require full-time pharmacists to be present for dosing the oral concentrate formulation. Moreover, commenters stated that supplies used in dispensing the oral concentrate, such as electric pumps and pipettes, and their related software, require maintenance, replacement, acquisition, and storage, which result in additional costs to OTPs.

Response: We thank commenters for raising these additional factors that impact the cost of administering methadone oral concentrate as opposed to methadone tablets. We may consider addressing these issues in future rulemaking. However, we note that in section III.F.2 of this final rule, we are finalizing a change to the drug pricing methodology for methadone for CY 2023 and future years to provide that payment amount for methadone will be the payment amount determined for CY 2021 updated by the PPI for Pharmaceuticals for Human Use (Prescription) (WPUSI07003). We believe that this PPI is an appropriate factor by which to adjust the payment rate for methadone to reflect the changes in methadone costs for OTPs over time. We are also revising § 410.67(d)(2)(i)(B)(2) to reflect this new drug pricing methodology for methadone. Please see the discussion in section III.F.2 of this final rule for additional information regarding the final polices for methadone pricing for CY 2023 and future years under the Medicare OTP benefit.

Comment: One commenter suggested CMS use the TRICARE rate for oral methadone concentrate reimbursement and create separate payment codes for tablet methadone and oral concentrate methadone.

Response: We thank the commenter for this suggestion. The regulation at § 410.67(d)(2)(i)(B)(1) states that if ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. However, when CMS was establishing the methadone payment rate for CY 2022, we found that the TRICARE rate would have also decreased the payment amount for methadone by $13.34 compared to the CY 2021 payment rate. Thus, using the TRICARE rate would have still decreased the payment amount for methadone during both the COVID–19 pandemic and a worsening opioid overdose crisis, which may have created access barriers to treatment for beneficiaries. This further demonstrated the need for an interim final rule to freeze methadone payment for CY 2022 at the CY 2021 rate in order to provide the agency more time to reconsider methadone payment methodologies. Please see the discussion in section III.F.2 of this final rule regarding the final polices for methadone pricing for 2023 and future years under the Medicare OTP benefit.

Regarding the comment on creating separate payment codes for tablet methadone and oral concentrate, we thank the commenter for this recommendation. We may consider this recommendation through future rulemaking at such a time that more robust ASP data for the different formulations of methadone is available.

In summary, after consideration of the public comments, we are finalizing without modification the revisions made in the Methadone IFC to the regulation text at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception for CY 2022 and to make a conforming change to the reference to 42 CFR part 414, subpart J.

B. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (CMS–1744–IFC)

In this final rule, we are responding to public comments and stating our final policies for certain provisions in the IFC titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (CMS–1744–IFC), which appeared in the April 6, 2020 **Federal Register** ((85 FR 19230); hereinafter referred to as the April 6, 2020 IFC).

1. Improving Access to Virtual Communication Services Furnished by Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC)

In the April 6, 2020 IFC (85 FR 19253–19254), we implemented on an interim final basis the expansion of services that can be included in the payment for virtual communications in RHCs and FQHCs. We explained that in order to minimize risks associated with exposure to COVID–19, and to provide the best care possible during the PHE for the COVID–19 pandemic, we believed that RHCs and FQHC practitioners, like many other health care providers, should explore the use of interactive communications technology in the place of services that would have otherwise been furnished in person and reported and paid under the established methodologies. To that end, we included the following services in the payment of virtual communications: CPT code 99421 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*); 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*); and 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*).

Prior to the COVID–19 PHE, HCPCS code G0071 was set at the average of the national non-facility PFS payment rates for HCPCS code G2012 (communication technology-based services) and HCPCS code G2010 (remote evaluation services), updated annually based on the PFS national non-facility payment rate for these codes. Furthermore, prior to services being furnished under HCPCS code G0071, patient consent was required both prior to the service being furnished and before these services were billed.

Effective for services furnished on or after March 1, 2020 and throughout the PHE for the COVID pandemic, we finalized on an interim final basis the payment rate for HCPCS code G0071 as the average of the PFS national non-facility payment rate for HCPCS code G2012 (communication technology-based services), HCPCS code G2010 (remote evaluation services), CPT code 99421, CPT code 99422, and CPT code 99423. The RHC and FQHC face-to-face requirements do not apply to these services.

Additionally, in order to ensure these services would be available to beneficiaries who otherwise would not have access to clinically appropriate in-person treatment, we placed in our interim final rule a provision stating that all virtual communication services billed by HCPCS code G0071 would be available to new patients not seen by the RHC or FQHC within the previous months. Lastly, CMS changed requirements regarding when patient consent was required for these services, in order to promote timely provision of care. Specifically, we allowed consent to be obtained when the services were furnished instead of prior to the service

being furnished and before the services were billed. Consent could also be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication codes during the COVID–19 PHE.

As a result of these changes made on an interim final basis, we received several comments related to these policies.

Comment: The majority of commenters were supportive of these additional flexibilities granted during the COVID–19 PHE. Commenters stated that use of online digital assessment services would provide additional flexibilities and allow providers to better meet patients' needs and ensure access to care during the pandemic. One commenter noted that the flexibility to bill HCPCS code G0071 for new patients would better help Urban Indian Organizations (UIOs) serve AI/AN communities. The commenter noted that this patient population often faces challenges in accessing medical professionals regularly within a 12-month span since they need to travel longer distances to reach dispersed reservation-based Indian Health Services (IHS) or tribal health services.

Response: We appreciate the commenters' support for these policies during the COVID–19 pandemic, especially in regards to positive impacts these flexibilities had on underserved communities, including AI/AN communities.

Comment: A few commenters asked that the flexibilities for virtual communication services be extended beyond the COVID–19 PHE in order to continuously allow providers to furnish services in ways that best meet the needs of their patients.

Response: We appreciate the commenters' support of this policy during the COVID–19 PHE. We continue to believe that outside of the context of the COVID–19 PHE, our standard policies regarding virtual communication services furnished by RHCs and FQHCs would continue to be appropriate. Therefore, once the COVID–19 PHE ends, we do not intend to further extend these flexibilities. Moreover, sections 1834(m)(7) and (m)(8) of the Act restrict payment for many RHC/FQHC telehealth services to a period that ends on the 151st day after the end of the PHE. We note that we will continue to evaluate the effectiveness of these flexibilities granted during the pandemic in promoting access to timely, quality care for Medicare beneficiaries. In the event that future circumstances warrant additional flexibilities, we will reconsider these issues in future rulemaking.

Comment: A few commenters recommended that CMS increase the payment rate for HCPCS code G0071 in order to help RHCs and FQHCs support the uptake in resource costs needed to expand and maintain updated telehealth systems, which was needed to increase capacity during the pandemic.

Response: CMS acknowledges that many providers were required to invest in telecommunication systems in order to continue to provide care during the pandemic amidst rising infection rates that limited in-person visits; however, we believe that the reimbursement is adequate.

Comment: A few commenters encouraged CMS to allow FQHCs and RHCs to furnish remote therapeutic monitoring (RTM) and remote patient monitoring (RPM) services in combination to the services reflected in HCPCS code G0071, so that they could monitor patient-generated health data for patients diagnosed with COVID–19.

Response: Although out-of-scope for this interim final rule, we would like to thank commenters for this suggestion. We note that for FQHCs and RHCs, RPM and RTM services are not stand-alone billable services. However, when these services are furnished incident to an FQHC or RHC visit, payment is included in the FQHC PPS rate or RHC all-inclusive AIR rate whose costs are reflected in cost reports.

Given the public comments we received, we are finalizing the provisions of the April 6, 2020 IFC without modification. Accordingly, these policies will terminate at the end of the COVID–19 PHE. Therefore, when the COVID–19 PHE ends, CPT codes 99421, 99422 and 99423 will no longer be included in the payment for HCPCS code G0071, virtual communication services will only be available to patients that have been seen in the RHC or FQHC within the previous 12 months, and beneficiary consent for these services must be acquired under direct supervision and prior to the services being furnished.

2. Revision of Home Health Agency Shortage Area Requirements for Furnishing Visiting Nursing Services by RHCs and FQHCs

In the April 6, 2020 IFC (85 FR 19254 and 19255), we implemented, on an interim final basis, changes to the requirements for visiting nursing services furnished in the home by RHCs and FQHCs. We refer readers to the April 6, 2020 IFC for a more detailed overview of that policy.

Prior to the COVID–19 PHE, visiting nursing services were only covered if an RHC or FQHC was located in an area designated by the Secretary to have a shortage of HHAs. In addition to this requirement, these services were only paid if rendered to a homebound individual. Other conditions establishing payable visiting nursing services can be found at § 405.2416. However, as a result of the COVID–19 PHE, we believed the need for visiting nursing services furnished by RHCs and FQHCs would increase, as would the need for services in historically underserved communities. To address an increased need for these medically necessary services, on an interim basis for the duration of the COVID–19 PHE, we determined that any area typically served by the RHC, and any area that is included in the FQHCs service area plan, was determined to have a shortage of HHAs with no request for this determination required. However, as an additional requirement, we mandated RHCs and FQHCs to check the HIPAA Eligibility Transaction System (HETS) before providing visiting nursing services to ensure that the patient was not already under a home health plan of care. If a patient was under a home health plan of care, the HHA had to provide optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs (§ 484.105). RHC and FQHC visiting nursing services could not be covered by Medicare if such services were found to overlap with a 30-day period of home health care.

Finally, we revised, on an interim basis, § 405.2416 to add paragraph (a)(5), to state that during the PHE for the COVID–19 pandemic, an area typically served by the RHC, and an area that is included in the FQHC's service area plan, is determined to have a shortage of HHAs, and no request for this determination is required.

We received a few comments related to this policy.

Comment: One commenter expressed support for expanding access to home health services within RHC and FQHC service areas. However, the same commenter was concerned that expanding these services would exacerbate existing shortages of home healthcare professionals since the policy broadened eligible service areas, and consequently the number of patients within these areas needing these services.

Response: We appreciate the commenter's general support of this policy and we also want to acknowledge the existing shortage of home healthcare

workers and the PHE's impact on underserved rural and urban communities. We believe this flexibility is important for patient access to nursing services in the home and the potential for HHAs that may be overwhelmed during COVID–19 PHE.

Given the public comments we received, we are finalizing the provisions of the April 6, 2020 IFC without modification. Accordingly, this policy will terminate when the COVID–19 PHE ends and the regulations at 42 CFR 405.2416(a)(5) will be removed in future rulemaking once the PHE has ended. After the COVID–19 PHE ends, visiting nurse services will only be covered if the RHC or FQHC is located in an area designated by the Secretary to have a shortage of HHAs and, and the services meet the other conditions set out at § 405.2416.

C. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS–5531–IFC)

In this final rule, we are also responding to public comments and stating our final policies for certain provisions in the IFC titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (CMS–5531–IFC), which appeared in the May 8, 2020 **Federal Register** ((85 FR 27550); hereinafter referred to as the May 8, 2020 IFC).

1. Revision of Bed Count Methodology for Determining Provider-Based RHCs' Exemption From the RHC Payment Limit

In the May 8, 2020 IFC (85 FR 27569), we implemented a policy on an interim final basis related to calculation of the bed count methodology that determined when a provider-based RHC was exempted from the national RHC per-visit payment limit. We refer readers to the May 8, 2020 IFC for a more detailed overview of that policy (85 FR 27569).

An RHC that is provider-based to a hospital with fewer than 50 beds is excepted from the national RHC per-visit payment limit and is reimbursed based on actual reasonable costs. However, due to the COVID–19 PHE, many hospitals had to increase inpatient bed capacity to address the surge in need for inpatient care. This could have affected payment for provider-based RHCs if their associated hospital had expanded their number of beds beyond 50, which would have then made them ineligible for the limit exception. CMS did not want to discourage hospitals from increasing bed capacity to meet patient needs and hoped to allow provider-based RHCs to continue to receive payment amounts they would otherwise receive in the absence of the COVID–19 PHE. As a result, on an interim basis, we revised the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs would be subject to the payment limit. Instead, CMS utilized the number of beds from the cost reporting period prior to the start of the COVID–19 PHE as the official hospital bed count for determining provider-based RHCs exempted from the RHC payment limit. This meant RHCs with provider-based status that were exempt from the national per-visit payment limit in the period prior to the effective date of the COVID–19 PHE (January 27, 2020) would continue to be exempt for the duration of the COVID–19 PHE, as defined at § 400.200.

After the publication of the May 8, 2020 IFC, section 130 of the Consolidated Appropriations Act of 2021 was passed and referred to this IFC's provision under section 1833(f)(3)(B) of the Act as a consideration for the bed count criterion. We note that the criteria in section 1833(f)(3)(B)(i) of the Act specified *a hospital with less than 50 beds*; therefore, beginning April 1, 2021, we applied the bed definition at § 412.105(b) exclusively. As we stated in the CY 2022 PFS final rule (86 FR 65203), we adopted an interim final policy to use the number of beds from the cost reporting period prior to the start of the COVID–19 PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were excepted from the national statutory payment limit in the period prior to the effective date of the COVID–19 PHE (January 27, 2020) would continue to be excepted from the bed count requirement for the duration of the PHE for the COVID–19 pandemic, as defined at § 400.200, even if the hospital raised its bed count above 50. Once the COVID–19 PHE ends, a hospital will need to lower its bed count to less than 50 beds to maintain the RHC exception. We received one comment related to this policy.

Comment: One commenter, representing RHCs and provider-based RHCs, commented on changes in utilization and settings of care during the pandemic, which may artificially reduce the RHC's all-inclusive rate (AIR). Specifically, the commenter noted that a minimum productivity standard, based on visits per FTE for different types of practitioners, is applied to the AIR rate. The commenter raised that this standard does not include telehealth visits as encounters that would be designated as visits under the minimum productivity standard. The commenter stated that RHCs and provider-based RHCs experienced an uptake in telehealth visits and a drop in in-person visits due to the pandemic, which may artificially lower the minimum productivity standard and AIR rate to RHCs. The commenter further mentioned that RHCs as a whole faced a drop in all visits even after accounting for telehealth visits. As a result of these changes in utilization, the commenter asked for CMS to waive the minimum productivity standard for a period of months after the COVID–19 PHE officially ends to allow time for patients to re-engage with providers.

Response: While this comment is out-of-scope since it relates to the methodology for the calculation of the minimum productivity standard instead of the bed-count methodology, we thank the commenter for raising this issue. We note that in the Medicare Benefit Policy Manual, Chapter 13, Section 80.4, ''RHC Productivity Standards'', RHCs may receive an exception to this productivity standard. The MAC has the discretion to make an exception to the productivity standard based on individual circumstances and CMS issued guidance to this effect in the MLN Matters SE20016, titled *New & Expanded Flexibilities for RHCs & FQHCs during the COVID–19 PHE*.[562]

In this final rule, we are finalizing the provisions of the May 8, 2020 IFC without modification. Accordingly, this policy will terminate when the COVID–19 PHE ends. As such, when Medicare Administrative Contractors (MACs) apply the rate setting process described in § 405.2464(a), they will no longer use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count when determining if a RHC retains its specified provider-based RHC status for purposes of section 1833(f)(3)(B)(i) of the Act. That is, an RHC will retain its specified provider-based status until the hospital which they are affiliated submits a cost report with more than 50 beds. An RHC will no longer retain its

[562] *https://www.cms.gov/files/document/se20016-new-expanded-flexibilities-rhcs-fqhcs-during-covid-19-phe.pdf.*

specified provider-based status nor be eligible for specified status in the future once the hospital which they are affiliated submits a cost report with more than 50 beds.

E. Origin and Destination Requirements Under the Ambulance Fee Schedule

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.

Under § 410.40 (e)(1), nonemergency transportation by ambulance is appropriate if either the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. That section further provides that bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation but is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, § 410.40 (e)(1) states that all of the following criteria must be met: (1) the beneficiary is unable to get up from bed without assistance, (2) the beneficiary is unable to ambulate, and (3) the beneficiary is unable to sit in a chair or wheelchair.

The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f). As provided in that section, Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, critical access hospital (CAH), or skilled nursing facility (SNF) that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition;
- From a hospital, CAH, or SNF to the beneficiary's home;
- From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip; and
- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

We continue to believe that our current regulatory requirements governing coverage of ambulance services are appropriate under normal circumstances. However, in the context of the PHE for the COVID–19 pandemic, we recognized that providers and suppliers furnishing ground ambulance services and other health care professionals are faced with new challenges regarding potential exposure risks, for Medicare beneficiaries and for members of the community at large. We recognized that this was a particularly emerging situation at the early phase of the PHE for COVID–19 when health care facilities and ground ambulance providers and suppliers were adapting to the COVID–19 pandemic, facing evolving facility capacity limits and service locations, and establishing new safety and health protocols for employees, volunteers, and beneficiaries.

In the interim final rule with comment period (85 FR 19276), on an interim basis, we expanded the list of destinations at § 410.40(f) for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services (EMS) protocols established by State and/or local laws where the services will be furnished. The EMS protocols are recognized operating procedures that all emergency service professionals such as emergency medical technicians (EMTs) and paramedics must follow for patient assessment, treatment, transportation and delivery to definitive care. These protocols are designed by national, State and/or local medical authorities and institutions. Based on these protocols, a patient suspected of having COVID–19 that requires a medically necessary transport may be transported to a testing facility to get tested for COVID–19 instead of a hospital in an effort to prevent possible exposure to other patients and medical staff.

These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physicians' offices, urgent care facilities, ambulatory surgery centers (ASCs), any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home. This expanded list of destinations applies to medically necessary emergency and non-emergency ground ambulance transports of beneficiaries during the PHE for the COVID–19 pandemic. Consistent with section 1861(s)(7) of the Act, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered.

In the interim final rule with comment period (85 FR 19276), we revised § 410.40 that added a new paragraph (f)(5), to state that during the PHE for the COVID–19 pandemic only, a covered destination includes a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with State and local EMS protocols where the services will be furnished. These destinations include, but are not limited to, any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physician offices, urgent care facilities, ASCs, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home. Home may be an appropriate destination for a COVID–19 patient who is discharged from the hospital to home to be under quarantine (as noted above, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered).

Comment: We received 17 comments in support of the temporary expansion of the list of covered ground ambulance destinations during the PHE for the COVID–19 only. Two commenters stated that this is exceptional and provides welcome relief to ambulance providers and suppliers who are working collaboratively with their local partners to preserve scarce healthcare resources. Another commenter applauded CMS for recognizing that during the duration of crisis it is important to allow ground ambulance organizations to transport patients to destinations other than hospitals, CAHs, and nursing homes. The commenter further stated that in addition to reducing hospital surge and reducing the risk of exposure, covering and reimbursing transports to alternative destinations is also likely to reduce the

overall Medicare costs and coinsurance obligations for these patients.

Response: We recognize that providers and suppliers furnishing ground ambulance services during the PHE for the COVID–19 pandemic have been faced with new challenges regarding potential exposure risks, for Medicare beneficiaries and for members of the community at large.

Comment: Two commenters questioned if it is a correct interpretation of the temporary expanded list of covered destinations that it would apply to any beneficiary, not only beneficiaries experiencing a COVID–19 related clinical presentation.

Response: The expanded list of covered ground ambulance transports during the PHE for the COVID–19 applies to any beneficiary with or without a COVID–19 related clinical presentation.

Comment: Two commenters noted that the beneficiary's home is listed as an appropriate alternate destination. The commenters inquired that since a medically necessary ambulance transportation to a beneficiary's home is already a covered destination, does including the beneficiary's home as an appropriate alternate destination mean that a clinically appropriate 'Treatment in Place' determination as contemplated in CMS' Emergency Triage, Treatment and Transport (ET3) payment model, where the beneficiary can be appropriately managed in the home, without ambulance transport, is a covered benefit.

Response: Consistent with section 1861(s)(7) of the Act, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered, and this interim regulation spoke to certain of those circumstances.

Separately, section 9832 of the American Rescue Plan Act of 2021 provides the Secretary with authority to implement a waiver applicable to ground ambulance services during the PHE for the COVID–19. Effective March 1, 2020 through the end of the PHE for the COVID–19, we are waiving the requirement under sections 1861(s)(7) and 1834(l) of the Act that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under § 410.40(f) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the PHE for the COVID–19. We would refer the reader to the COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document for further information at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*.

Comment: While three commenters supported the temporary revision to expand covered ground ambulance destinations during the PHE for the COVID–19 only, the commenters also recommended that CMS evaluate the effectiveness of this interim expansion and consider developing permanent revisions that can address broader issues. One commenter stated that an appropriate flexibility would provide alternatives to transporting a patient to a hospital emergency department when a lower level of care would meet patient needs safely, more efficiently, and at reduced cost to the beneficiary. The commenter further stated that hospital emergency departments are routinely overburdened, even before the current pandemic, often with patients not in need of emergency care. One commenter stated that given the likelihood that this policy change will result in a better patient care experience, a lower cost of care, and improved efficiencies for fire departments and EMS agencies, suggested CMS to make this change permanent.

Response: The CMS Innovation Center currently has an Emergency Triage, Treatment and Transport (ET3) Model which is a voluntary, 5-year payment model that will pay participants to transport to an alternative destination partner or initiate and facilitate treatment in place with a qualified health care partner, either at the scene of the 911 emergency response or via telehealth. We continue to believe that this model is well designed to evaluate the potential benefits described by the commenters in a broader set of circumstances that are not ascribed to a public health emergency. Due to the urgency of establishing the flexibility, we were unable to develop tracking mechanisms for such an analysis. To reduce burden so the focus would be on patient care, we instructed ground ambulance providers and suppliers to report the existing ambulance modifiers instead of developing new modifiers for each for covered destination.

We continue to believe that our current regulatory requirements governing coverage of ambulance services are appropriate under non-PHE circumstances. Therefore, we are finalizing our interim final policy that the expanded list of covered destinations for ground ambulance transports was for the duration of the PHE for the COVID–19 only. These destinations include, but are not limited to, any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physician offices, urgent care facilities, ASCs, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

When the PHE for the COVID–19 ends, our regulations will reflect the long-standing ambulance services coverage for the following destinations: hospital; CAH; rural emergency hospital (REH) (effective with services on or after January 1, 2023); SNF; beneficiary's home; and dialysis facility for an end-stage renal disease (ESRD) patient who requires dialysis. Any future refinements to the list of covered ground ambulance destinations will be addressed in rulemaking with an opportunity for the public to comment.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

In our April 6, 2020 IFC (85 FR 19230), November 19, 2021 IFC (86 FR 66031), and July 29, 2022 proposed rule (87 FR 45860), we solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements. The comments received are responded to in the sections below.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 101 presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate the average cost for the purpose of calculating total cost is a reasonably accurate estimation method.

TABLE 101: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43-3021	20.55	20.55	41.10
Computer System Analysts	15-1211	49.14	49.14	98.28
Licensed Practical and Licensed Vocational Nurses	29-2061	24.93	24.93	49.86
Medical and Health Services Managers	11-9111	57.61	57.61	115.22
Secretaries and Administrative Assistants	43-6014	19.75	19.75	39.50

In the data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), there is no single occupational code that we could use for ''Physician'' wage data. As shown in Table 102, in order to estimate the burden for Physicians, we are using a rate of $259.98/hr which is the average of the mean wage rates for Anesthesiologists; Family Medicine Physicians; General Internal Medicine Physicians; Obstetricians and Gynecologists; Pediatricians, General; Physicians, All Other; Psychiatrists; Orthopedic Surgeons, Except Pediatric; Pediatric Surgeons; Surgeons, All Other; and Surgeons, Except Ophthalmologists [($318.44/hr + $226.86/hr + $232.88/hr + $284.82/hr + $190.80/hr + $222.60/hr + $240.16/hr + $294.44/hr + $279.14/hr + $286.34/hr + $283.20/hr) ÷ 11]. In the average

TABLE 102: National Occupational Employment and Wage Estimates (Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	159.22	159.22	318.44
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine Physicians	29-1216	116.44	116.44	232.88
Obstetricians and Gynecologists	29-1218	142.41	142.41	284.82
Pediatricians, General	29-1221	95.40	95.40	190.80
Physicians, All Other	29-1229	111.30	111.30	222.60
Psychiatrists	29-1223	120.08	120.08	240.16
Orthopedic Surgeons, Except Pediatric	29-1242	147.22	147.22	294.44
Pediatric Surgeons	29-1243	139.57	139.57	279.14
Surgeons, All Other	29-1249	143.17	143.17	286.34
Surgeons	29-1240	141.60	141.60	283.20
Total				2,859.69
Average Physician Wage (2,859.68/11)				259.98

As indicated, we adjusted BLS' hourly wage estimates by a factor of 100 percent to obtain the adjusted hourly wage estimate. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of their appearance in sections II., III., IV., and V. of this final rule.

1. ICRs Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§ 414.940)

The following changes will be submitted to OMB for approval under control number 0938-New (CMS–10835).

As discussed in section III.A.7. of this final rule, as a part of implementing section 1847A(h) of the Act, as added by section 90004 of the Infrastructure Act, we recognize the need for establishing a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. We are finalizing that each manufacturer has an opportunity to dispute the report, described in section III.A.4. of this final rule, by submitting an error report.

We are finalizing that to assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error. The dispute must include the following information: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why the Secretary should use the proposed corrected data instead.

As discussed in section VII.E.1. of this final rule, our estimates show a projected 25 billing and payment codes meeting the definition of refundable single-dose container or single-use package drug with 10 percent or more discarded units, which is the applicable percentage specified in section 1847A(h)(3) of the Act. Therefore, we anticipate a similar number of drugs could owe a refund pursuant section 90004 of the Infrastructure Act. Since each of these billing and payment codes is a single source drug code, each code represents 1 manufacturer and we expect disputes from fewer than 10 manufacturers per year.

Consistent with the estimated annual burden per response/recordkeeper for similar error reports utilized to implement the Branded Prescription Drug Fee (76 FR 51310), we estimate the annual time per respondent/recordkeeper to be 40 hours. As we anticipate no more than 10 disputes per year, we estimate a total annual reporting and recordkeeping burden of 400 hours (10 error reports per year × 40 hr per response) at a cost of $15,800 ($39.50/hr × 400 hr).

2. ICRs Regarding the Clinical Laboratory Fee Schedule: Data Reporting by Laboratories

As described in section III.C.5. of this final rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories'' and we revised the regulations at § 414.504(a)(1) to account for a delay in reporting until January 1, 2023 through March 31, 2023. As stated in section 1834A(h)(2) of the Act chapter 35 of title 44 U.S.C., which includes such provisions as the PRA does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any requirements or burden for public review and OMB approval as prescribed under the PRA.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to section VII.E.7. of this final rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this final rule.

4. ICRs for Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services (§ 410.40(e)(2)(ii))

In section III.I. of this final rule, we discuss our clarifications to § 410.40(e)(2)(ii) that reorganize existing language and state that the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is required. We are also clarifying that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance. Finally, we are clarifying that coverage includes observation or other services rendered by qualified ambulance personnel. We do not expect that our proposal will yield a change in the information collection requirements or burden that is currently approved by OMB under control number 0938–1380 (CMS–10708) and 0938–0969 (CMS–10417) as this policy does not require providers and suppliers to submit additional information. We are simply clarifying existing policy requirements. We did not receive any comments on our proposed clarifications and are finalizing as-proposed.

5. ICRs for Medicare Provider and Supplier Enrollment Changes (§ 424.518)

This rule revises § 424.518 as follows:

- Add provider or supplier ownership changes as provider enrollment transactions falling within the scope of § 424.518. (As explained in section III.J. of this final rule, the applicable owner(s) will have to submit fingerprints and be subject to a fingerprint-based criminal background check if the provider or supplier is in the ''high'' level of categorical screening.)
- State that any screening level adjustment to ''high'' also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier that originally triggered the screening level increase.
- Moves SNFs from the ''limited'' level of categorical screening to the ''high'' screening level.

These changes will result in an increase in the annual number of providers and suppliers that must submit the fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) of all individuals who maintain a 5 percent or

greater direct or indirect ownership interest in the provider or supplier. The burden is currently approved by OMB under control number 1110–0046. We are not scoring the burden under this ICR section since the fingerprint card is not owned by CMS. However, an analysis of the impact of this requirement can be found in the RIA section of this rule.

None of our other Medicare provider enrollment provisions implicate information collection requirements.

6. ICRs for State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

We do not anticipate any information collection burden associated with our revision to § 455.107(b), for the latter merely involves giving the states somewhat greater flexibility in executing the provisions of § 455.107.

7. ICRs Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.L. of this final rule, we extended the existing compliance action of sending letters to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024 through December 31, 2024). Additionally, effective January 1, 2023, we changed the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions (§ 423.160(a)(5)(ii)). We also will determine whether a prescriber qualifies for the emergency or disaster exception (§ 423.160(a)(5)(iii)) based on the prescriber's valid address in PECOS (Medicare Provider Enrollment, Chain, and Ownership System), instead of the NCPDP Pharmacy Database address, and for prescribers who are not enrolled or do not have a valid PECOS address, we will use the address in the National Plan and Provider Enumeration System (NPPES) data. We do not expect that our finalized policies will yield a change in the information collection burdens described in CY 2022 PFS final rule (86 FR 65562 through 65564). We would like to clarify that the data collections discussed in CY 2022 PFS final rule will now be submitted through the standard PRA process under a new PRA package (OMB control number pending, CMS–10834) rather than submitted under OMB control number 0938–1396 (CMS–10755) as we stated in the CY 2022 PFS final rule (86 FR 65562). The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with opportunities for public review and comment.

8. ICRs Regarding the Medicare Ground Ambulance Data Collection System (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, this collection of information section does not set out any burden for the provisions. Please see section VII. of this preamble for a discussion of the estimated impacts.

We did not receive any public comments on our claim that the provision is exempt from the PRA and are finalizing that claim as proposed.

9. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Final Rule)

The following QPP-specific ICRs reflect this final rule's policy changes as well as adjustments to the policies that have been finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 59452, 84 FR 62568,85 FR 84472, and 86 FR 64996, respectively) due to revised assumptions based on updated available at the time of the publication of this final rule.

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

There is a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the revisions in the policies associated with the CY 2023 PFS final rule and the finalized revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The finalized estimated burden will be submitted to OMB under control number OMB 0938–1314 (CMS–10621). We note that CMS has already received approvals for the collection of information associated with the CAHPS for MIPS survey under OMB control number 0938–1222 (CMS–10450) and the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(2) Summary of Quality Payment Program Changes: MIPS

We have included the change in estimated burden for the CY 2023 performance period/2025 MIPS payment year due to the finalized policies and information collections in this final rule. The finalized policies in this rule impact the burden estimates for the CY 2023 MIPS performance period/2025 MIPS payment year.

The following six MIPS ICRs show changes in burden due to the finalized policies in this rule: (1) Quality performance category data submission by Medicare Part B claims collection type; (2) Quality performance category data submission by QCDR and MIPS CQM collection type; (3) Quality performance category data submission by eCQM collection type; (4) MVP quality performance category submission; (5) MVP registration, and (6) Promoting Interoperability performance category data submission. In aggregate, we estimate the finalized policies will result in a net decrease in burden of 3,708 hours and $405,213 for the CY 2023 performance period/2025 MIPS payment year. The remaining changes to our currently approved burden estimates are adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this final rule. As discussed in section IIV.E.16.a. of this final rule, we are basing our estimates on the newly available CY 2021 MIPS performance period data.

We have added one new ICR, ''third party intermediary plan audits,'' in section VI.B.9.c. of this rule for third party intermediaries to distinctly capture the burden related to: (1) QCDR and qualified registry targeted audits as established under the conditions for approval at § 414.1400(b)(3)(vi) through (viii); and (2) all the requirements for remedial action and termination at § 414.1400(e). For simplicity, we added this ICR to capture the requirements and burden for third party intermediaries to submit additional requirements for compliance with both the conditions of approval and remedial action and termination criteria under one ICR. We note that the addition of this ICR is not due to policy changes in this rule, but rather it is a change in our approach to representing the currently approved estimated burden for the ICRs related to the third party intermediaries in the CY

2022 PFS final rule. (86 FR 65569 through 65576).

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups; CAHPS survey vendor applications; group registration for CAHPS for MIPS survey; CAHPS for MIPS survey beneficiary participation; subgroups registration; call for Promoting Interoperability measures; nomination of improvement activities and opt-out of performance data display on Compare Tools for voluntary participants. See section VI.B.9. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted by two primary factors. First, we are unable to predict with absolute certainty who will be a QP for the CY 2023 performance period/2025 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the CY 2023 performance period/2025 MIPS payment year compared to the CY 2021 performance period/2023 MIPS payment year, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data. Additionally, we will continue to update our estimates annually as data becomes available.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the CY 2023 performance period/2025 MIPS payment year. We did not implement any changes to the Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of Data for QP determinations under the All-Payer Combination Option.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 103 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 103, MIPS eligible clinicians and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in a MIPS Value Pathway (MVP). We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS.

Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 103.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule that the APP is available for both ACO participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2023 performance period/2025 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in the CY 2022 PFS final rule (86 FR 65259 through 65263), the CMS Web Interface collection type is available through the CY 2024 performance period/2026 MIPS payment year only for clinicians participating in the Shared Savings Program. Per section 1899 of the Act (42 U.S.C. 1395jjj), submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. As described in section IV.A.6.c.(5)(b) of this final rule, we finalized the introduction of a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 QPP final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 PFS final rule (82 FR 53841 through 53844).

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TABLE 103: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in the Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures (CMS Web Interface will be available only to clinicians participating in Shared Savings Program ACOs **through** the CY **2024** performance period/**2026** MIPS payment year**)**	As a virtual group, group, subgroup, individual clinician, or APM Entity.[a]	As a virtual group, group, subgroup, individual clinician, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or APM Entity TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting]. [b]	As a virtual group, group, subgroup, or individual clinician. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. MVP participants electing to submit data for the measures and activities in an MVP must register. Clinicians in MIPS APMs electing the APM Performance Pathway. (CMS Web Interface will be available to only clinicians in ACOs **through** the CY **2024** performance period/**2026** MIPS payment year.) APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email. [d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by a Shared Savings Program ACO are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Section 1899 of the Act (42 U.S.C. 1395jjj) states that the Shared Savings Program is not subject to the PRA.

[b] Promoting Interoperability performance category data may be submitted at the group TIN, APM Entity TIN and individual clinician level. If group TIN, APM Entity TIN, and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. For multi-TIN APM Entities that do not submit at the APM Entity level, the TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021,

and CY 2022 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472 and 86 FR 64996), and continued in this final rule create some additional data collection requirements not listed in Table 103. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs related to MIPS third-party intermediaries (see section VI.B.9. of this final rule):

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314)
- Third party intermediary plan audits (New)
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 through 84970).

Additional ICRs related to the data submission and the quality performance category (see section VI.B.9. of this final rule):

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs related to the Promoting Interoperability performance category (see section VI.B.9.g. of this final rule):

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities (see sections VI.B.9.f., VI.B.9.h., VI.B.9.j., and VI.B.9.k. of this final rule):

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314)

Additional ICRs related to MIPS (see section VI.B.9.o. of this final rule):

- Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections VI.B.9.m. and VI.B.9.n. of this final rule):

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule does not create any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any changes under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2022 PFS final rule, for the burden related to the third party intermediaries, we combined the burden associated with the submission of: targeted audits, corrective action plans, participation plans and transition plans under the ICRs for QCDR and qualified registry self-nomination process (86 FR 65569 through 65576). In the CY 2023 PFS proposed rule, we proposed changes in our existing approach to capture the estimated burden for third party intermediaries (87 FR 46346). We proposed to separate the burden for submission of the targeted audits and other plans listed above under the ICR for third party intermediary plan audits. We stated that the change more accurately captures the associated burden for the QCDR and qualified registry self-nomination process because not every QCDR or qualified registry that submits a self-nomination application will also submit a targeted audit, corrective action plan (CAP), participation plan, or a transition plan. We are finalizing the proposed addition of the new ICR. This change is not due to any finalized policies related to third party intermediaries in this rule, rather it is a change in representing the estimated burden from adopted policies.

In section IV.A.6.g.(1)(b) of this rule, we finalized the proposed updates to the definition of a third party intermediary at § 414.1305, and to make other minor conforming technical edits to the CFR governing third party intermediaries set forth in § 414.1400. We also finalized our proposal to revise QCDR measure self-nomination and measure approval requirements to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/CY 2026 MIPS payment year.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[563] The processes for self-nomination of entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

As described below, in this rule we are adjusting the number of self-nomination applications used to calculate our burden estimates based on current data (from 84 to 63) from the CY 2022 QCDR self-nomination period for the CY 2023 performance period/2025 MIPS payment year. We are also adjusting our estimates for the number of existing or borrowed QCDR measures submitted for consideration by each

[563] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

QCDR at the time of self-nomination and the average time required to submit information for each QCDR measure. We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 through 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969, and 86 FR 65569 through 65573, respectively) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

(a) Self-Nomination Process and Other Requirements

In this rule, as explained below due to availability of updated data, we are adjusting: (1) the number of self-nomination applications (from 84 to 63) and (2) the estimated time required for QCDRs to submit a self-nomination application for the simplified (from 9.5 hours to 8.1 hours) and full self-nomination process (from 11.5 hours to 10.1 hours) due to an adjustment in the estimated weighted average time required for each QCDR to submit a measure (from 0.75 to 0.63 hours). In section IV.A.6.g.(1)(b) of this rule, we discuss our updates to the definition of a third party intermediary at § 414.1305 to align with existing policies and to make other minor conforming technical edits to the regulation text governing third party intermediaries set forth in § 414.1400. We assume that the revised definition of a (third party intermediary) and the conforming technical edits do not require additional information or change any of our active burden estimates during the self-nomination process. Therefore, we are not making such revisions under the aforementioned OMB control number.

(b) QCDR Measure Requirements

We previously finalized QCDR measure self-nomination requirements at § 414.1400(b)(4)(i), including the requirement at § 414.1400(b)(4)(i)(B) that entities must publicly post the measure specifications for QCDR measures no later than 15 calendar days following CMS' approval of any QCDR measure specifications.

In section IV.A.6.g.(2)(b) of this rule, we are finalizing our proposed revision to § 414.1400(b)(4)(i)(B) that clarifies requirements for publicly posting the QCDR measure specifications. Specifically, we are finalizing our proposal to revise QCDR measure self-nomination and measure approval requirements, including to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year. We are finalizing our proposal to continue delaying this requirement based on our recognition of the continuing impact of the COVID–19 public health emergency on the ability of QCDRs to test measures. We will not revise or adjust our active requirements or burden estimates as a result of this clarification because the finalized policy will only delay measure testing requirements and it will not substantively change the estimated average weighted time of 0.63 hours (discussed below in section) required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

Additionally, in section IV.A.6.g.(2)(c) of this rule, we finalized our proposal to amend § 414.1400(b)(4)(iii)(A)(*3*) to delay the requirement for QCDR measure full testing until the CY 2024 performance period/2026 MIPS payment year. We will not revise or adjust our active requirements or burden estimates as result of this change because we assume that the delay does not meaningfully change the existing requirements, or the time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

Based on the number of QCDR measures submitted for consideration during the CY 2022 QCDR self-nomination period for the CY 2023 performance period/2025 MIPS payment year, we continue to estimate that each QCDR will submit 12 measures, on average. However, we are adjusting our estimated number of new (from 2 to 1) and existing or borrowed measures from 10 to 11 based on the number of QCDRs that borrowed measures during the CY 2022 QCDR self-nomination period. Due to this change, we are also adjusting the estimated weighted average time required for each QCDR to submit a measure from 0.75 hours to 0.63 hours [((1 new measure × 2 hr) + (11 existing or borrowed measures × 0.5 hr))/total # of measures (12)] (a change of 0.12 hours). We note that we are not revising or adjusting our active estimated per response time for a QCDR to submit a new measure (2 hr/response) and an existing or borrowed measure (0.5 hr/response).

Based on the actual number of applications received during the CY 2022 self-nomination period for the CY 2023 performance period/2025 MIPS payment year, we are adjusting the number of QCDRs that will submit self-nomination applications in the CY 2023 PFS proposed rule (87 FR 46347) from 90 to 63 (a decrease of 27 self-nomination applications). Based on the updated data, this will result in a decrease of 21 self-nomination applications (from 84 to 63) from the currently approved number of QCDR self-nomination applications.

We note that we are not making any changes to the currently approved time of 0.5 hours required for the QCDR simplified self-nomination process and 2.5 hours for the full self-nomination process. For QCDRs that submit measures as part of their self-nomination process, due to the estimated increase in the number of existing or borrowed QCDR measures and a decrease in the number of new QCDR measures submitted with the self-nomination application discussed above, we are adjusting our estimated time for the QCDR self-nomination process from a minimum of 8.1 hours [0.5 hr for the simplified self-nomination process + (12 measures × 0.63 hr/measure for QCDR measure submission)] to a maximum of 10.1 hours [2.5 hr for the full self-nomination process + (12 measures × 0.63 hr/measure for QCDR measure submission)]. In this regard the minimum time has decreased by 1.4 hours (from 9.5 to 8.1) while the maximum time has decreased by 1.4 hours (from 11.5 to 10.1).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on behalf of MIPS eligible clinicians.

As shown in Table 104, we assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $98.28/hr. We estimate the burden per response will range between S796.06 (8.1 hr × $98.28/hr) for the simplified self-nomination process and $992.63 (10.1 hr × $98.28/hr) for the full self-nomination process. In aggregate, the estimated annual burden for the simplified and full-self nomination process for 63 QCDRs will range from 510 hours (63 responses × 8.1 hr) to 636 hours (63 responses × 10.1 hr)at a cost ranging from $50,152 (63 responses × $796.06/hr) to $62,536 63 responses × $992.63).

TABLE 104: Final Burden for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	63	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	63
Total Applications (c)	**63**	**63**
Annual Hours Per QCDR for Simplified Process (d)	8.1	0
Annual Hours Per QCDR for Full Process (e)	0	10.1
Total Annual Hours for Self-nomination (f) = (a) * (d) and (b) * (e)	**510**	**636**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $98.28/hr) (g) = (d) * $98.28/hr	$796.06	0
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $98.28/hr) (h) = (e) * $98.28/hr	0	$992.63
Total Annual Cost (**i**) = (a) * (**g**) (min) and (b) * (**e**) (max)	**$50,152**	**$62,536**

As shown in Table 105, we use the currently approved burden as the baseline for calculating the net change in burden for the QCDR self-nomination process. For the CY 2023 performance period/2025 MIPS payment year, the change in the representation of burden for this ICR described above and the estimated decrease of 21 respondents results in a change of minus 408 hours and minus $40,069 for the simplified self-nomination process (or minimum burden) and minus 540 hours and minus $53,041 for the full self-nomination process (or maximum burden). We note that the decrease in burden accounts for the change due to separating the estimated burden for targeted audits, CAPs, and participation plans and including that burden under a new ICR for third party intermediary plan audits (see Table 109).

We note that for the purpose of scoring the impact of this rule, we use only the maximum burden estimate in Tables 142, 143, and 145 of this rule.

TABLE 105: Burden Adjustments for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Time (hr) (a)	918	1,176
Total Annual Time (hr) for Respondents in CY 2023 PFS final rule (b) (See Table 104, row (f))	510	636
Difference (c) = (b) - (a)	**-408**	**-540**
Total Currently Approved Annual Cost (d)	$90,221	$115,577
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 104, row (i))	$50,152123	$62,536
Difference (f) = (e) - (d)	**-$40,069**	**-$53,041**

We did not receive any comments on our proposed requirements and burden estimates for the QCDR self-nomination process. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46346 through 46348) due to the availability of updated data.

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to § 414.1400 which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

In section IV.A.6.g.(1)(b) of this rule, we finalized the updated definition of a third party intermediary at § 414.1305 to include subgroups and APM Entities and to make minor edits for technical clarity. The revised definition of a third party intermediary will update the CFR to align with existing policy and does not create and new or revised requirements or burden. The number of respondents is unaffected by this change.

Based on the actual number of applications received during the CY 2022 self-nomination period for the CY 2023 performance period/2025 MIPS payment year, we are adjusting the number of qualified registries that will submit self-nomination applications in the CY 2023 PFS proposed rule (87 FR 46348), from 160 to 132. For this final rule, we estimate that 132 qualified registries will submit applications for self-nomination for the CY 2023 performance period/2025 MIPS payment year, a decrease of 15 applications from the currently approved estimate of 147 (86 FR 65574). We note that we are not making any changes to our currently approved per response time estimate of 0.5 hours for the simplified qualified registry self-

nomination process and 2 hours for the full qualified registry self-nomination process (86 FR 65574 through 65575).

As shown in Table 106, we assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. Using the change in estimated number of respondents, combined with the estimated time required for a self-nomination process ranging from a minimum of 0.5 hours to a maximum of 2 hours, we estimate that the burden ranges from a minimum of 66 hours (132 responses × 0.5 hr) and $6,487 (132 hr × $98.28/hr) to a maximum of 264 hours (132 applications × 2 hr) to $25,946 (264 hr × $98.28/hr), respectively.

Both the minimum and maximum burden shown in Table 106 reflect the updates in the estimated burden due to availability of more recent data. Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 106: Final Burden for Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	132	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	132
Total Applications (c)	**132**	**132**
Annual Hours Per Qualified Registry for Simplified Process (d)	0.5	0
Annual Hours Per Qualified Registry for Full Process (e)	0	2
Total Annual Hours for Self-Nomination for min. (f) = (a) * (d) and max. (b) * (e)	**66**	**264**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $98.28/hr) (g)	$49.14	0
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $98.28/hr) (h)	0	$196.56
Total Annual Cost (i) = (a) * **(g) (min.)** and (b) * **(h) (max.)**	**$6,487**	**$25,946**

As shown in Table 107, for the CY 2023 performance period/2025 MIPS payment year, the change in the representation of burden for this ICR described above in this section and the estimated decrease in 15 respondents results in a change of −325 hours at a cost of −$31,940 for the simplified self-nomination process (or minimum burden) and −577 hours at a cost of −$56,707 for the full self-nomination process (or maximum burden). We note that the decrease in burden accounts for the change due to separating the estimated burden for targeted audits and participation plans and including that burden under a new ICR for third party intermediary plan audits (see Table 109).

We note that for the purposes of calculating estimated change in burden in Tables 142, 143, and 145 of this rule, we use only the maximum burden estimate.

TABLE 107: Burden Adjustments for Qualified Registry Self -Nomination

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Hours (a)	391	841
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 106, row (f))	66	320
Difference (c) = (b) - (a)	**-325**	**-577**
Total Currently Approved Annual Cost (d)	$38,427	$82,653
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 106, row (i))	$6,487	$25,946
Difference (f) = (e) - (d)	**-$31,940**	**-$56,707**

We did not receive any comments on our proposed requirements and burden estimates for the qualified registry self-nomination process.

(4) Third Party Intermediary Plan Audits

The following finalized requirements and burden associated with developing the plans and audits by QCDRs and qualified registries will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed previously in this section of the final rule, we are finalizing the addition of a new ICRto distinctly capture the burden for requirements related to QCDR and

qualified registry targeted audits at § 414.1400(b)(3)(vi) through (viii) and the requirements for remedial action and termination of third party intermediaries at § 414.1400(e) during the third party intermediary self-nomination process. We note that we capture the estimated burden for third party intermediaries to submit additional requirements for compliance with both the conditions of approval and remedial action and termination criteria under one ICR.

In the CY 2022 PFS final rule, we combined the burden associated with the submission of the targeted audits, corrective action plans, participation plans and transition plans with the ICR for QCDR self-nomination process and other requirements (86 FR 65569 through 65573) and the ICR for qualified registry self-nomination process and other requirements (86 FR 65573 through 65576). For the purposes of this ICR, we refer to these audits and plans collectively as ''plan audits.'' For this final rule, we determined that it is necessary to set forth a new ICR to separately estimate the burden for QCDR and qualified registry targeted audits from self-nomination application burden because it will more accurately represent the burden.

In section IV.A.6.g.(3) of this rule, we finalized the proposed changes to the requirements for remedial actions and terminations set forth in § 414.1400(e). These include one revised and one new requirement for Corrective Action Plans (CAPs), and termination of certain approved QCDRs and qualified registries that continue to fail to submit performance data. The burden associated with these finalized policies is discussed below.

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 through 65548), we finalized that beginning with the CY 2021 performance period/CY 2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS final rule for the QCDRs (86 FR 65574) and qualified registries (86 FR 65571) that will submit targeted audits, we estimate that the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume that the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr.

For this final rule, we received updated data and as a result, we estimate that 32 third party intermediaries (13 QCDRs and 19 qualified registries) will submit targeted audits for the CY 2023 performance period/2025 MIPS payment year (See Table 108). We note that we are adjusting the number of third party intermediaries that will submit targeted audits from our estimate of 70 targeted audits in the CY 2023 PFS proposed rule (87 FR 46350) based on the actual number of targeted audits submitted by QCDRs and qualified registries during the CY 2022 self-nomination period. We estimate that the cost for a QCDR or a qualified registry to submit a targeted audit will range from $491.40 (5 hours × $98.28/hr) to $982.80 (10 hours × $98.28/hr). In aggregate, the total impact associated with QCDRs and qualified registries completing targeted audits will range from 160 hours (32 responses × 5 hr/audit) and $18,673 (32 responses- × $491.40/response $98.28/hr) to minus 320 hours (32 responses × 10 hr/audit) and $31,450 (32 responses × $982.80/response) for the simplified and full self-nomination process, respectively (see Table 109 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that did not submit performance data and therefore will need to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for current policies for remedial action and termination of third-party intermediaries.

In section IV.A.10.g.(3)(b) of this final rule, we finalized a new termination policy for approved QCDRs and qualified registries which are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii). We finalized the termination of those QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period and continue to not submit MIPS data to CMS for the applicable performance period. Specifically, we finalized the addition of a new ground for termination at § 414.1400(e)(5) stating that, beginning with the CY 2024 performance period/CY 2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii), will be terminated. As a result of this policy, CMS will terminate the qualified registry or QCDR as applicable under § 414.1400(e)(5) and we assume that it will not require additional requirements for interested parties to submit their information during the qualified registry and QCDR self-nomination process. (86 FR 65574). We refer readers to section IV.A.10.g.(3)(b) of this rule for additional details related to these finalized policies.

Consistent with our assumptions in the CY 2022 PFS final rule for the QCDRs (86 FR 65574) and qualified registries (86 FR 65571) that will submit participation plans, we estimate that it will take 3 hours for a QCDR or qualified registry to submit a participation plan during the self-nomination process. We assume that the staff involved in submitting a participation plan will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr.

As shown in Table 108, we estimate that 75 third party intermediaries [5 self-nomination participation plans (2 QCDRs and 3 qualified registries) and 70 QCDR measure participation plans] will submit participation plans for the CY 2023 performance period/2025 MIPS payment year. We note that we adjusted the number of third party intermediaries that will submit participation plans from the estimate of 29 in the CY 2023 PFS proposed rule (87 FR 46350) due to a significant increase in the number of QCDR measure participation plans required for the CY 2023 performance period/2025 MIPS payment year.

As shown in Table 109, we estimate that the cost for a QCDR or a qualified registry to submit a participation plan is $294.84 (3 hours × $98.28/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans will be 225 hours (75 responses × 3 hr/plan) at a cost of $66,339 (75 responses hr × $294.84/response). (See Table 109 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In section IV.A.10.g.(3)(a) of this rule, we finalized the proposed revision of the CAP requirement at § 414.1400(e)(1)(i)(B) to require the third party intermediary to address in its CAP the impact to individual clinicians, groups, or virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to

participating in the MIPS, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed. We also finalized the proposed addition of a new CAP requirement to require the third-party intermediary to notify the parties identified in § 414.1400(e)(1)(i)(B) of the impact to these parties by submitting a communication plan. We also finalized the proposed addition at § 414.1400(e)(1)(i)(E) to require the third party intermediary to develop a communication plan for communicating the impact to the parties identified in § 414.1400(e)(1)(i)(B). The intent of this policy is to enable affected parties to better understand and prepare for any operational and other challenges as needed. We believe having third party intermediaries submit a communication plan as part of their CAP will ensure third party intermediaries directly communicate the situation and its impact to these parties in a timely and consistent manner. However, due to the relatively low number of CAPs (an average of 10 responses) that we expect to receive from QCDRs and qualified registries for the CY 2023 performance period/2025 MIPS payment year, we are unable to estimate the burden associated with the development of a communication plan.

We are not making any changes to our currently approved estimates for the QCDRs and qualified registries that will submit CAPs. We continue to estimate that 10 third party intermediaries will submit CAPs for the CY 2023 performance period/2025 MIPS payment year and that it will take 3 hours for a QCDR or qualified registry to submit a CAP. We also assume that the staff involved in submitting the CAP will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. As shown in Table 109, we estimate that the cost for a QCDR or a qualified registry to submit a CAP is $294.84 (3 hours × $98.28/hr). Therefore, we estimate the total impact associated with QCDRs and qualified registries to CAPs will be 30 hours (10 responses × 3 hr/plan) at a cost of $2,948 (10 responses × $294.84/response). (See Table 109 for the cost per audit).

(d) Transition Plans

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we established a policy at § 414.1400(a)(4)(vi) that a condition of approval for the third party intermediary is to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. In the CY 2020 PFS final rule (84 FR 63115), we did not estimate the total burden associated with the development of CMS approved transition plans because of the uncertain, but low frequency (less than 10 per year historically) with which third party intermediaries have elected to discontinue services during a performance period. We received updated data for the transition plans submitted by the registries and QCDRs. Based on the actual number of transition plans received during the CY 2022 self-nomination period, we believe that we overestimated the number of transition plans in the CY 2023 PFS proposed rule (87 FR 46351). Therefore, we are adjusting the estimated number of third party intermediaries that will submit transition plans for the CY 2023 performance period/2025 MIPS payment year from 15 to 10. As a result, we estimate that we will receive 10 transition plans for the CY 2023 performance period/2025 MIPS payment year We estimate that it will take approximately 1 hour for a computer system analyst or their equivalent at a labor rate of $98.28/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. We did not receive any comments on the estimated burden for a QCDR or qualified registry to submit a transition plan. Therefore, we estimate the impact associated with qualified registries completing transition plans is 10 hours (10 transition plans × 1 hr/plan) and minus $983 (10 hr × $98.28/hr). We refer readers to section VII.E.16.e.(2)(c) of this final rule where we discuss our impact analysis for the transition plans submitted by QCDRs and qualified registries.

In section IV.A.6.g.(3) of this rule, we finalized the proposal to revise conforming changes to § 414.1400(e)(2), which currently states that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group under certain circumstances. Rather than amend this provision to add references to subgroups and APM Entities, we finalized the revision of § 414.1400(e)(2) to state that that CMS may immediately or with advance notice ''terminate a third party intermediary'' under the specified circumstances. The revision will simply provide that CMS may immediately or with advance notice ''terminate a third party intermediary' under the specified circumstances. The change is intended to revise the CFR in conjunction with the finalized policies in section IV.A.6.g.(1)(b) of this rule to amend the definition of a ''third party intermediary'' to refer to subgroups and APM Entities, and do not require additional information from QCDRs and qualified registries during the self-nomination process.

In section IV.A.6.g.(4)(b) of this rule, we finalized the proposed update at § 414.1400(f)(1) to require that the entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email. The change is intended to update the CFR to align it with the updates to the definition of a ''third party intermediary'' at § 414.1305 and to account for third party intermediaries reporting on behalf of subgroups and APM entities. We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to this finalized policy. Additionally, we refer readers to section VII.E.16.e.(2)(c) of this final rule where we discuss the details in our impact analysis for these finalized policies.

e. Final Burden for Third Party Intermediary Plan Audits

In aggregate, as shown in Table 108, we assume that 127 third party intermediaries will submit plan audits (32 targeted audits, 75 participation plans, 10 CAPs, and 10 transition plans).

TABLE 108: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	32
# of Participation Plans (b)	75
# of Corrective Action Plans (CAPs) (c)	10
# of Transition Plans (d)	10
Total Respondents (e) = (a) + (b) + (c) + (d)	**127**

As shown in Table 109, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. For the CY 2023 performance period/2025 MIPS payment year, in aggregate, the estimated annual burden for the simplified (or minimum) and full (or maximum) self-nomination process will range from 425 hours (see Table 109, row i) to 585 hours (see Table 109, row i)) at a cost ranging from $41,769 (425 hr × $98.28/hr) and $57,494 (585 hr × $98.28/hr), respectively.

TABLE 109: Final Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Minimum	Maximum
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 32 Targeted Audits (b)	**160**	**320**
# of Hours per Submission of Participation Plan (c)	3	3
Total Annual Hours for Submission of 75 Participation Plans (d)	**225**	**225**
# of Hours per Submission of CAP (e)	3	3
Total Annual Hours for Submission of 10 CAPs (f)	**30**	**30**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 10 Transition Plans (h)	**10**	**10**
Total Annual Hours for Submission of Plan Audits (i) = (b) + (d) + (f) + (h)	**425**	**585**
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $98.28/hr) (j) = (a) * $98.28/hr	$491.40	$982.80
Cost Per Participation Plan (@ computer systems analyst's labor rate of $98.28/hr) (k) = (c) * $98.28/hr	$294.84	$294.84
Cost per CAP (@ computer systems analyst's labor rate of $98.28/hr) (l) = (e) * $98.28/hr	$294.84	$294.84
Cost per Transition Plan @computer systems analyst's labor rate of $98.28/hr (m) = (g) * $98.28/hr	$98.28	$98.28
Total Annual Cost (n) = 32 * (j) + 75 * (k) + 10 * (l) + 10 * (m) (min) and 32 * (j) + 75 * (k) + 10 * (l) + 10 * (m) (max)	**$41,769**	**$57,494**

As shown in Table 110, for the CY 2023 performance period/2025 MIPS payment year, the addition of this ICR for third party intermediary plan audits results in a change of +425 hours at a cost of +$41,769 for the simplified self-nomination process (or minimum burden) and +585 hours at a cost of +$57,494 for the full self-nomination process (or maximum burden).

We note that for the purposes of calculating proposed estimated change in burden in Tables 142, 143, and 145 of this rule, we use only the maximum burden estimate.

TABLE 110: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Hours (a)	0	0
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 109, row (i))	425	585
Difference (c) = (b) - (a)	**+425**	**+585**
Total Currently Approved Annual Cost (d)	$0	$0
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 109, row (n))	$41,769	$57,494
Difference (f) = (e) - (d)	**+$41,769**	**+$57,494**

We did not receive any comments on our proposed addition of the ICR and burden estimates for the third party intermediary plan audits. As discussed above in this section, we finalized the addition of this ICR and adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46349 through 46352) due to the availability of updated data.

(5) Survey Vendor Requirements

This rule does not create any new or revised collection of information requirements or burden related to CAHPS Survey vendors. The requirements and burden for CAHPS survey vendors to submit data for eligible clinicians are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes under that control number.

d. ICRs Regarding Open Authorization (OAuth) Credentialing and Token Request Process

The requirements and burden associated with the OAuth Credentialing and token request process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2021 and the CY 2022 PFS final rules (85 FR 84969 through 85 FR 84970 and 86 FR 65576) for our previously finalized requirements and burden estimates for the information collection related to the OAuth credentialing and token request process.

This rule does not create any new or revised collection of information requirements or burden related to the OAuth credentialing and token request process. However, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, we made administrative changes in the process for interested parties to submit their application for OAuth credentialing and token process. Based on the changes to the workflows, the CMS Office of Information Technology (OIT) has centralized Okta Administrator privileges. In previous years, the Quality Payment Program maintained the privileges for Administrator roles. As a result of this administrative change, interested parties that will submit their information for OAuth Credentialing and Token request process are now required to meet with both Quality Payment Program and OIT for final approvals to have their applications integrated with the CMS Okta production environment. Therefore, we are revising our estimates that it will take 2 hours for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email. This is an increase of 1 hour from the currently approved estimated time of 1 hour for interested parties to provide their documentation and any follow-up communication via email.

As shown in Table 111, we are not making any changes to our currently approved estimate of 15 respondents that will complete this process for the CY 2023 performance period/2025 MIPS payment year. In aggregate, accounting for the increase in time required for a computer systems analyst (or their equivalent) to complete the token request process, we estimate a revised annual burden of 30 hours (15 vendors × 2 hr) at a cost of $2,948 (30 hr × $98.28/hr).

TABLE 111: Final Burden for the OAuth Credentialing and Token Request Process

Burden and Respondent Descriptions	Burden Estimate
# of Respondents (a)	15
Total Hours per Respondent	2
Total Annual Hours (c) = (a) * (b)	**30**
Labor Rate for Computer System Analyst (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$2,948**

As shown in Table 112, using our unchanged currently approved number of respondents (86 FR 65576), the increase in the amount of time required for the OAuth credentialing and token request process results in a change of +15 hours (+15 responses × 1 hr/response) at a cost of +$1,474 (+15 hr × $98.28/hr) from our currently approved burden of 15 hours (15 responses × 1 hr/response) at a cost of $1,474 (15 hr × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 112: Change in Burden for OAuth Credentialing and Token Request Process

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	15
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 111, row (c))	30
Difference (c) = (b) - (a)	**+15**
Total Currently Approved Annual Cost (d)	$1,474
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 111, row (e))	$2,948
Difference (f) = (e) - (d)	**+$1,474**

We did not receive any comments on our proposed requirements and burden estimates for the OAuth Credentialing and Token Request process. As discussed above in this section, we adjusted the currently approved burden estimates due to the administrative change in the OAuth credentialing and token request process.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 through 77503 and 82 FR 53908 through 53912, respectively), the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, and 86 FR 65576 through 65588, respectively) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: those who submit data as MIPS eligible clinicians, and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the third snapshot date for the 2021 QP Performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2023 performance period/2025 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future for the CY 2023 performance period/2025 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). In the CY 2023 proposed rule, we noted that we continued to use CY 2019 performance period/CY 2021 MIPS payment year data to estimate the number of respondents (87 FR 46354). We note that in this final rule, we have adjusted the number of respondents from 27,006 to 14,736 (a change of minus 12,270 respondents) based on the submissions received for the CY 2021 performance period/2023 MIPS payment year.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2021 and CY 2022 PFS final rules (85 FR 84972 and 86 FR 65567), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section VI.B.9.a.(4) of this final rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2023 performance period/2025 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 performance period/CY 2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2021 performance period/CY 2023 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this final rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[564]

For the CY 2023 performance period/2025 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. Additionally, we capture the burden for clinicians who choose to submit via these collection types for the quality

[564] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

performance category of MVPs. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2021 performance period/CY 2023 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 113 uses methods similar to those described above to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the CY 2023 performance period/2025 MIPS payment year. For the CY 2023 performance period/2025 MIPS payment year, we estimate that approximately 14,736 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 11,458 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 18,362 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2021 performance period/CY 2023 MIPS payment year, these are decreases of 10,691, 24,998, and 18,039 respondents from the currently approved estimates of 25,427, 36,456, and 36,401 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

TABLE 113: Revisions to the Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2023 MIPS performance period (excludes QPs) (a)	16,746	13,020	20,866	50,632
MVP Adjustment @ 12% (b) = (a)* 0.12	-2,010	-1,562	-2,504	-6,076
2023 MIPS Performance Period (excludes QPs and Adjusted for MVP) (c)= (a) – (b)	**14,736**	**11,458**	**18,362**	**44,556**
**Currently approved 2023 MIPS Performance Period (excludes QPs) (d)	25,427	36,456	36,401	98,284
Difference (**e) = (c) – (d**)	**-10,691**	**-24,998**	**-18,039**	**-53,728**

* We estimate 12 percent of clinicians will participate in MVP reporting as discussed in section VI.B.9. of this rule.
**Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 113 are not mutually exclusive.

Table 114 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2023 performance periods/2025 MIPS payment year. We assume that clinicians who submitted quality data as groups in the CY 2021 performance period/CY 2023 MIPS payment year will continue to submit quality data either as groups, or virtual groups for the same collection types for the 2023 performance period/2025 MIPS payment years. We used the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2021 performance period/2023 MIPS payment year.

As shown in Table 114, for the CY 2023 performance period/2025 MIPS payment year we estimate that 6,458 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 5,527 groups and virtual groups will submit for eCQM collection types. These are decreases of 3,976 and 1.845 respondents from the currently approved estimates of 10,434, and 7,372 for the groups and virtual groups that will submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

As the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities will participate through traditional MIPS and base our estimates on submissions received in the CY 2021 performance period/CY 2023 MIPS payment year.

TABLE 114: Revisions to the Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2023 MIPS performance period (excludes QPs) (a) prior to adjustments	0	7,339	6,281	13,620
Adjustment for MVPs (12%) (b) = (a) * 0.12	0	-881	-754	-1,635
2023 MIPS performance period (excludes QPs and) Adjusted for MVP). (c) = (a) – (b)	0	**6,458**	**5,527**	**11,985**
**Currently approved 2023 MIPS performance period (excludes QPs) (d)	0	10,434	7,372	17,806
Difference (e) = (d) - (c) - (d)	0	**-3,976**	**-1,845**	**--5,821**

* We estimate 12 percent of clinicians will participate in MVP reporting as discussed in section VI.B.9. of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group TINs could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. we refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 through 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2023 performance period/2025 MIPS payment year, we finalized a measure set of 198 quality measures. The new MIPS quality measures finalized for inclusion in MIPS for the CY 2023 performance period/2025 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures finalized for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 115, as well as counts of new, removed, and substantively changed measures. There are no changes to the remaining measures not included in Appendix 1. We refer readers to section IV.A.6.c.(1) of this final rule for additional information.

TABLE 115: Summary of Quality Measures Finalized for the CY 2023 Performance Period/2025 MIPS Payment Year

Collection Type	# Measures Finalized as New	# Measures Finalized for Removal*	# Measures Finalized with a Substantive Change*	# Measures Finalized for CY 2023*
Medicare Part B Claims	0	-4	15	30
MIPS CQMs Specifications	+8	-10	57	172
eCQM Specifications	+1	-2	42	47
Survey – CSV	0	0	1	1
Administrative Claims	+1	0	0	4
Total*	+9	-11**	76	198

*A measure may be specified under multiple collection types but will only be counted once in the total.
**We are finalizing to remove 15 MIPS quality measures and partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs.

For the CY 2023 performance period/2025 MIPS payment year, we are finalizing 198 measures, a net reduction of 2 quality measures across all collection types compared to the currently approved estimate of 200 measures. Specifically, as discussed in section IV.A.6.c.(1)(c) of this rule, we are finalizing to add 9 new MIPS quality measures, remove 11 MIPS quality measures, partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs, and make substantive updates to 76 MIPS quality measures. We do not anticipate that our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures.

(3) Quality Payment Program Identity Management Application Process

This rule does not create any new or revised collection of information requirements or burden related to the identity management application process. We are adjusting our currently approved estimates based on the updated data received for the number of respondents that will submit their information to obtain new user accounts in the HARP system for the CY 2023 performance period/2025 MIPS payment year. The finalized requirements and burden discussed below will be submitted to OMB under control number 0938–1314 (CMS–10621).

Based on historical trends for the number of eligible clinicians, groups, or third parties that register for new accounts, we noticed that we inadvertently underestimated our assumptions in the CY 2022 PFS final rule (86 FR 65582). In order to accurately capture the incremental change in the number of respondents in previous years, we are using a rolling average of the number of respondents that will register for obtaining new accounts. Therefore, we proposed to adjust our estimates from 3,741 to 6,500 for the number of respondents that will submit their information to obtain new user accounts in the HARP system for the CY 2023 performance period/2025 MIPS payment year. This will result in an increase of 2,759 respondents. We did not propose to adjust the currently approved estimated time of 1 hour per response to obtain a new account. As shown in Table 116, it will take 1 hour at $98.28/hr for a computer systems analyst (or their equivalent) to obtain an account for the HARP system. In aggregate we estimate an annual burden of 6,500 hours (6,500 registrations × 1 hr/registration) at a cost of $638,820 (6,500 hr × $98.28/hr).

TABLE 116: Final Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Description	Burden Estimate
# of New Users completing the Identity Management Application Process (a)	6,500
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a)*(b)	**6,500**
Cost Per Application @ computer systems analyst's labor rate of $95.22/hr.) (d)	$98.28
Total Annual Cost for completing the Identity Management Application Process (e) = (a)*(d)	**$638,820**

As shown in Table 117, we used the currently approved burden estimate to calculate the net change in burden for the ICR. In aggregate, using the currently approved time per response, the increase of 2,759 respondents from 3,741 to 6,500 for the CY 2023 performance period/2025 MIPS payment year will result in an estimated

increase of 2,759 hours (+2.759 responses × 1hr/response) at a cost of $271,155 (2,759 hr × 98.28/hr).

TABLE 117: Burden Changes for Quality Payment Program Identity Management Application Process

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	3,741
Total Annual Hours for Respondents in CY 2023 PFS final rule (See Table 116, row (c)) (b)	6,500
Difference (c) = (b) – (a)	**+2,759**
Total Currently Approved Annual Cost (d)	$367,665
Total Annual Cost for Respondents in CY 2023 PFS final rule (See Table 116, row (e)) (e)	$638,820
Difference (f) = (e) – (d)	**+271,155**

We did not receive any comments on our proposed requirements and burden estimates for the Quality Payment Program Identity Management application process. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46356 through 46357) due to the availability of updated data.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

While rule does not propose any new or revised collection of information requirements or burden related to the submission of Medicare Part B claims data for the quality performance category, We received updated data for the quality data submissions from clinicians using the Medicare Part B Claims-based collection type Therefore, we are adjusting our currently approved burden estimates based on our changes in assumptions for calculating the data. We refer readers to Table 126 of this section for the change in associated burden related to the submission of Medicare Part B claims data for the MVP quality performance category in the CY 2023 performance period/2025 MIPS payment year.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912, respectively), the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60004 through 60005, 84 FR 63124 through 63126, 85 FR 84975 through 84976, and 86 FR 65582 through 65584, respectively) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 113, based on updated data from the CY 2021 performance period/2023 MIPS payment year, we estimate that 14,736 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 10,691 from the currently approved estimate of 25,427 (86 FR 65583).

As shown in Table 113, consistent with our currently approved per response time figures, we continue to estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) for a computer systems analyst at a cost of $14.74 (0.15 hr × $98.28/hr) to 7.2 hours for a computer systems analyst at a cost of $707.61 (7.2 hr × $98.28/hr). The burden also accounts for the effort needed to become familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $115.22/hr for a medical and health services manager, 1 hour at $259.98/hr for a physician, 1 hour at $49.86/hr for an LPN, 1 hour at $98.28/hr for a computer systems analyst, and 1 hour at $41.10/hr for a billing and posting clerk.

As shown in Table 118, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In aggregate, the total annual time for the CY 2023 performance period/2025 MIPS payment year ranges from 105,362 hours (7.15 hr × 14,736 clinicians) to 209,251 hours (14.2 hr × 14,736 clinicians). The estimated annual cost (per clinician) ranges from $809.62 [(0.15 hr × $98.28/hr) + (3 hr × $115.22/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr) + (1 hr × $259.98/hr)] to a maximum of $1,502.49 [(7.2 hr × $98.28/hr) + (3 hr × $115.22/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr) + (1 hr × $259.98/hr)]. The total annual cost for the CY 2023 performance period/2025 MIPS payment year ranges from a minimum of $11,930,560 (14,736 clinicians × $810) to a maximum of $22,140,693 (14,736 clinicians × $1,502.49).

TABLE 118: Final Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	14,736	14,736	14,736
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	**105,362**	**118,625**	**209,251**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr @ varying times) (j)	$14.74	$103.19	$707.61
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr @ 3 hr) (k)	$345.66	$345.66	$345.66
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr @ 1 hr) (l)	$98.28	$98.28	$98.28
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr @1 hr) (m)	$49.86	$49.86	$49.86
Cost to Review Measure Specifications (@ billing clerk's labor rate of $41.10/hr @ 1 hr) (n)	$41.10	$41.10	$41.10
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr @ 1 hr) (o)	$259.98	$259.98	$259.98
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$809.62	$898.07	$1,502.49
*Total Annual Cost (q) = (a) * (p)	**$11,930,560**	**$13,233,960**	**$22,140,693**

As shown in Table 119, we used the currently approved burden as the baseline to calculate the net burden for the quality data submissions from clinicians using the Medicare Part B Claims-based collection type. In aggregate, using our currently approved per response time estimates, the decrease in number of responses from 25,427 to 16,746 (−10,691) results in a total maximum adjustment of −151,812 hours (−10,691 responses × 14.2 hr/response) at a cost of −$16,063,120 (−10,691 response × $1,502.49/response). For purposes of calculating total burden associated with this final rule as shown in Tables 142, 143, and 145, only the maximum burden is used.

TABLE 119: Burden Adjustments for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	361,063
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (see Table 118, row (i))	209,251
Difference (c) = (b) - (a)	**-151,812**
Total Currently Approved Annual Cost (d)	$38,203,813
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (see Table 118, row (q)	$22,140,693
Difference (f) = (d) - (e)	**-16,063,120**

We did not receive any comments on our proposed requirements and burden estimates for clinicians to submit data for the quality performance category via the Medicare Part B claims collection type. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46357 through 46359) due to the availability of updated data.

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 through 77505 and 82 FR 53912 through 53914, respectively), the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60005 through 60006, 84 FR 63127 through 63128, 85 FR 84977 through 84979, and 86 FR 65584 through 65586, respectively) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 126 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2023 performance period/2025 MIPS payment year.

As noted in Tables 113 and 114, based on updated data from the CY 2021 performance period/2023 MIPS payment year, for the CY 2023 performance period/2025 MIPS payment year, we assume that 17,916 clinicians (11,458 individuals and 6,458 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is a decrease of 24,998 individuals and a decrease of 3,976 groups from the currently approved estimates of 36,456 individuals and the 10,434 groups provided in the CY 2022 PFS final rule (86 FR 65585). Given that the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data is total of 9 hours at a cost of $982.65 per response. This consists of 3 hours at $98.28/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $115.22/hr for a medical and health services manager, 1 hour at $98.28/hr for a computer systems analyst, 1 hour at $49.86/hr for a LPN, 1 hour at $41.10/hr for a billing clerk, and 1 hour at $259.98/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hr) at $98.28/hr for a computer systems analyst at a cost of $8.15 (0.083 hr × $98.28/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $982.65/response [(3 hr × $98.28/hr) + (2 hr × $115.22/hr) + (1 hr × $259.98/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr) + (0.083 hr × $98.28/hr)].

As shown in Table 120, For the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 162,731 hours [9.083 hr/response × (11,458 clinicians submitting as individuals + 6,458 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians, a total of 17,916 responses)] at a cost of $17,605,157 (17,916 responses × $982.65/response).

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TABLE 120: Final Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	11,458
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	6,458
Total # of Respondents (c)=(a)+(b)	**17,916**
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)*(k)	**162,731**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr) (m)	$294.84
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (n)	$230.44
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (o)	$98.28
Cost LPN Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (p)	$49.86
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $41.10/hr) (q)	$41.10
Cost Physician Review Measure Specifications (@ physician's labor rate of $259.98/hr) (r)	$259.98
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $98.28/hr) (s)	$8.15
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$982.65
Total Annual Cost (u) = (c) * (t)	**$17,605,157**

As shown in Table 121, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden in the CY 2022 PFS final rule (86 FR 65584 through 65586). In aggregate, using the unchanged currently approved time per response estimate, the decrease of 28,974 respondents from 46,890 to 17,916 for the CY 2023 performance period/CY 2025 MIPS payment year results in a decrease of 263,171 hours (−28,974 responses × 9.083 hr/response) at a cost of −$28,471,302 (−28,974 responses × $982.65/response).

TABLE 121: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	425,902
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (see Table 120, row (l))	162,731
Difference (c) = (b) - (a)	**-263,171**
Total Currently Approved Annual Cost (d)	$46,076,459
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (see Table 120, row (u))	$17,605,157
Difference (f) = (e) - (d)	**-28,471,302**

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We did not receive any comments on our proposed requirements and burden estimates for clinicians to submit data for the quality performance category via the MIPS CQM and QCDR collection type. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46359 through 46360) due to the availability of updated data.

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130), CY 2021 PFS final rule (85 FR 84979 through 84980) and the CY 2022 PFS final rule (86 FR 65586 through 65588) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 126 of this section.

Based on updated data from the CY 2021 performance period/CY 2023 MIPS payment year data, we assume that 23,889 clinicians (18,362 individual clinicians and 5,527 groups and virtual groups) will submit quality data using the eCQM collection type for the CY 2023 performance period/CY 2025 MIPS payment year. This is a decrease of 18,039 individuals and a decrease of 1,845 groups from the estimates of 36,401 individuals and 7,372 groups provided in the CY 2021 PFS final rule (86 FR 65587). We assume the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $98.28/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $115.22/hr for a medical and health services manager, 1 hour at $259.98/hr for a physician, 1 hour at $98.28/hr for a computer systems analyst, 1 hour at $49.86/hr for an LPN, and 1 hour at $41.10/hr for a billing clerk. Overall, we estimate a cost of $876.22/response [(2 hr × $98.28/hr) + (2 hr × $115.22/hr) + (1 hr × $259.98/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr)].

As shown in Table 122, for the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 191,112 hours [8 hr x 23,889 (18,362 clinicians + 5,527 groups and virtual groups)] at a cost of $20,932,020 (23,889 responses × $876.22/response).

TABLE 122: Final Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	18,362
# of Groups submitting via EHR on behalf of individual clinicians (b)	5,527
Total # of Respondents (c)=(a)+(b)	**23,889**
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	**191,112**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr) (l)	$196.56
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (m)	$230.44
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (n)	$98.28
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (o)	$49.86
Cost to Review Measure Specifications (@ clerk's labor rate of $41.10/hr) (p)	$41.10
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr) (q)	$259.98
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$876.22
Total Annual Cost (s) = (c) * (r)	**$20,932,020**

In Table 123, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2022 PFS final rule (86 FR 65586 through 65588). In aggregate, using our currently approved time per response burden estimate, the decrease of 19,884 respondents from 43,773 to 23,889 for the CY 2023 performance period/2025 MIPS payment year results in a decrease of 159,072 hours ($-19{,}884$ responses $\times$ 8 hr/response) at a cost of $-\$17{,}422{,}758$ ($-19{,}884$ responses $\times$ $876.22/response).

TABLE 123: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	350,184
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (see Table 122, row (k))	191,112
Difference (c) = (b) - (a)	**-159,072**
Total Currently Approved Annual Cost (d)	$38,354,778
Total Annual Cost for Respondents in CY 2022 PFS final rule (e) (see Table 122, row (s))	$20,932,020
Difference (f) = (e) - (d)	**-$17,422,758**

We did not receive any comments on our proposed requirements and burden estimates for clinicians to submit data for the quality performance category via the eCQM collection type. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46361 through 46362) due to the availability of updated data.

(7) ICRs Regarding Burden for MVP Reporting

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Public comments were received with regard to our proposed burden estimates for MVP registration. See below for a summary of the comments and our response.

(a) Burden for MVP Reporting Requirements

We refer readers to the CY 2022 PFS final rule (86 FR 65588 through 65592) for our previously finalized burden and requirements for submission of data for the MVP quality performance category. In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 PFS final rule for our previously finalized assumptions on the estimated number of clinicians participating as subgroups in the CY 2023 performance period/2025 MIPS payment year (86 FR 65589).

For the requirements related to MVP participants, we used the MIPS submission data from the CY 2021 performance period/2023 MIPS payment year. In Appendix 3: MVP Inventory of this rule, we finalized the proposal to revise the 7 MVPs finalized in Appendix 3: MVP Inventory of the CY 2022 PFS final rule (86 FR 65998 through 66031). Specifically, these revisions are based on the removal of certain improvement activities in section IV.A.6.(3)(b)(ii) of this rule, the addition of other relevant existing quality measures for MVP participants to select from and the addition of the ONC direct review attestation requirement in the Promoting Interoperability performance category to all previously finalized MVPs. Additionally, we finalized 5 new MVPs beginning with the CY 2023 performance period/CY 2025 MIPS payment year. Therefore, MVP participants will have a total of 12 MVPs available for the CY 2023 performance period/2025 MIPS payment year. Due to the availability of new MVPs and addition of relevant quality measures to existing MVPs, we expect an increase in the number of MVP participants. Therefore, we estimate that 12 percent of the clinicians will participate in MVP reporting in the CY 2023 performance period/2025 MIPS payment year. This is an increase of 2 percentage points from the currently approved estimate of 10 percent in the CY 2022 PFS final rule (86 FR 65588 through 65589).

We assume that the changes to the existing MVPs and the addition of new MVPs will not impact the currently approved number of subgroups. We expect that clinician participation in subgroups will be relatively low for the CY 2023 performance period/2025 MIPS payment year due the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we did not make any adjustments to our previously finalized assumption in the CY 2022 PFS final rule (86 FR 65589) of 20 subgroups that will participate in MVP reporting.

In section IV.A.4.e.(4)(b) of this rule, we finalized the modification of § 414.1365(d)(3)(i)(A)(*1*) to read that subgroups are scored on each selected population health measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We also finalized the addition of § 414.1365(d)(3)(i)(B)(*1*) so that subgroups are scored on each selected outcomes-based administrative claims measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points. We assume that the finalized policies are related to the subgroup scoring of administrative claim measures and do not impact clinician participation in subgroups. Therefore, we are not making any adjustments to our previously finalized assumptions for subgroup reporting burden of the MVP quality performance category in the CY 2022 PFS final rule (86 FR 65592). Furthermore, clinicians do not submit data for the administrative claims measures and hence, there is no associated burden relevant to these measures for clinicians participating as subgroups.

Additionally, in section IV.A.4.e.(4)(c) of this rule, we finalized at § 414.1318(b)(1) that we will not assign a score for a subgroup that registers and does not submit data for the applicable performance period. We also finalized the proposal to make conforming changes at § 414.1318(b) to state that, except as provided under § 414.1317(b) and (b)(1), each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment. We assume that subgroups that register for MVP reporting intend to submit data for the measures and activities in an MVP. These policies are meant to clarify the scoring for subgroups in instances when a subgroup does not submit data as originally intended when registering as a subgroup. Therefore, we are not making any adjustments to our previously finalized assumptions for subgroup reporting burden of the MVP quality performance category in the CY 2022 PFS final rule (86 FR 65592).

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2022 PFS final rule (86 FR 65589 through 65590) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

As discussed above, based on updated data from the CY 2021 performance period/CY 2023 MIPS payment year, the changes to existing MVPs and the addition of new MVPs, we estimate that approximately 12 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2023 performance period/2025 MIPS payment year, we assume that the total number of individual clinicians, groups, subgroups and APM Entities to complete the MVP registration process is 7,731. To further clarify, we estimate that we will receive a total of 7,731 submissions for the measures and activities included in MVPs. As shown in Table 124, we estimate that it will take 1,933 hours (7,731 responses × 0.25 hr/response) at a cost of $189,975 (1,938 hr × 98.28/hr) for individual clinicians, groups and APM Entities to register for MVPs in the CY 2023 performance period/2025 MIPS payment year.

TABLE 124: Final Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	7,731
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time (hr) for MVP Registration (c) = (a) * (b)	**1,933**
Computer systems analyst's labor rate ($/hr). (d)	98.28
Estimated Total Annual Cost for MVP Registration (e) = (c) * (d)	**$189,975**

In Table 125, we illustrate the net change in burden for MVP registration using the currently approved burden in the CY 2022 PFS final rule (86 FR 65588 through 65589). In aggregate, for the CY 2023 performance period/CY 2025 MIPS payment year, the adjustment in the number of respondents expected to register for MVP reporting from 12,917 to 7,731 results in a decrease of 5,186 responses. In aggregate, when combined with the currently approved per response time estimate, this will result in a decrease of 1,296 hours (3,229 hours − 1,933 hours) at a cost of −$127,371 (−1,296 hr × 98.28/hr).

TABLE 125: Burden Adjustment for MVP Registration: Individuals, Groups, and APM Entities

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	3,229
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 124, row (c))	1,933
Difference (c) = (b) - (a)	**-1,296**
Total Currently Approved Annual Cost (d)	$317,346
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 124, row (e))	$189,975
Difference (f) = (e) - (d)	**-$127,371**

The following is a summary of the comments received for our proposed burden estimates for MVP registration and our responses.

Comment: One commenter shared their results from a clinician poll that 13 percent of practices will participate in MVP reporting for the CY 2023 performance period/CY 2023 MIPS payment year.

Response: We thank the commenter for their feedback on MVP participation estimates for the CY 2023 performance period/2025 MIPS payment year. We note that the estimate received is slightly higher than our proposed estimate of 12 percent for MVP participant registration. However, we do not believe that we can make adjustments to our estimate of 12 percent for MVP participants based on this information as we do not have additional details (poll sample size, participant pool, etc.) of the poll.

After consideration of the public comments received for our proposed requirements and burden estimates for the MVP registration process, we did not make any further changes. As discussed above in this section, we updated the burden estimates from the CY 2023 PFS proposed rule (87 FR 46362 through 46364) due to the availability of updated data.

(ii) Burden for Subgroup Registration

We previously established at § 414.1365(b) a registration process for clinicians who choose to report MVPs through a subgroup. We refer readers to the CY 2022 PFS final rule for our previously finalized burden relevant to subgroup registration for clinicians participating in MVP reporting (86 FR 65590).

In section IV.A.4.e.(2) of this rule, we finalized our proposed update to the definition of a single specialty group at § 414.1305 to state that single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims. We also finalized our proposed update to the definition of a multispecialty group at § 414.1305 to state that multispecialty group means a group that consists of two or more specialty types as determined by CMS using Medicare Part B claims. We believe that these definitions will help groups understand their specialty determination. However, we will not adjust the subgroups burden relevant to these policies because we believe that these definitions will not impact the utilization of subgroups by groups and hence, would not change the way groups choose to organize clinicians in subgroups.

In section IV.A.4.e.(3)(b) of this rule, we finalized that as part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. Under this policy, we will identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text—only

field, if the options we provide do not correctly describe the subgroup. We assume that the burden associated with choosing a key scenario will minimize the time required for subgroups to provide a narrative description. Additionally, we anticipate the narratives to be short descriptions of the nature of a group practice and appropriately reflect the subgroup composition. Therefore, we are not adjusting the burden for subgroup registration because we assume that the narrative requirement will not add significant burden to the currently approved half an hour for subgroup registration in the CY 2022 PFS final rule (86 FR 65590). We refer readers to section IV.A.8.e.(3)(b) of this rule for examples of the subgroup narrative description.

In section IV.A.4.f.(3)(d) of this rule, we finalized our proposed addition at § 414.1318(a)(4) that CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the initial 12-month segment of the applicable MIPS determination period. Additionally, we finalized the proposal to make conforming changes at § 414.1318(a)(1) to state that, except as provided under paragraph (a)(2) of this section and subject to paragraph (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310. We assume that these policies will provide clarification for groups to identify their eligibility to form subgroups and also ensure that an individual eligible clinician or group will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. This policy does not change the application of low-volume threshold and special status as described under § 414.1318(a)(1) for clinicians in subgroups. Therefore, we are not adjusting the currently approved burden for subgroup registration.

In section IV.A.4.e.(3)(c) of this rule, we finalized at § 414.1318(a)(3) that an individual eligible clinician, as represented by a TIN–NPI combination may register for no more than one subgroup within a group's TIN. We assume that the policy will limit the number of subgroups that a clinician could participate under a TIN and will not result in additional burden for clinicians to participate as subgroups. Therefore, we are not adjusting the number of subgroups and the currently approved burden for subgroup registration.

As noted above, we are not making any changes to our previously finalized subgroup registration burden. The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes pertaining to subgroup registration under that control number. Similar to our assumptions in the CY 2022 PFS final rule, we continue to capture the burden associated with subgroup quality reporting in the ICR for MVP quality performance category submission (directly below). The burden associated with subgroup submissions for Promoting Interoperability and improvement activities is included in the relevant ICRs (Promoting Interoperability data submission and improvement activities submission), and in sections VI.B.9.g.(3) and VI.B.9.i. of this rule.

(iii) Burden for MVP Quality Performance Category Submission.

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we previously finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). As discussed in section IV.A.8.b. of this rule, we did not propose new requirements to submit data for the quality performance category of MVPs. Therefore, we did not propose any changes to our currently approved per response time estimates for submitting the MVP quality performance category data.

As described above in section VI.B.9.e. of this final rule, we estimate that 12 percent of the clinicians who participated in MIPS for the CY 2021 performance period/2023 MIPS payment year will submit data for the quality performance category of MVP in the CY 2023 performance period/2025 MIPS payment year. We also estimate that there will be 20 subgroups reporters in the CY 2023 performance period/2025 MIPS payment year. As shown in Table 126, we estimate that 3,258 clinicians and 10 subgroups will submit data using eCQMs collection type at $580.44/response (see line q for eCQMs); 2,443 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type at $646.29/response (see line q for CQM and QCDRs); and 2,010 clinicians and 0 subgroups will submit data for the MVP quality performance category using the Medicare Part B claims collection type at $998.67/response (see line q for claims). For the CY 2023 performance period/2025 MIPS payment year, using our currently approved per response time estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 17,320 hours [5.3 hr × 3,268 (3,258 + 10) responses] at a cost of $1,896,878 (3,268 responses × $580.44/response) for the eCQM collection type, 14,644 hours [5.97 hr × 2,453 (2,443 + 10)] at a cost of $1,585,349 (2,453 responses × $646.29/responses) for the MIPS CQM and QCDR collection type, and 18,974 hours (9.44 hr × 2,010 clinician responses) at a cost of $2,007,327 (2,010 responses × $998.67/response) for the Medicare Part B claims collection type.

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TABLE 126: Final Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	3,258	2,443	2,010
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	3,268	2,453	2,010
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**17,320**	**14,644**	**18,974**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr @ varying times) (k)	$130.71	$196.56	$471.74
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (l)	$153.24	$153.24	$230.44
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (m)	$64.87	$64.87	$64.87
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (n)	$32.91	$32.91	$32.91
Cost to Review Measure Specifications (@ billing clerk's labor rate of $41.10/hr) (o)	$27.12	$27.12	$27.12
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr) (p)	$171.59	$171.59	$171.59
*Total Annual Cost Per Clinician (q) = (k) + (l) + (m) + (n) + (o) + (p)	$580.44	$646.29	$998.67
***Total Annual Cost (r) = (c) * (q)**	**$1,896,878**	**$1,585,349**	**$2,007,327**

Table 127 illustrates the changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and claims collection types in the CY 2023 performance period/2025 MIPS payment year. We note that we used the currently approved burden in the CY 2022 PFS final rule (86 FR 65590 through 65592) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the decrease in 5,166 respondents that will submit data for the MVP quality performance category will result in a decrease of 8,502 hours and $931,027 for the eCQM collection type, a decrease of 16,519 hours and $1,788,285 for the CQM and QCDR collection type, and a decrease of 7,714 hours and $813,916 for the claims collection type.

TABLE 127: Burden Adjustments for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	25,822	31,163	26,688
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 126, row (k))	17,320	14,644	18,974
Difference (c) = (b) **- (a)**	**-8,502**	**-16,519**	**-7,714**
Total Currently Approved Annual Cost (d)	$2,827,905	$3,373,634	$2,821,243
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 126, row (r))	$1,896,878	$1,585,349	$2,007,327
Difference (f) = (e) - (d	**-$931,027**	**-$1,788,285**	**-$813,916**

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We did not receive any comments on our proposed requirements and burden estimates for the submission of measures in the MVP quality performance category. As discussed above in this section, we adjusted our burden estimates from the CY 2023 PFS proposed rule (87 FR 46365 through 46367) due to the availability of updated data.

(8) Beneficiary Responses to CAHPS for MIPS Survey

This rule does not create any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any CAHPS for MIPS Survey changes under that control number.

(9) Group Registration for CAHPS for MIPS Survey

This rule does not create any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making CAHPS for MIPS Survey registration changes under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

This rule does not create any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, based on the actual number of quality measure submissions received for CMS consideration during the 2022 Annual Call for Quality Measures, we are adjusting our burden estimates for the CY 2023 performance period/CY 2025 MIPS payment year.

In this rule, we estimate that we will receive 29 quality measure submissions during the 2023 Annual Call for Quality Measures, an increase of 1 from the currently approved number of quality measure submissions for consideration (86 FR 65594 through 65596). We are not making any changes to the 5.5 hour (2.4 hr for practice administrator + 3.1 hr for clinician) per response time estimate for quality measure submissions.

As shown in Table 128, we estimate an annual burden of 160 hours (line f: 29 measure submissions × 5.5 hr/measure) at a cost of $31,392 (line j: 29 measure submissions × [(2.4 hr × $115.22/hr) + (3.1 hr × $259.98/hr)]) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 128: Final Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	29
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**160**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $115.22/hr) * 2.4 hr = (g)	$276.53
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $259.98/hr) * 3.1 hr = (h)	$805.94
Total Annual Cost Per Submitted Measure (i)	$1,082.47
***Total Annual Cost (j)=(a)*(i)**	**$31,392**

In Table 129, we illustrate the net change in estimated burden for the call for quality measures using the currently approved burden in the CY 2022 PFS final rule (86 FR 65594 through 65596). In aggregate, the estimated increase in the number of quality measure submissions will result in an adjustment of +6 hours (+1 measure submission × 5.5 hr/measure submission) at a cost of $1,083 (+1 measure submission × $1082.47/measure submission) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 129: Burden Adjustments for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	154
Total Annual Hours for Respondents in CY 2023 PFS Final Rule (b) (See Table 128, row (f))	160
Difference (c) = (b) - (a)	**+6**
Total Currently Approved Annual Cost for Respondents (d)	$30,309
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 128, row (j))	$31,392
Difference (f) = (e) - (d)	**+$1,083**

We did not receive any comments on our proposed requirements and burden estimates for the submission of applications to request reweighting for the Promoting Interoperability and other performance categories. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46367) due to the availability of updated data.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2023 performance period/2025 MIPS payment year, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis, and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), and the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60011 through 60012, 84 FR 63134 through 63135, 85 FR 84984 through 84985, and 86 FR 65596 through 65598, respectively) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

In section IV.A.6.c.(4)(h) of this rule, we finalized the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals only for the CY 2023 performance period/CY 2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)*(4)(i)* to reflect the proposal. We also finalized the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2024 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)(*4*)(*iii*) to reflect the proposal. We are not adjusting the number of respondents submitting reweighting applications due to these proposals because it does not change the existing reweighting policy for these clinician types participating in MIPS in the CY 2023 performance period/2025 MIPS payment year.

Table 130 summarizes the burden for clinicians to apply for reweighting of the Promoting Interoperability performance category to zero percent due to a significant hardship or as a result of a decertification of an EHR. Based on the number of reweighting applications received at the time of the publication of this rule for the CY 2022

performance period/2024 MIPS payment year, we are adjusting our burden estimates relevant to this ICR in the CY 2023 PFS proposed rule (87 FR 46367 through 46369). In this rule, we estimate that we will receive a total of 5,439 reweighting applications for the CY 2023 performance period/2025 MIPS payment year. Out of the 5,439, we estimate that 986 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. We estimate that the remaining 4,451 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. Additionally, we estimate that 2 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2023 performance period/CY 2024 MIPS payment year. This adjustment results in a decrease of 37,388 respondents compared to our currently approved estimate of 42,827 respondents (86 FR 65597). This decrease is based on the actual number of reweighting applications submitted for the CY 2022 performance period/2024 MIPS payment year. Similar to the data used to estimate the number of respondents in the CY 2021 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief.

Consistent with our assumptions in the CY 2022 PFS final rule (86 FR 65596 through 65598), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the application. As shown in Table 130, we estimate an annual burden of 1,360 hours (5,439 applications × 0.25 hr/application) and $133,661 (1,360 hr × $98.28/hr).

TABLE 130: Final Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	5,437
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	2
Total Applications Submitted (c)	**5,439**
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	**1,360**
Labor Rate for a computer systems analyst (f)	$98.28/hr
Total Annual Cost (g) = (e) * (f)	**$133,661**

In Table 131, we illustrate the net change in estimated burden for submission of reweighting applications for Promoting Interoperability and other performance categories using the currently approved burden in the CY 2022 PFS final rule (86 FR 65596 through 65598). The adjustment in the estimated number of respondents, from 42,827 to 5,439 respondents, results in a decrease of 37,388 respondents. In aggregate, using our currently approved per response time estimate, as shown in Table 131, the decrease in 37,388 respondents results in a decrease of 9,347 hours (−37,388 responses × 0.25 hr/response) and $918,623 (−9,347 hr × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 131: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2022 PFS final rule (a)	10,707
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 130, row (c))	1,360
Difference (c) = (b) - (a)	**-9,347**
Total Currently Approved Annual Cost in CY 2022 PFS final rule (d)	$1,052,284
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 130, row (e))	$133,661
Difference (f) = (e) - (d)	**-$918,623**

We did not receive any comments on our proposed requirements and burden estimates for the submission of applications to request reweighting for the Promoting Interoperability and other performance categories. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46367 through 46369) due to the availability of updated data.

(3) Submitting Promoting Interoperability Data

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, and 82 FR 53919 through 53920, respectively), and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 60013 through 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, and 86 FR 65598 through 65600, respectively) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In section IV.A.6.c.(4)(d)(i)(D)(ab) of this final rule, we finalized the proposal to require MIPS eligible clinicians to report the Query of PDMP measure (which requires reporting a ''yes/no'' response) for the Promoting Interoperability performance category. Additionally, we finalized two exclusions beginning with the performance period in CY 2023: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period, and (3) Any MIPS eligible clinician for whom querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period they select in CY 2023. Due to lack of sufficient data regarding the number of clinicians who voluntarily submitted data for optional measures in the Promoting Interoperability performance category, we have consistently been unable to estimate the associated burden for the reporting of such measures. Therefore, we did not make additional changes to the currently approved time required for clinicians to submit data for the Promoting Interoperability performance category because we are unable to account for any change in burden due to the finalized policy to require the currently optional Query of PDMP measure.

In section IV.A.6.c.(4)(e) of this rule, we finalized the proposal to add an additional measure through which a MIPS eligible clinician could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we finalized the proposal to add the following new measure to the Health Information Exchange Objective beginning with the performance period in CY 2023: Enabling Exchange Under TEFCA measure. We finalized that MIPS eligible clinicians will have three reporting options for the Health Information Exchange Objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable); (2) report on the HIE Bi-Directional Exchange measure; or (3) report on the Enabling Exchange Under TEFCA measure. We believe that given the alignment between the Enabling Exchange under TEFCA measure and the existing HIE Bi-Directional exchange measure, adding this measure offers clinicians more opportunities to earn credit for the Health Information Exchange Objective. Because the addition of Enabling Exchange Under TEFCA measure is optional for the Health Information Exchange Objective, we are unable to estimate the number of clinicians that will report this measure. Therefore, we did not propose to adjust our currently approved burden for clinicians to submit data for the Promoting Interoperability performance category because we are unable to account for any change in burden due to the change.

The following is a summary of the comments we received for our estimates on the measures in the Health Exchange Objective of the Promoting Interoperability performance category and our responses.

Comment: One commenter supported CMS' recommendation to not adjust the estimated time required for a clinician to submit the measures in the Health Information Exchange Objective for the Promoting Interoperability performance category.

Response: We thank the commenter for their support.

In section IV.A.6.c.(4)(f)(ii) of this rule, we finalized proposed revisions to the three active engagement options. Specifically, we finalized the proposal to consolidate current options 1 and 2 into one option beginning with the performance period in CY 2023. Additionally, for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures a MIPS eligible clinician chooses to report, we finalized the proposal to require MIPS eligible clinicians to submit their level of active engagement, either Pre-production and Validation or Validated Data Production (as described in section IV.A.6.c.(4)(f)(ii)(C) of this final rule), for each measure they report beginning with the performance period in CY 2023. In the CY 2023 PFS proposed rule (87 FR 46369), we estimated that it would add an additional 1 minute (0.02 hr) to the currently approved estimated time of 2.69 hours for MIPS eligible clinicians to submit their level of active engagement, resulting in a total estimated time of 2.71 hours (2.69 hr + 0.02 hr), for clinicians to submit data for the Promoting Interoperability performance category. In the FY 2023 Medicare Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Long-term Care Hospital Prospective Payment System final rule (87 FR 49394), it was finalized that it would take an estimated time of 30 seconds (or 0.5 minutes) for eligible hospitals and CAH (Critical Access Hospital) s to submit their level of active engagement. We assume that it will take a MIPS eligible clinician the same time estimated for a CAH or an eligible hospital to submit their level of active engagement. We recognize that our proposed estimate of 1 minute is an overestimate. Therefore, we are revising our estimate that it would take 0.5 minutes (0.0083 hr) for MIPS eligible clinicians to submit their level of active engagement, resulting in a total estimated time of 2.70 hours, for clinicians to submit data for the Promoting Interoperability performance category. We refer readers to the FY 2023 IPPS final rule (87 FR 49394) for additional details on the estimated burden relevant to the measure.

We did not receive any comments on our proposed requirements and burden estimates for clinicians to submit their level of active engagement. As described above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46369) due to the availability of additional information.

In section IV.A.6.c.(4)(f)(ii)(D) of this rule, we also finalized that beginning with the performance period in CY 2023, that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level

of active engagement per measure, and that they must progress to the Validated Data Production level in the next performance period for which they report a particular measure. We refer readers to sections IV.A.6.c.4.(d) and IV.A.6.c.(4)(g) of this rule for additional information on measure descriptions and changes to scoring methodologies in the Promoting Interoperability performance category.

As shown in Table 132, based on updated data from the CY 2021 performance period/2023 MIPS payment year, we are adjusting our proposed estimate in the CY 2023 PFS proposed rule (87 FR 46370) for the total number of respondents that will submit Promoting Interoperability data in the CY 2023 performance period/2025 MIPS payment year. We estimate that a total number of 30,107 respondents, consisting of 22,293 individual MIPS eligible clinicians, 7,794 groups and virtual groups, and 20 subgroups will submit data for the Promoting Interoperability performance category in the CY 2023 performance period/2025 MIPS payment year. We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APP. As a result, we do not anticipate any change in burden for APM Participants submitting data for the Promoting Interoperability performance category. In section IV.A.6.c.(5)(b) of this rule, we finalized the proposal to introduce a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year. Because the reporting of the Promoting Interoperability performance category is voluntary, we are unable to estimate the number of APM Entities that will submit data on behalf of their clinicians for this category. Therefore, we assume that each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 and 59823). Burden estimates for this rule assume group TIN-level reporting as we believe this is the most reasonable assumption for MIPS eligible clinicians participating in the Shared Savings Program, which requires that ACOs include full TINs as ACO participants.

TABLE 132: Adjustments to the Number of Respondents to Submit Promoting Interoperability Performance Data

Burden and Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability in CY 2023 (a)	22,293
Number of groups to submit Promoting Interoperability in CY 2023 (b)	7,794
# of Subgroups to submit Promoting Interoperability in MVPs during the CY 2023 MIPS performance period (c)	20
Total Respondents in **2023 MIPS** performance period (CY 2022 PFS Final Rule) (**d**) = (a) + (b) + **(c)**	**30,107**
Currently Approved Respondents in 2023 MIPS performance period (e)	51,667
Difference (**f**) = (d) – **(e)**	**-21,560**

As shown in Table 133, accounting for the change in our per response time estimate due to the requirement for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective and the decrease in the number of respondents from 51,667 to 30,107, we estimate that it will result in a total burden of 81,289 hours (30,107 responses × 2.70 incremental hr for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $7,989,083 (81,289 hr × $98.28/hr)) to submit data for the Promoting Interoperability performance category in the CY 2023 performance period/2025 MIPS payment year.

TABLE 133: Final Burden for Promoting Interoperability Performance Category Data Submission in CY 2023

Burden and Respondent Description	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	22,293
Number of groups to submit Promoting Interoperability (b)	7,794
Number of subgroups to submit Promoting Interoperability (c)	20
Total **(d)** = (a) + **(b)** + **(c)**	**30,107**
Total Annual Hours Per Respondent (e)	2.70
Total Annual **Hours (f)** = (d) * **(e)**	**81,289**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (g)	$98.28/hr
Total Annual Cost (h) = **(f) * (g)**	**$7,989,083**

As shown in Table 134, accounting for the changed per response time estimate, the decreased number of respondents results in a change of minus 57,695 hours (−21,560 responses × 2.69 hr + 30,107 × 0.01 hr) at a cost of −$5,670,265 (−57,695 hr × $98.28/hr).

TABLE 134: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	138,984
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (see Table 133, row (f))	81,289
Difference (c) = (b) - (a)	**-57,695**
Total Currently Approved Annual Cost (d)	$13,659,348
Total Annual Cost for Respondents in CY 2022 PFS final rule (e) (see Table 133, row (h))	$7,989,083
Difference (f) = (e) - (d)	**-$5,670,265**

After consideration of the public comments received for our proposed requirements and burden estimates relevant to the submission of measures and objectives in the Promoting Interoperability performance, we did not make any further changes. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46369 through 46371) due to the availability of updated data.

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does create any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.6.c.(3)(b)(ii) of this rule, we finalized changes to the improvement activities Inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding 4 new improvement activities; modifying 5 existing improvement activities; and removing 6 previously adopted improvement activities. We do not believe the changes will impact our currently approved time for interested parties to submit information, because MIPS eligible clinicians are still required to submit the same number of activities and the estimated per response time for each activity is uniform. Therefore, we did not propose to adjust our currently estimated time of 5 minutes or 0.083 hours (per response) for improvement activities submission.

In this rule, we are adjusting the estimates in the CY 2023 PFS proposed rule (87 FR 46372) due to availability of updated data. As represented in Table 133, based on data from the CY 2021 performance period/CY 2023 MIPS payment year, we estimate that a total of 44,136 respondents consisting of 31,743 individual clinicians, 12,373 groups and 20 subgroups will submit improvement activities during the CY 2023 performance period/CY 2025 MIPS payment year. This adjustment represents a decrease of 37,446 respondents (32,102 individuals, 5,344 groups and 0 subgroups) from the currently approved estimate of 81,582 respondents (63,845 individuals and 17,717 groups, and 20 subgroups) in the CY 2022 PFS final rule (86 FR 65603).

As discussed in sections VI.B.9.e.(2) and VI.B.9.g.(3) of this final rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability

performance categories, we are updating our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or participating in an ACO in the CY 2021 performance period/2023 MIPS payment year but will be QPs in the CY 2023 performance period/2025 MIPS payment year, and will therefore not be required to submit improvement activities data.

TABLE 135: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2023 MIPS performance period (a)	31,743
# of Groups to submit improvement activities on behalf of clinicians during the CY 2023 MIPS performance period (b)	12,373
# of Subgroups to submit improvement activities in MVPs during the CY 2023 MIPS performance period (c)	20
Total # of Respondents (Groups, **Subgroups,** Virtual Groups, and Individual Clinicians) to submit improvement activities data during the CY **2023** MIPS performance period **(d)** = (a) + (b) + **(c)**	**44,136**
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 MIPS performance period (CY 2022 PFS Final Rule) (e)	81,582
Difference **(f)** = (d) **- (e)**	**-37,446**

Consistent with the CY 2022 PFS final rule, we continue to estimate that the time required per response per individual or group is 5 minutes or 0.083 hours for a computer system analyst at a labor rate of $98.28/hr to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (86 FR 65603). As shown in Table 136, we estimate an annual burden of 3,663 hours (44,136 responses × 0.083 hr) at a cost of $360,000 (3,663 hr × $98.28/hr)) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 136: Final Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 performance period (a)	44,136
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) * (b)	**3,663**
Labor rate for a computer systems analyst to submit improvement activities (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$360,000**

In Table 137, we illustrate the net change in estimated burden for the submission of improvement activities using the currently approved burden in the CY 2022 PFS final rule (86 FR 65603). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents results in a decrease of 3,108 hours (−37,446 responses × 0.083 hr/response) at a cost of −$305,454 (−3,108 hr × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 137: Change in Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	6,771
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 135, row (c))	3,663
Difference (c) = (b) - (a)	**-3,108**
Total Currently Approved Annual Cost (d)	$665,454
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 135, row (e))	$360,000
Difference (f) = (e) - (d)	**-$305,454**

We did not receive any comments on our proposed requirements and burden estimates for the submission of improvement activities. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46371 through 46373) due to the availability of updated data.

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

This rule does not create any new or revised collection of information requirements or burden related to the nomination of improvement activities. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

k. Nomination of MVPs

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2021 PFS and CY 2022 PFS final rules (85 FR 84990 through 84991 and 86 FR 65605, respectively) for our previously finalized requirements and burden for collection of information relevant to nomination of MVPs for inclusion in the Quality Payment Program.

In section IV.A.4.a.(2) of this rule, we finalized updates to the previously finalized policies for the MVP development and maintenance process in the CY 2021 and 2022 PFS final rules (85 FR 84849 through 84856 and 86 FR 65410, respectively). Specifically, we finalized the proposal to modify the MVP development process such that we will evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we will post a draft version of the submitted candidate MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. Interested parties and general public will have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We will review the feedback received and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determined changes should be made to the candidate MVP, we will not notify the interested party who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. We also finalized the proposal to modify the MVP maintenance process such that interested parties and the general public will be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We will then review the submitted recommendations and determine whether any are potentially feasible and appropriate. If we identify any submitted recommendations that are potentially feasible and appropriate, we will host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We will publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. If we decide to make any revisions to an established MVP based on the recommendations submitted, we will adopt such revisions through notice and comment rulemaking.

We also stated that these changes do not require additional steps to the MVP nomination process described in the CY 2021 PFS final rule (85 FR 84990 through 84991). Therefore, we did not make any changes to the currently approved 12 hours per response (86 FR 65605) time for interested parties to submit their MVP candidates utilizing a standard template. Additionally, we refer readers to section VII.E.16.e.(2)(a) of this final rule where we discuss our impact analysis for these proposals.

In this rule, based on the actual number of respondents that submitted MVP nominations, we are adjusting the estimated number of MVP nominations in the CY 2023 PFS proposed rule (87 FR 46373 through 46374). We estimate that we will receive approximately 10 MVP nominations for the CY 2023 performance period/2025 MIPS payment year. This adjustment will result in a decrease of 15 MVP nominations from our currently approved estimate of 25 nominations in the CY 2022 PFS final rule (86 FR 65605). As shown in Table 138, for the CY 2023 performance period/2025 MIPS payment year, we continue to estimate that the per response time is 12 hours. This will result in an estimated annual burden of 120 hours (10 nominations × 12 hr/nomination) at a cost of $20,775 (10 × [(7.2 hr × $115.22/hr for a medical and health services manager) + (4.8 hr × $259.98/hr for a physician)]).

TABLE 138: Final Burden for Nomination of MVPs

Burden and Respondent Descriptions	Burden Estimate
# of Nominations of New MVPs (a)	10
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a) * (d)	**120**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $115.22/hr) (f) = (b) x $115.22/hr	$829.58
Cost to Nominate an MVP (@ physician's labor rate of $259.98/hr =) (g) = (c) x $259.98/hr	$1,247.90
Total Annual Cost Per Respondent (h) = (f) + (g)	$2,077.48
Total Annual Cost (i) = (a) * (h)	**$20,775**

In Table 139, we illustrate the net change in estimated burden for nomination of MVPs using the currently approved burden in the CY 2022 PFS final rule (86 FR 65605). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents submitting MVP nominations results in a total annual adjustment of −180 hours (−15 responses × 12 hr/nomination) at a cost of −$31,162 (−15 × [(7.2 hr × $115.22/hr) + (4.8 hr × $259.98/hr)]) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 139: Change in Estimated Burden for Nomination of MVPs

Burden and Respondent Descriptions	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	300
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 138, row (d))	120
Difference (c) = (b) - (a)	**-180**
Total Currently Approved Annual Cost (d)	$51,937
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 138, row (i))	$20,775
Difference (f) = (e) - (d)	**-$31,162**

We did not receive any comments on our proposed requirements and burden estimates relevant to the MVP nomination process. As discussed above in this section, we adjusted the burden estimates from the CY 2023 PFS proposed rule (87 FR 46373 through 46374) due to the availability of updated data.

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not making any changes under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule does not create any new or revised collection of information requirements or burden related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we proposed to adjust our currently approved burden estimates based on updated projections for the CY 2023 performance period/2025 MIPS payment year. We did not receive any public comments related to the proposed burden estimates for Partial QP election. We are not making any adjustments to the proposed burden estimate for the ICR in the CY 2023 PFS rule (87 FR 46374 through 46375). The finalized adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 140, based on our predictive QP analysis for the 2023 QP performance period/2025 MIPS payment year, which accounts for historical response rates in the CY 2021 performance period/2023 MIPS payment year, we are finalizing to revise our estimate that a total of 287 respondents (156 APM Entities and 131 individual eligible clinicians representing approximately 7,182 Partial QPs) will make the election to participate as a Partial QP in MIPS. This is an increase of 37 from the 250 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we are adjusting our estimated annual burden to 72 hours (287 responses × 0.25 hr/response) and $7,076 (72 hr × $98.28/hr).

TABLE 140: Final Burden for Partial QP Election

Burden and Respondent Description	Burden Estimate
# of respondents making Partial QP election (156 APM Entities, 131 eligible clinicians) (a)	287
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	**72**
Labor rate for computer systems analyst (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$7,076**

As shown in Table 141, using our currently approved per respondent time estimate (86 FR 65605), the increase in the number of Partial QP elections results in an adjustment of + 9 hours (+ 37 respondents × 0.25 hr/election) at a cost of + $884 ($7,076 − $6,192) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 141: Burden Adjustments for Partial QP Election

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	63
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 140, row (c))	72
Difference (c) = (b) - (a)	**+9**
Total Currently Approved Annual Cost (d)	$6,192
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 140, row (e))	$7,076
Difference (f) = (e) - (d)	**+$884**

We received no comments on our proposed requirements and burden estimates for the partial QP election process. As discussed above in this section, we adjusted the currently approved burden estimates due to the availability of updated data.

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer-Initiated Process (§ 414.1445)

This rule does not create any new or revised collection of information requirements related to the Payer-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Payer-Initiated process under that control number.

(2) Eligible Clinician-Initiated Process (§ 414.1445)

This rule does not create any new or revised collection of information requirements or burden related to the Eligible Clinician-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Eligible Clinician-Initiated Process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule does not create any new or revised collection of information requirements or burden related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden for the All-Payer Combination option are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

This rule does not create any new or revised collection of information requirements or burden related to the election by voluntary participants to opt-out of public reporting on Compare Tools. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

p. Summary of Annual Quality Payment Program Burden Estimates

Table 142 summarizes this final rule's total burden estimates for the Quality Payment Program for the CY 2023 performance period/2025 MIPS payment year.

In the CY 2022 PFS final rule, the total estimated burden for the CY 2023 performance period/2025 MIPS payment year (see Table 142, row a) was 1,383,049 hours at a cost of $139,501,770 (86 FR 65613). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2022 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2022 PFS final rule into the CY 2023 performance period/2025 MIPS payment year is 1,386,803 hours at a cost of $148,008,071 (see Table 142, row b). These represent an increase of 3,754

hours and an increase of $8,506,301. To understand the burden implications of the policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2022 PFS final rule into the CY 2023 performance period/2025 MIPS payment year. This burden estimate of 714,352 hours at a cost of $76,092,343 (see Table 142, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a decrease of 672,451 hours and $71,915,728 (see Table 142, row d). This burden estimate is lower than the burden approved for information collection related to the CY 2022 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2023 performance period/2025 MIPS payment year is 710,644 hours and $75,687,130 (see Table 142, row e), which represents a decrease of 676,159 hours and $72,320,941 from the CY 2022 PFS final rule (see Table 142, row f). The difference of −3,708 hours (672,451 hours − 676,159 hours) and −$405,213 ($71,915,728 − $72,320,941) (see Table 142, row g) between this estimate and the total burden shown in Table 142 is the decrease in burden associated with impacts of the policies for the CY 2023 performance period/2025 MIPS payment year.

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TABLE 142: Summary of Burden Estimates and Requirements from the CY 2023 PFS Final Rule

CY 2023 Performance Period/2025 MIPS Payment Year		
Burden Estimate Description	Time (Hours)	Cost
Currently approved burden in CY 2022 PFS Final Rule (a)	1,383,049	$139,501,770
CY 2022 PFS Final Rule w/ updated wage rates and ICRs (b)	1,386,803	$148,008,071
CY 2022 PFS Final Rule w/ updated data and assumptions (c)	714,352	$76,092,343
Change in burden due to updated data and assumptions (d) = (c) – (b)	-672,451	-$71,915,728
CY 2023 PFS Final Rule Total Burden (e)	710,644	$75,687,130
Total change in burden (as shown in Table 143) (f) = (e) – (b)	-676,159	-$72,320,941
Change in burden associated with policies (g) = (f) – (d)	-3,708	-$405,213

TABLE 143: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses	CMS-1770-F Responses	Change in Responses	Currently Approved Total Time (Hours)*	CMS-1770-F Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see Table 105)	84	63	-21	1,176	636	-540
§ 414.1400 Registry self-nomination (see Table 107)	147	132	-15	841	264	-577
§ 414.1400 Third Party Intermediary Plan Audits (see Table 110)	0	127	127	0	585	+585
Open Authorization (OAuth) Credentialing and Token Request Process (see Table 112)	15	15	0	15	30	+15
Quality Payment Program Identity Management Application Process (see Table 117)	3,741	6,500	2,759	3,741	6,500	+2,759
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see Table 119)	25,427	14,736	-10,691	361,063	209,251	-151,812
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see Table 121)	46,890	17,916	-28,974	425,902	162,731	-263,171
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Table 123)	43,773	23,889	-19,884	350,184	191,112	-159,072
MVP Registration (see Table 125)	12,917	7,731	-5,186	3,229	1,933	-1,296
MVP Quality Submission (see Table 127)	12,917	7,731	-5,186	83,673	50,938	-32,735
Call for Quality Measures (see Table 129)	28	29	+1	154	160	+6
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 131)	42,827	5,439	-37,388	10,707	1,360	-9,347
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see Table 134)	51,667	30,107	-21,560	138,984	81,289	-57,695
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see Table 137)	81,582	44,136	-37,446	6,771	3,663	-3,108
Nomination of MVPs (see Table 139)	25	10	-15	300	120	-180
§ 414.1430 Partial Qualifying APM Participant (QP) Election (Table 141)	250	287	37	63	72	+9
TOTAL	322,290	158,848	-163,442	1,386,803	710,644	-676,159

Table 144 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to finalized policies and those related to adjustments in burden continued from the CY 2022 PFS final rule policies that reflect updated data and revised methods.

TABLE 144: Reasons for Change in Burden Compared to the Currently Approved CY 2023 Information Collection Burden

ICR Title	Changes in burden due to CY 2023 final rule policies	Adjustments in burden continued from CY 2022 PFS final rule policies due to revised methods or updated data
QCDR Self-Nomination and other Requirements (See Table 104)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Qualified Registry Self-Nomination and other Requirements (See Table 106)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
§ 414.1400 Third Party Intermediary Plan Audits (see Table 108)	None	New ICR. Increase in number of respondents and hours due to restructuring the burden for third party intermediaries to submit a targeted audit, CAP, transition plan, or a participation plan.
Open Authorization (OAuth) Credentialing and Token Request Process (see Table 111)	None	Increase in the number of hours due to changes in administrative workflow for the application process.
Quality Payment Program Identity Management Application Process (see Table 116)	None	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see Table 118)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see Table 120)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Table 122)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
MVP Registration (see Table 124)	Increase in number of respondents due to finalized addition of 5 new MVPs.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
MVP Quality Submission (see Table 126)	Increase in number of respondents due to finalized addition of 5 new MVPs.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
Call for Quality Measures (see Table 128)	None	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 130)	None	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.

ICR Title	Changes in burden due to CY 2023 final rule policies	Adjustments in burden continued from CY 2022 PFS final rule policies due to revised methods or updated data
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see Table 132)	Increase in the estimated time (+0.0083 hrs) for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective in the Promoting Interoperability performance category.	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see Table 135)	None	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year
Nomination of MVPs (see Table 138)	None	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see Table 140)	None	Increase in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year.

C. Summary of Annual Burden Estimates for Changes

TABLE 145: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 414.940 (Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts)	0938-New	10	10	40	400	39.50	15,800
§§ 414.802 and 414.806 (Requiring Certain Manufacturers to Report Drug Pricing Information for Part B) *	0938-0921	740	2,960	13	38,480	38.86	1,495,333
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan) *	0938-1396	100	100	0.1667	16.67	210.44	3,508
Part 403 (Open Payments Provisions included in the CY 2022 PFS)	0938-1237	2,398	2,398	Varies	1,263	Varies	64,561
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	0938-1314	117,697	-2,193	Varies	-676,159	Varies	-73,320,941
TOTAL		120,945	3,275	Varies	-635,999.33	varies	-$71,741,739

*The finalized requirements and burden will be submitted to OMB using the standard PRA process which includes the publication of non-rule 60- and 30-day Federal Register notices.

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VII. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we are finalizing payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 (CAA, 2021); sections 301, 302, 303, 304, and 305 under the Consolidated Appropriations Act, 2022 (CAA, 2022); and sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018, section 90004 of the Infrastructure Investment and Jobs Act, and section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act. Our policies in this rule specifically address: changes to the PFS; other changes to Medicare Part B

payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; improvements to the Medicare Shared Savings Program (Shared Savings Program) requirements that promote health equity and strengthen financial incentives for participation; updates to the Quality Payment Program; updates to the Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); changes to the Medicare policies for laboratory specimen collection fees and travel allowance; and updates to the Medicare Ground Ambulance Data Collection System. The policies reflect CMS's stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Extension of Certain Medicare Telehealth Flexibilities, Under Section 1834(m) of the Act, as Amended by the Consolidated Appropriations Act, 2022

Section II.D.1.e. of this final rule implements sections 301, 302, 304, and 305, of the Consolidated Appropriations Act, 2022, which extended the geographic restrictions (section 301), extended the temporary expansion of practitioner types who are eligible to furnish Medicare telehealth (section 302), delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS (section 304), and extended audio-only flexibilities for certain telehealth services that will otherwise not be available via telehealth (section 305) after the expiration of the PHE to remain on the Medicare Telehealth Services List for a 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. This provision is necessary to fulfill the statutory requirement to implement this extension until the 152nd day after the end of the PHE for COVID–19.

b. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs Payable Under Medicare Part B To Provide Refunds With Respect to Discarded Amounts

Section III.A. of this final rule implements section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) which requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. These provisions are necessary to fulfill the statutory requirement to implement this policy effective January 1, 2023 and reduce unnecessary Medicare spending for discarded drug.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section III.B.3. of this final rule implements sections 303 and 304 of the Consolidated Appropriations Act, 2022. Section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to temporarily continue payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE using the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which, in accordance with section 1834(m)(8)(B) of the Act, is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

Section 304 of the CAA, 2022 delays the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology for a 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. These provisions are necessary to fulfill these statutory requirements.

We also note in section III.B.3. of this final rule we discuss implementation of sections 301 and 305 of the CAA, 2022 that will apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. That is, section 301 of the CAA, 2022 extended the geographic restrictions and section 305 of the CAA, 2022 extended audio-only flexibilities for certain telehealth services that will otherwise not be available via telehealth.

d. Clinical Laboratory Fee Schedule (CLFS)—Revisions Consistent With Recent Statutory Changes

Section III.C.5. of this rule finalizes conforming regulations text changes for CLFS data reporting requirements due to the enactment of Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA). For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), the PMAFSCA delays the next data reporting period by one year. Instead of taking place from January 1, 2022 through March 31, 2022, data reporting will now take place from January 1, 2023 through March 31, 2023, based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle (2026, 2029, etc.). Additionally, PMAFSCA amends the statutory provisions that phase in payment reductions resulting from private payor rate implementation to provide that for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

e. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In the CY 2023 PFS proposed rule, we proposed changes to the electronic prescribing for controlled substances (EPCS) requirement specified in section 2003 of the SUPPORT Act (87 FR 46238 through 46240). Previously finalized policies did not include actions for non-compliance after the 2023 year. Additionally, previously finalized policies for exceptions may not have properly identified prescribers that are small prescribers during the compliance period and may have misidentified prescribers in locations with a recognized emergency or natural disaster. The provisions in this final rule define the action for non-compliance with the electronic prescribing of controlled substances requirement for the 2024 year and refine policies to better identify prescribers who qualify for the small prescriber and recognized emergency exceptions to the EPCS requirement.

f. Medicare Ground Ambulance Data Collection System

Section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. In this final rule, we are finalizing our proposed series of changes to the Medicare Ground Ambulance Data Collection System including the proposal to update § 414.626(d)(1) and (e)(2) to give us the necessary flexibility to specify how ground ambulance

organizations should submit the hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational, and proposed revisions to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

Comment: We received one comment on the impacts. The commenter encouraged CMS to implement this proposal in a way that does not increase administrative burden and in a way that is revenue neutral given the increase in expenses to provide care to patients.

Response: As we described in the CY 2020 PFS final rule (84 FR 62868), we designed the Medicare Ground Ambulance Data Collection System to collect the information required in section 1834(l)(17)(A) of the Act while: (1) accommodating a wide range of ground ambulance organizations; and (2) minimizing respondent burden. Subsequent improvements in the Medicare Ground Ambulance Data Collection System in the CY 2022 PFS final rule (86 FR 65306), and those described in this final rule, aim to further streamline the Medicare Ground Ambulance Data Collection System and reduce burden.

g. Quality Payment Program

This final rule is also necessary to make changes to the Quality Payment Program to move the Quality Payment Program forward to focus more on measurement efforts, refine how clinicians will be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and encourage participation in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for MIPS is not required to be coordinated across performance categories. These policies are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories, and make changes to scoring that will provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. RHCs and FQHCs

In section III.B.2. of this final rule, we are finalizing a policy to include chronic pain management (CPM) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code G3002 will be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there is no change to the average used to calculate the G0511 payment rate.

In addition, in section III.B.2. of this final rule we are finalizing coding and payment for general behavioral health integration (BHI) services (HCPCS code G0323). We explain that since clinical psychologists (CPs) and clinical social workers (CSWs) are considered practitioners that can provide services in RHCs/FQHCs, we acknowledge when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511.

These provisions are necessary in that we evaluate coding provisions in this rule and their applicability to RHCs and FQHCs.

Section III.B.4. of this final rule finalizes the clarification regarding the use of short-period cost reports vs 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs. This provision is necessary to accurately reflect the costs of providing RHC services and will establish a more accurate base from which the payment limits will be upgraded going forward.

b. Clinical Laboratory Fee Schedule (CLFS) Specimen Collection and Travel Allowance

As discussed in section III.C.6. of this rule we are finalizing revisions to the CLFS regulations to clarify and codify the CLFS specimen collection and travel allowance payment policies.

In general, section 1833(h)(3) of the Act requires the Secretary to pay a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). CMS' longstanding instructions regarding the statutory requirements for CLFS specimen collection and travel allowance are described in Medicare Claims Processing manual guidance. OIG and other interested parties have expressed concerns regarding inconsistent MAC implementation of the payment policies as well as unclear or conflicting guidance to laboratories related to the CLFS travel allowance. In the CY 2022 PFS final rule we solicited comments regarding these two payment policies; commenters supported clarification to the existing policies and also made suggestions regarding possible refinements.

The payment policies related to CLFS specimen collection fees and travel allowance finalized in this rule are necessary to clarify existing policy, address concerns expressed by interested parties, and reduce administrative burden. For the specimen collection policy, we are increasing the specimen collection fee amount to account for the increases in resource costs, including the impact of inflation, so as to continue to provide appropriate payment for the costs of collecting, drawing and handling the specimen.

c. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In section III.F. of this final rule, we explain that because of the limitations of the voluntarily reported ASP data for orally-administered methadone, which reflects data from a small subset of methadone manufacturers, we do not believe this voluntarily reported ASP data currently provides a reliable source for pricing the methadone codes. We previously issued an interim final rule with comment period to establish a limited exception to the methodology for determining the payment amount for the drug component of an episode of care under the OTP benefit in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021. For CY 2023 and subsequent years, we are finalizing a revision to our methodology for pricing methadone under the OTP benefit, specifically, the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone, so that it will not rely on voluntarily-submitted ASP data. We believe this policy change will stabilize the payment amount for methadone dispensed by OTPs during an episode of care and therefore maintain access to treatment with methadone in the OTP setting for Medicare beneficiaries. Additionally, in section III.F. of this final rule, we are finalizing a modification to the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk code describing a longer

duration of psychotherapy compared to the current crosswalk code. We believe this modification is needed in order to more accurately reflect the resource costs involved with furnishing therapy in the OTP setting.

d. Medicare Part B Payment for Preventive Vaccine Administration Services

Sections III.H.2. and 3. of this final rule discuss the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit. Section III.H.4. of this final rule clarifies the timing of payment policies for COVID–19 vaccines and COVID–19 monoclonal antibody products. These provisions are necessary to provide stable payment for preventive vaccine administration to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

e. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

We proposed to modify nonemergency, repetitive, scheduled ambulance policy at § 410.40(e)(2)(ii) by clarifying that (1) the physician certification statement and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance; and (2) that coverage includes observation or other services rendered by qualified ambulance personnel. Existing regulations at § 410.40(e)(2) are interpreted too narrowly by some interested parties, excluding beneficiaries in need of monitoring. This language clarifies the intent of existing regulatory language by explicitly stating that beneficiaries who may not be in need of tangible services, but otherwise are in need of monitoring, qualify for this limited ambulance benefit. This is not a statutorily-mandated provision but addresses a longstanding ambiguity potentially affecting vulnerable populations. We did not receive any comments on this regulatory impact analysis and are finalizing as proposed.

f. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

In CY 2019, the last year for which incidence data are available, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[565] The Center for Disease Control and Prevention (CDC) advises, ''Colorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [566] This final rule will expand coverage for colorectal cancer screening tests by reducing the minimum age payment limitation for certain tests from 50 to 45 years of age. In addition, we proposed to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Our provisions will update Medicare coverage and payment policies to align with our new understanding of CRC screening, the latest recommendations from the U.S. Preventive Services Task Force and recommendations from professional societies and other appropriate organizations. We proposed to expand coverage of colorectal cancer screening tests by exercising our authority under sections 1834(n) and 1861(pp)(1)(D) of the Act. We believe these provisions will expand access to quality care and improve health outcomes through prevention, early detection, more effective treatment and reduced mortality. Moreover, it will directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC.

g. Removal of Selected National Coverage Determinations

CMS periodically identifies and proposes to remove National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries. Since the CY 2021 PFS final rule (85 FR 84472), we have used notice and comment rulemaking to obtain public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Eliminating an NCD that provides national coverage or non-coverage for items and services means that the item or service will no longer be automatically, nationally covered or non-covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs).

As described in section III.E. of this final rule, we are removing as proposed, NCD 160.22 Ambulatory EEG Monitoring (06/12/1984), because the NCD contains outdated language that is inconsistent with, and contrary to current standards of care. We believe that allowing local contractor discretion to make coverage decision for this service better serves the needs of the Medicare program and its beneficiaries. We estimate there will be de minimis change to 2023 payments, compared to 2021 because this is a long-established service for which the MACs already have LCDs and guidance articles. Therefore, we believe removing the NCD will allow MACs to update local coverage guidance for this established diagnostic test, but will not result in significant changes to utilization or payments.

h. Medicare Shared Savings Program

As we seek to advance the overall value-based care strategy of growth, alignment, and equity, we are finalizing modifications to the Medicare Shared Savings Program to increase program participation by supporting organizations new to value-based care and shared savings, especially for organizations serving underserved populations, and providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign their care processes to be successful under risk arrangements. As part of this effort, we are establishing advance investment payments for new, low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives. To address the social needs of people with Medicare, these payments will increase with the number of beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS), dually eligible for Medicare and Medicaid, and/or who live in areas with high deprivation (measured by the area deprivation index (ADI)) assigned to the ACO. We are also building on the existing Shared Savings Program benchmarking methodology by finalizing modifications to strengthen financial incentives for long term participation by reducing the impact of

[565] *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[566] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

ACOs' performance on their benchmarks, to address the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks, and to strengthen the business case for participation for ACOs serving high-risk and high dually eligible populations, which will help sustain participation and grow the program. Additionally, we are finalizing modifications to the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment. We are also finalizing changes to the quality reporting and the quality performance requirements to support the transition of ACOs to all payer quality measure reporting. These provisions include implementing a health equity adjustment to an ACO's MIPS quality performance category score to recognize high performing ACOs serving a high proportion of underserved beneficiaries. Finally, we are making changes that are important for improved operations of the Shared Savings Program, including policies to reduce ACO administrative burden while maintaining program integrity.

i. Provider Enrollment and DMEPOS Conditions of Payment

This final rule is also needed to make regulatory enhancements to our provider enrollment policies and to our DMEPOS conditions of payments. These provisions focus on, but are not limited to: (1) expanding the bases for denying or revoking a provider's or supplier's Medicare enrollment; (2) subjecting a greater number of providers and suppliers, such as skilled nursing facilities, to the highest level of screening, which includes fingerprinting all 5 percent or greater owners of these providers and suppliers; and (3) denying payment to DMEPOS suppliers that are not appropriately licensed. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and that owners of these entities are carefully screened. As explained in section III.J. of this final rule, we believe that fulfilling both of these objectives will assist in protecting the Trust Funds and Medicare beneficiaries.

j. Proposed Revisions to HCPCS Level II Coding Policies for Skin Substitutes

The HCPCS is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The HCPCS Level I code set is comprised of Current Procedural Terminology (CPT®) codes, which are owned and maintained by the American Medical Association. The HCPCS Level II code set is used primarily to identify items, services, supplies, and equipment that are not identified by CPT® codes. CMS updates and maintains the HCPCS Level II code set on a periodic and routine basis.

One of the categories of items and supplies that are typically described by HCPCS Level II codes are skin substitutes. After consideration of public comments, we are not finalizing the coding policies we proposed for skin substitute products under the PFS, as discussed in section III.N. of this final rule.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this final rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated

costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This final rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this final rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this final rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement provisions of the statute. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2022 with payment rates for CY 2023 using CY 2021 Medicare utilization. The payment impacts described in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2023, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, the Protecting Medicare and American Farmers from Sequester Cuts Act provided a one-time 3.00 percent increase in PFS payment amounts for services furnished on or after January 1, 2022, and before January 1, 2023 and required that the supplementary increase shall not be taken into account in determining PFS payment rates for subsequent years. The expiration of this 3.00 percent increase in payment amounts will result in the CY 2023 conversion factor being calculated as though the 3.00 percent increase for the CY 2022 conversion factor had never been applied.

To calculate the CY 2023 PFS conversion factor (CF), we took the CY 2022 conversion factor without the 1-year 3.00 percent payment increase provided by the Protecting Medicare and American Farmers from Sequester Cuts Act and multiplied it by the BN adjustment required as described in the preceding paragraphs. We estimate the CY 2023 PFS CF to be 33.0607 which reflects the −1.60 percent BN adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.00 percent payment increase for services furnished in CY 2022, as provided in the CAA. We estimate the CY 2023 anesthesia CF to be 20.6097 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 146: Calculation of the CY 2023 PFS Conversion Factor

CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.60 percent (0.9840)	
CY 2023 Conversion Factor		**33.0607**

TABLE 147: Calculation of the CY 2023 Anesthesia Conversion Factor

CY 2022 National Average Anesthesia Conversion Factor		21.5623
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		20.9343
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.60 percent (0.9840)	
CY 2023 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.05 percent (1.0005)	
CY 2023 Conversion Factor		**20.6097**

Table 148 shows the payment impact of the policies contained in this final rule on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 148 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 148.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2021 utilization and CY 2022 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2023 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 148: CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$233	0%	-1%	0%	-2%
Anesthesiology	$1,749	-1%	0%	0%	-2%
Audiologist	$71	-1%	0%	-1%	-2%
Cardiac Surgery	$199	-1%	-1%	0%	-2%
Cardiology	$6,331	0%	-1%	0%	-1%
Chiropractic	$674	-1%	1%	0%	0%
Clinical Psychologist	$791	-1%	0%	-1%	-2%
Clinical Social Worker	$861	-1%	0%	-1%	-2%
Colon and Rectal Surgery	$156	-1%	-1%	0%	-2%
Critical Care	$354	1%	0%	0%	1%
Dermatology	$3,760	-1%	0%	0%	-1%
Diagnostic Testing Facility	$817	0%	7%	0%	7%
Emergency Medicine	$2,544	0%	0%	0%	0%
Endocrinology	$534	0%	0%	0%	0%
Family Practice	$5,817	0%	0%	0%	0%
Gastroenterology	$1,595	0%	-1%	0%	-1%
General Practice	$378	0%	0%	0%	0%
General Surgery	$1,772	-1%	-1%	0%	-2%
Geriatrics	$177	2%	0%	0%	2%
Hand Surgery	$256	-1%	0%	0%	-1%
Hematology/Oncology	$1,713	0%	-1%	0%	-1%
Independent Laboratory	$600	0%	0%	0%	0%
Infectious Disease	$590	4%	0%	0%	4%
Internal Medicine	$9,881	2%	0%	0%	3%
Interventional Pain Mgmt	$929	-1%	-1%	0%	-2%
Interventional Radiology	$467	-1%	-3%	0%	-3%
Multispecialty Clinic/Other Phys	$151	0%	-1%	0%	-1%
Nephrology	$2,032	1%	0%	0%	1%
Neurology	$1,406	0%	-1%	0%	-1%
Neurosurgery	$732	-1%	0%	0%	-1%
Nuclear Medicine	$54	-1%	-1%	0%	-2%
Nurse Anes / Anes Asst	$1,122	-1%	0%	0%	-2%
Nurse Practitioner	$5,842	1%	0%	0%	1%
Obstetrics/Gynecology	$596	-1%	0%	0%	-1%
Ophthalmology	$4,849	-1%	0%	0%	-1%
Optometry	$1,316	-1%	0%	0%	-1%
Oral/Maxillofacial Surgery	$74	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,476	-1%	0%	0%	-1%
Other	$59	0%	-1%	0%	-2%
Otolaryngology	$1,139	-1%	0%	0%	-1%
Pathology	$1,173	-1%	0%	0%	-1%
Pediatrics	$58	0%	0%	0%	0%
Physical Medicine	$1,097	2%	0%	0%	2%
Physical/Occupational Therapy	$4,925	-1%	1%	-1%	-1%
Physician Assistant	$3,182	0%	0%	0%	0%
Plastic Surgery	$324	-1%	0%	0%	-1%
Podiatry	$2,013	-1%	-1%	0%	-1%
Portable X-Ray Supplier	$78	0%	2%	0%	1%
Psychiatry	$990	1%	0%	0%	2%
Pulmonary Disease	$1,402	1%	0%	0%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Radiation Oncology and Radiation Therapy Centers	$1,615	-1%	0%	0%	-1%
Radiology	$4,734	-1%	-1%	0%	-2%
Rheumatology	$548	-1%	-1%	0%	-2%
Thoracic Surgery	$318	-1%	-1%	0%	-2%
Urology	$1,758	-1%	-1%	0%	-1%
Vascular Surgery	$1,104	0%	-3%	0%	-3%
Total	$91,414	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

In recent years, we have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately-owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. We published an RFI in the NPRM this year to gather feedback on this issue and refer readers to section II.B. of this final rule. As part of our holistic review of how best to update our data, and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For this rulemaking cycle, we are providing an additional impact table that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 149.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2021 utilization and CY 2022 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2023 combined impact on total allowed charges.

TABLE 149: CY 2023 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$233	-2%
	Non-Facility	$225	-2%
	Facility	$9	-1%
ANESTHESIOLOGY	*TOTAL*	$1,749	-2%
	Non-Facility	$368	-4%
	Facility	$1,381	-1%
AUDIOLOGIST	*TOTAL*	$71	-2%
	Non-Facility	$69	-2%
	Facility	$2	-2%
CARDIAC SURGERY	*TOTAL*	$199	-2%
	Non-Facility	$39	-3%
	Facility	$160	-2%
CARDIOLOGY	*TOTAL*	$6,331	-1%
	Non-Facility	$4,652	-2%
	Facility	$1,679	1%
CHIROPRACTIC	*TOTAL*	$674	0%
	Non-Facility	$673	0%
	Facility	$1	-1%
CLINICAL PSYCHOLOGIST	*TOTAL*	$791	-2%
	Non-Facility	$614	-2%
	Facility	$177	-2%
CLINICAL SOCIAL WORKER	*TOTAL*	$861	-2%
	Non-Facility	$661	-2%
	Facility	$199	-2%
COLON AND RECTAL SURGERY	*TOTAL*	$156	-2%
	Non-Facility	$56	-2%
	Facility	$100	-1%
CRITICAL CARE	*TOTAL*	$354	1%
	Non-Facility	$53	-1%
	Facility	$300	1%
DERMATOLOGY	*TOTAL*	$3,760	-1%
	Non-Facility	$3,623	-1%
	Facility	$136	0%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$817	7%
	Non-Facility	$817	7%
	Facility	$	1%
EMERGENCY MEDICINE	*TOTAL*	$2,544	0%
	Non-Facility	$233	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Facility	$2,310	0%
ENDOCRINOLOGY	*TOTAL*	$534	0%
	Non-Facility	$428	-1%
	Facility	$106	2%
FAMILY PRACTICE	*TOTAL*	$5,817	0%
	Non-Facility	$4,660	-1%
	Facility	$1,157	4%
GASTROENTEROLOGY	*TOTAL*	$1,595	-1%
	Non-Facility	$605	-1%
	Facility	$990	-1%
GENERAL PRACTICE	*TOTAL*	$378	0%
	Non-Facility	$307	-1%
	Facility	$71	4%
GENERAL SURGERY	*TOTAL*	$1,772	-2%
	Non-Facility	$512	-1%
	Facility	$1,260	-2%
GERIATRICS	*TOTAL*	$177	2%
	Non-Facility	$99	0%
	Facility	$78	6%
HAND SURGERY	*TOTAL*	$256	-1%
	Non-Facility	$136	-1%
	Facility	$121	0%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,713	-1%
	Non-Facility	$1,134	-2%
	Facility	$579	1%
INDEPENDENT LABORATORY	*TOTAL*	$600	0%
	Non-Facility	$599	0%
	Facility	$	-2%
INFECTIOUS DISEASE	*TOTAL*	$590	4%
	Non-Facility	$94	-2%
	Facility	$497	6%
INTERNAL MEDICINE	*TOTAL*	$9,881	3%
	Non-Facility	$5,088	-1%
	Facility	$4,792	7%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$929	-2%
	Non-Facility	$732	-2%
	Facility	$196	0%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$467	-3%
	Non-Facility	$367	-4%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Facility	$100	-1%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$151	-1%
	Non-Facility	$76	-1%
	Facility	$75	0%
NEPHROLOGY	*TOTAL*	$2,032	1%
	Non-Facility	$1,287	-2%
	Facility	$745	5%
NEUROLOGY	*TOTAL*	$1,406	-1%
	Non-Facility	$948	-2%
	Facility	$458	1%
NEUROSURGERY	*TOTAL*	$732	-1%
	Non-Facility	$131	-1%
	Facility	$601	-1%
NUCLEAR MEDICINE	*TOTAL*	$54	-2%
	Non-Facility	$51	-2%
	Facility	$3	3%
NURSE ANES / ANES ASST	*TOTAL*	$1,122	-2%
	Non-Facility	$25	-5%
	Facility	$1,097	-2%
NURSE PRACTITIONER	*TOTAL*	$5,842	1%
	Non-Facility	$3,804	-1%
	Facility	$2,039	5%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$596	-1%
	Non-Facility	$411	-1%
	Facility	$184	-1%
OPHTHALMOLOGY	*TOTAL*	$4,849	-1%
	Non-Facility	$3,455	-1%
	Facility	$1,394	0%
OPTOMETRY	*TOTAL*	$1,316	-1%
	Non-Facility	$1,254	-1%
	Facility	$62	0%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$74	-2%
	Non-Facility	$62	-2%
	Facility	$12	-1%
ORTHOPEDIC SURGERY	*TOTAL*	$3,476	-1%
	Non-Facility	$1,566	-1%
	Facility	$1,910	-1%
OTHER	*TOTAL*	$59	-2%
	Non-Facility	$48	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Facility	$11	0%
OTOLARNGOLOGY	*TOTAL*	$1,139	-1%
	Non-Facility	$904	-1%
	Facility	$234	-1%
PATHOLOGY	*TOTAL*	$1,173	-1%
	Non-Facility	$1,147	-1%
	Facility	$26	-1%
PEDIATRICS	*TOTAL*	$58	0%
	Non-Facility	$38	-1%
	Facility	$20	3%
PHYSICAL MEDICINE	*TOTAL*	$1,097	2%
	Non-Facility	$579	-2%
	Facility	$518	7%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$4,925	-1%
	Non-Facility	$4,925	-1%
	Facility	$	-2%
PHYSICIAN ASSISTANT	*TOTAL*	$3,182	0%
	Non-Facility	$2,109	-1%
	Facility	$1,073	2%
PLASTIC SURGERY	*TOTAL*	$324	-1%
	Non-Facility	$142	-1%
	Facility	$182	-1%
PODIATRY	*TOTAL*	$2,013	-1%
	Non-Facility	$1,793	-2%
	Facility	$220	0%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$78	1%
	Non-Facility	$78	1%
PSYCHIATRY	*TOTAL*	$990	2%
	Non-Facility	$532	-1%
	Facility	$458	5%
PULMONARY DISEASE	*TOTAL*	$1,402	1%
	Non-Facility	$586	-1%
	Facility	$816	3%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,615	-1%
	Non-Facility	$1,545	-1%
	Facility	$69	-2%
RADIOLOGY	*TOTAL*	$4,734	-2%
	Non-Facility	$4,503	-2%
	Facility	$230	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
RHEUMATOLOGY	*TOTAL*	$548	-2%
	Non-Facility	$491	-2%
	Facility	$57	-1%
THORACIC SURGERY	*TOTAL*	$318	-2%
	Non-Facility	$67	-3%
	Facility	$251	-2%
UROLOGY	*TOTAL*	$1,758	-1%
	Non-Facility	$1,259	-2%
	Facility	$499	-1%
VASCULAR SURGERY	*TOTAL*	$1,104	-3%
	Non-Facility	$816	-4%
	Facility	$287	-2%
TOTAL	***TOTAL***	$91,414	0%
	Non-Facility	$61,480	-1%
	Facility	$29,934	2%

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2. CY 2023 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including infectious disease, internal medicine, geriatrics, diagnostic testing facility, and physical medicine reflect increases relative to other physician specialties. These increases can largely be attributed to the revaluation of the other E/M services and/or the second-year transition to updated clinical labor pricing. The services that make up these specialties rely primarily on E/M services or on clinical labor for their practice expense costs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including clinical social workers, clinical psychologists, radiology and interventional radiology, vascular surgery, and cardiac surgery, reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of the revaluation of other E/M services and/or the second year transition to updated clinical labor pricing. The services that make up these specialties were also negatively affected by updated malpractice premium data for CY 2023, or rely primarily on supply/equipment items for their practice expense costs and therefore were affected negatively by the transition to updated clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 148), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 148 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed above, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses some of the concerns raised about lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2021 utilization data, Total RVUs change between −1 percent and 1 percent for more than 36 percent of practitioners, representing approximately 35 percent of the changes in Total RVUs for all practitioners, with variation by

specialty. Specialties, such as chiropractic, hand surgery, ophthalmology, and optometry, exhibit little variation in changes in total RVUs per practitioner. For these specialties, more than 85 percent of these practitioners will experience a change in Total RVUs between −1 percent and 1 percent. The specific service mix *within* a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 148 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates a 4 percent increase in RVUs for the infectious disease specialty as a whole, however, only 32 percent of infectious disease specialty practitioners—representing over 46 percent of Total RVUs for the specialty—will experience a 5 percent or more increase in Total RVUs. Meanwhile, nearly 15 percent of infectious disease specialty practitioners will experience 1 percent or more decreases in Total RVUs, and these practitioners account for about 8 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

Many interested parties have requested that CMS maintain the 3.00 percent payment supplement to PFS payment amounts that was specified in the Protecting Medicare and American Farmers from Sequester Cuts Act for services furnished during CY 2022. We remind readers that this payment supplement was provided through a time-limited amendment to the statute, which CMS does not have legal authority to alter. The expiration of this 3.00 percent payment supplement to payment amounts will result in the CY 2023 conversion factor being calculated as though the 3.00 percent payment supplement for the CY 2022 conversion factor had never been applied. Several interested parties have requested clarification regarding whether the specialty impacts displayed in Table 148 reflected the expiration of the 3.00 percent payment supplement for CY 2023. We can clarify for the commenters that the specialty impacts displayed in Table 148 reflect changes that take place within the pool of total RVUs. The specialty impacts table therefore includes any changes in spending which result from finalized policies within BN (such as the revaluation of other E/M codes in CY 2023 or the clinical labor pricing update in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to BN adjustment, and therefore, have a neutral impact across all specialties. The expiration of the 3.00 percent payment supplement for CY 2023 is a statutory change that takes place outside of BN, and therefore, is not captured in the specialty impacts displayed in Table 148.

b. Impact

Column F of Table 148 displays the estimated CY 2023 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2023 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

D. Changes Related to Telehealth Services

In last year's final rule, we discussed various flexibilities that will expire at the end of the PHE. Further, we clarified certain policies that were initially implemented as temporary policies, and subsequently made permanent by provisions of the CAA, 2021 that amended section 1834(m) of the Act (refer to 86 FR 65055–65063). Also, we note that the CAA, 2022 includes provisions that further amend section 1834(m) of the Act. For a detailed discussion of our implementation of the CAA, 2022 provisions refer to section II.B of this final rule.

We note that the final day of the PHE remains uncertain, and it is possible that the CAA, 2022 transition period of 151 days following the final day of the PHE would occur during CY 2023. Because of this uncertainty, coupled with the possibility of a necessary mid-year transition in our policies related to the provision of Medicare telehealth services, we anticipate that Medicare telehealth utilization and non-telehealth utilization of E/M and Mental Health services may show anomalous shifts. CMS implemented many temporary policy changes during the PHE to facilitate continued safe access to care during the pandemic, and that those changes will end with the expiration of the PHE, or in the case of some policies, after 151 days following the end of the PHE; as specified in the relevant sections of the CAA, 2022. We would closely monitor for these patterns, but underscore that the low volume of services possibly impacted creates a two-pronged challenge with low numbers and confounders; we believe the impact would be minor, or rather, inappropriate to isolate and attribute to telehealth alone.

Following the expiration of the flexibilities put in place during the PHE for COVID–19, the statutory and regulatory restrictions on payment for Medicare telehealth services under section 1834(m) of the Act and our regulations at §§ 410.78 and 414.65 will likely apply once again. CAA 2022 provides exceptions to these the pre-PHE restrictions that allow Medicare telehealth services to be furnished without geographic limitations, to patients in their homes, and in some cases using audio-only technology, when the services are for the diagnosis, evaluation, or treatment of a mental health disorder (including a substance use disorder (SUD), including opioid misuse). There are also limited statutory exceptions for home dialysis monthly ESRD-related visits and for services for purposes of diagnosis, evaluation or treatment of symptoms of an acute stroke, to allow Medicare telehealth services to be furnished without geographic limitations, and to patients in their homes or certain other residence-like locations.

As such, after the expiration of the flexibilities put in place during the PHE, we expect a significant reduction in the volume of Medicare telehealth services overall, and a corresponding reduction in aggregate spending for Medicare telehealth services. However, because the provisions of the CAA, 2021 and CAA, 2022 required permanent changes to remove previous restrictions on the use of telehealth for the diagnosis, evaluation or treatment of a mental health disorder (including a substance use disorder (SUD), including opioid use disorder), we anticipate that volume and spending for Medicare telehealth mental health services will increase from pre-pandemic levels coming years.

In this final rule, we finalized in section II.D. ''Payment for Medicare Telehealth Services Under Section 1834(m) of the Act'' to continue including on the Medicare Telehealth Services List, either permanently or temporarily through the end of CY 2023, many of the services added to the list during the PHE. However, after the expiration of the flexibilities put in place during the PHE, payment for Medicare telehealth services will be

subject to the statutory and regulatory limitations described previously in this section of the RIA. Compared to overall utilization of these services during the PHE, we do not expect new significant overall growth in Medicare telehealth services by aggregate volume. Further, we estimate that the addition of telehealth services added to the Medicare Telehealth Services List will have a negligible impact on PFS expenditures.

We are also finalizing implementation of provisions of the CAA, 2022 ((Pub. L. 117–103, March 15, 2022) amended section 1834(m) of the Act) that extend the application of certain Medicare telehealth flexibilities for an additional 151 days after the end of the PHE for COVID–19, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S.; allowing the extended scope of eligible telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists; extending payment for telehealth services furnished by FQHCs and RHCs; and delaying the requirement that there be an in-person visit with the physician or practitioner within 6 months before an initial mental health telehealth service. We anticipate that these provisions will result in continued utilization of Medicare telehealth services during the remainder of the PHE and the immediate subsequent 151 days at levels comparable to observed utilization of these services thus far during the PHE for COVID–19.

Regarding our provision to retain on the Medicare Telehealth Services List until the end of CY 2023 many of the services that we added to the list on a temporary basis, we believe these provisions would provide clarity to interested parties, but will have a negligible impact on PFS expenditures, unless Congress further intervenes as they did with CAA 2022. For example, outside the circumstances and flexibilities available during the PHE, services that are permanently included on the Medicare Telehealth Services List are furnished via telehealth, on average, less than 0.1 percent of the time they are reported.[567] The statutory and regulatory requirements for payment of Medicare telehealth services that apply outside the circumstances of the PHE have limited net increases in utilization.

E. Other Provisions of the Regulation

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs Payable Under Medicare Part B To Provide Refunds With Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In section III.A of this final rule, we are finalizing implementation of this provision including: a definition of which drugs are subject to refunds (and exclusions), an applicable percentage for certain drugs reconstituted in hydrogel, how discarded amounts of drugs are determined, a refund calculation methodology, a dispute resolution process, and enforcement provisions. However, we are not finalizing that the initial reports will be sent no later than October 1, 2023. Although we are not finalizing the proposed timeline for sending reports to manufacturers, the effective date of the provision remains January 1, 2023, as required by statute, and reports will be sent for calendar quarters beginning on or after this date.

For the CY 2023 PFS proposed rule (87 FR 46396 through 46397), we provided an analysis of JW modifier data from 2020 to estimate anticipated quarterly refund amounts due from manufacturers and displayed this information in Table 140 of the proposed rule.

For this final rule, we reanalyzed JW modifier data from 2020 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[568] That is, to assess if there was a change in the status of the billing and payment codes that were identified in the proposed rule as met the definition of refundable single-dose container or single-use package drug and have 10 percent or more discarded units. We found one billing and payment code had a change in status from single source to multiple source. Therefore, we updated the analysis to reflect this change under the provisions finalized as proposed in section II.A. of the proposed rule and as provided in the upcoming section of this final rule.

Overall in the 2020 calendar year, Medicare paid nearly $720 million for discarded amounts of drugs from a single-dose container or single-use package paid under Part B. In that year, there were 39 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 9 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are multiple source drug codes; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling. After these exclusions, there were 25 billing and payment codes that met the definition of refundable single-dose container or single-use package drug and have 10 percent or more discarded units.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage). Then, we multiplied that percentage by the CY 2020 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there would be approximately $74.7 million in refunds due from manufacturers for the calendar year of 2020 ($18.68 million each calendar quarter). See Table 150.

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[567] *https://www.cms.gov/medicare-telemedicine-snapshot.*

[568] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

TABLE 150: Estimated Refund Amounts Based on CY 2020 JW Modifier Data

HCPCS Code	CY 2020 Total Allowed Amount	Percent Units Discarded	Percent Discarded Units – 10%	Estimated Annual Refund	Estimated Quarterly Refund
J9043	$135,486,070.48	28.14%	18.14%	$24,577,173.19	$6,144,293.30
J0223	$3,953,268.84	20.80%	10.80%	$426,953.03	$106,738.26
Q4195	$6,233,097.24	20.47%	10.47%	$652,605.28	$163,151.32
J0775	$55,922,761.61	20.18%	10.18%	$5,692,937.13	$1,423,234.28
J9262	$342,668.12	19.96%	9.96%	$34,129.74	$8,532.44
J0565	$2,724,776.12	19.55%	9.55%	$260,216.12	$65,054.03
J2796	$240,489,959.82	16.83%	6.83%	$16,425,464.26	$4,106,366.06
J9309	$49,591,437.88	15.79%	5.79%	$2,871,344.25	$717,836.06
Q4106	$2,098,353.95	15.07%	5.07%	$106,386.55	$26,596.64
J1640	$7,204,322.44	14.87%	4.87%	$350,850.50	$87,712.63
J9153	$8,651,250.34	14.63%	4.63%	$400,552.89	$100,138.22
J9179	$45,528,228.20	12.60%	2.60%	$1,183,733.93	$295,933.48
J9264	$352,102,440.73	14.46%	4.46%	$15,703,768.86	$3,925,942.21
J2562	$17,986,116.53	12.41%	2.41%	$433,465.41	$108,366.35
Q4101	$2,701,473.78	12.11%	2.11%	$57,001.10	$14,250.27
J9229	$25,178,218.24	12.06%	2.06%	$518,671.30	$129,667.82
J3300	$8,454,347.46	11.44%	1.44%	$121,742.60	$30,435.65
J0485	$65,351,086.26	11.43%	1.43%	$934,520.53	$233,630.13
J9042	$167,324,055.19	11.41%	1.41%	$2,359,269.18	$589,817.29
J2997	$71,164,289.22	11.34%	1.34%	$953,601.48	$238,400.37
J9352	$9,562,087.18	10.95%	0.95%	$90,839.83	$22,709.96
J0291	$264,734.03	10.80%	0.80%	$2,117.87	$529.47
J9205	$54,328,144.16	10.50%	0.50%	$271,640.72	$67,910.18
J9307	$22,242,951.07	10.27%	0.27%	$60,055.97	$15,013.99
J9228	$375,059,594.99	10.06%	0.06%	$225,035.76	$56,258.94
			Total	**$74,714,077.48**	**$18,678,519.35**

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There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved, this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also note that this estimate is based on CY 2020 data for discarded drug amounts, which, as discussed in section III.A. of this final rule, we believe to be an underestimate due to the frequent omission of the JW modifier. Once we begin to edit claims for both the JW and JZ modifiers, reported discarded drug amounts will likely increase. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file [569] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

[569] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

a. Impacts Related to the Proposed Dispute Resolution Process

As described in section VII.B.1. of this final rule, the information collection requirements, we estimate the annual burden per respondent/recordkeeper to be 40 hours. If we anticipate no more than 10 disputes per year, the total annual reporting and/or recordkeeping burden will be 400 hours (10 error reports per year × 40 hours per respondent). We estimate an annual cost of this burden to be $15,800 ($39.50/hour × 400 hours).

2. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, we are finalizing our policy to include chronic pain management services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code G3002 will be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there is no change to the average used to calculate the G0511 payment rate.

In addition, in section III.B.2. of this final rule we are finalizing policies regarding coding and payment for general behavioral health integration services (HCPCS code G0323). We explain that since clinical psychologists (CPs) and clinical social workers (CSWs) are considered practitioners that can provide services in RHCs/FQHCs, we acknowledge when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511.

In terms of estimated impacts to the Medicare program, expanding use of General Care Management HCPCS code G0511 to include chronic pain management services (G3002) and behavioral health integration services (G0323) for RHCs and FQHCs would have a negligible impact on Medicare spending because these services are already included in our calculations of overall expenditures.

In section III.B.4. of this final rule, we provide a discussion and clarification regarding the use of short-period cost reports vs 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs in accordance with section 1833(f)(3)(A) of the Act. We believe this clarification will have negligible impact on Medicare spending.

3. Clinical Laboratory Fee Schedule

In section III.C.5. of this final rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 4(b) of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, enacted December 10, 2021), we are finalizing certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are updating certain definitions and revising § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2023. The PMAFSCA delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2023 through March 31, 2023. Subsequently, the next private payor rate-based CLFS update for these tests will be effective January 1, 2024 instead of January 1, 2023. In addition, we are making conforming changes to our requirements for the phase-in of payment reductions to reflect the PMAFSCA amendments. Specifically, we revising § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.A. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the PMAFSCA amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to the unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, and calculating the updated CLFS rates.

Regarding the conforming changes to our requirements for the phase-in of payment reductions that we are finalizing in this rule, we note that for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2023.

In section III.C.6. of this final rule, we are finalizing an increase to the general nominal specimen collection fee amount from $3.00 to $8.57 for CY 2023. We are also finalizing that beginning January 1, 2024, we will update the specimen collection fee amount of $8.57 for each calendar year by the percent change in the CPI–U (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. Additionally, as required by PAMA, we will increase this amount by $2 for those specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA, which will result in a $10.57 specimen collection fee for those beneficiaries.

The estimated impact of this increase in the nominal fee for specimen collection from $3.00 to $8.57 in CY 2023 is an increase in spending of roughly $190 million. The estimated increase in the nominal fee from $5.00 to $10.57 for specimens collected from a Medicare beneficiary in a SNF or on behalf of an HHA in CY 2023 is an increase in spending of roughly $10 million.

4. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

In section III.D. of this final rule, we proposed to expand CRC screening test coverage by modifying coverage and payment limitations of certain CRC screening tests to begin at age 45 instead of 50. An updated modeling study that accompanied the May 2021 updated USPSTF CRC screening

recommendation found that the most efficient strategy for CRC screening began for individuals at 45 years of age. The expected benefits include longer life and fewer new cases and total deaths from colorectal cancer.[570] We considered the comparatively small population of traditional Medicare enrollees in the affected age group. The CMS website reports that total Medicare beneficiary enrollment in Part A and/or Part B aged 45–54 years in CY 2020 totaled only 1,956,634, whereas total Medicare beneficiary enrollment in Part A and/or Part B of all ages totaled 62,840,267.[571]

In addition, we propose to expand CRC screening test coverage to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. We anticipate the impact of beneficiary cost sharing no longer being applicable to the follow-on screening colonoscopy will be balanced, in part or in whole, by the benefits and savings of additional beneficiaries choosing a less expensive and non-invasive stool-based test as their first step in the CRC screening process.

We anticipate that both provisions will result in some additional service utilization, but we also anticipate the additional utilization to be balanced, in part or in whole, by benefits and savings resulting from increased prevention, early detection (allowing for less invasive and more effective treatment) and reduced mortality. We do not anticipate expanding CRC screening test coverage (in accordance with recommendations by the USPSTF and in consultation with other appropriate organizations described earlier in our provision) to result in a significant impact on the Medicare program.

An internal analysis by the CMS Office of the Actuary of CY 2019 Medicare FFS CRC screening test claims confirmed our understanding that our provisions will not likely result in a significant impact on the Medicare program. Regarding our provision to expand CRC screening test coverage by modifying coverage and payment limitations of certain CRC screening tests to begin at age 45 instead of 50, we calculated CY 2019 FFS CRC screening test spending and utilization for patients between 45 and 55 years old from the Integrated Data Repository (IDR), estimated CY 2019 Medicare FFS member months by age from the IDR, and assumed that current colorectal screening test utilization for 45–49 year old patients will increase on a per enrollee basis to that of patients between 50–55. We estimated the impact from additional utilization to be approximately $5 million in additional spending.

Similarly, regarding our provision to expand CRC screening test coverage to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result, we matched CY 2019 FFS colonoscopy claims to Cologuard usage claims, identified colonoscopy claims as screening or diagnostic based on the presence of HCPCS modifier PT on the claims, assumed that all diagnostic colonoscopy claims with a prior Cologuard test had a positive test result, and calculated the applicable beneficiary cost sharing for those claims. The coinsurance and deductible liability from these claims were assumed to be non-applicable under the policy. We estimated the impact from additional utilization to be approximately $5 million in additional spending.

Each of these proposals is estimated to increase fee-for-services (FFS) spending in CY 2023 by roughly $5 million, therefore, the estimated impact of approximately $10 million total in CY 2023 is based on the convergence of the two CRC provisions, and does not reflect secondary effects of the policies, such as increased utilization of preventive screening services, additional follow-up services, and potential offsetting savings (including prevention, more effective treatment through early detection and avoidance of over-servicing of colonoscopies) that may result from these expansions, as these secondary effects are difficult to predict, and may, in part, offset one another.

5. Removal of Selected National Coverage Determinations (NCDs)

As described in section III.E. of this final rule, we are removing as proposed, one older NCD that no longer contains clinically pertinent and current information. NCDs generally fall into one of two impact categories. First, eliminating an NCD for items and services that were previously nationally covered means that the item or service will no longer be automatically nationally covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous national coverage determination barred coverage for an item or service under title XVIII, MACs will now be able to cover the item or service under local coverage authority if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries.

Removing NCD 160.22 Ambulatory EEG Monitoring means moving from positive national coverage to local coverage by the MACs. Claims data for 2021 shows that for the 20 CPT/HCPCS codes associated with this NCD, CMS paid 167,242 Medicare FFS claims for approximately 78,267 unique beneficiaries totaling CMS payments of $48,702,876.00. We estimate there will be de minimis change to 2023 payments, compared to 2021 because this is a long-established service for which the MACs already have LCDs and guidance articles. The NCD contains outdated language that is inconsistent with, and contrary to current standards of care. Therefore, removing the outdated NCD will allow MACs to update local coverage guidance for this established diagnostic test, but will not result in significant changes to utilization or payments.

6. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F. of this final rule, for CY 2023 and subsequent years, we are revising our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. Under the revised methodology, we will base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription). We are also finalizing our proposal to update the methadone payment amount for CY 2023 based on the projected increase in the PPI for Pharmaceuticals for Human Use (Prescription) to reflect the forecasted price growth for prescription drugs for the 2-year period from CY 2021 to 2022 and from CY 2022 to 2023. Because we froze the payment amount for methadone at the 2021 amount for CY 2022, we are accounting for the inflation for both CY 2022 and CY 2023 in setting the payment rate for CY 2023. Based on the third quarter 2022 forecast from IHS Global Inc. (IGI), the CY 2023

[570] *https://www.uspreventiveservices taskforce.org/uspstf/document/final-modeling-study18/colorectal-cancer-screening.*

[571] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-total-enrollment.*

methadone payment amount will be $39.37, which is the CY 2022 payment amount of $37.38 increased by a projected 5.3 percent growth in the PPI for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023 ($37.38 * 1.053 = $39.37). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast various price proxies used in the CMS market baskets.

Overall, CMS estimates that the impact of our revision to the OTP methadone pricing methodology will increase Medicare spending by roughly $2.5 million in CY 2023. This estimate is based on actual utilization of the OTP benefit by Medicare beneficiaries under Part B through CY 2021. The estimate does not reflect any additional utilization that may occur in CY 2023.

Additionally, as discussed in section III.F. of this final rule, we are modifying the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), instead of a crosswalk to CPT code 90832 (*Psychotherapy, 30 minutes with patient*), as is our current policy. We believe CPT code 90834 most closely corresponds to a 50-minute therapy session, which interested parties have indicated is the typical amount of therapy received by patients in the first few months of treatment at an OTP. In the CY 2020 PFS final rule (84 FR 62658), we stated that we based the rate for individual therapy in the bundled payment on the 2019 non-facility payment rate for CPT code 90832, which was $68.47. Therefore, to change the rate for individual therapy, we are substituting the 2019 rate for CPT code 90832 included in the non-drug component of each of the bundled payments for an episode of care with the 2019 PFS non-facility payment rate for CPT code 90834, which was $91.18, to determine an adjusted payment rate for CY 2020 for the non-drug component of each applicable HCPCS code. As described in § 410.67(d)(4)(iii), we then applied the Medicare Economic Index (MEI) updates for 2021, 2022, and 2023 to these adjusted payment rates to determine the CY 2023 payment amounts for the non-drug component of the bundled payments for an episode of care.

The increase to the bundled rates to reflect longer individual therapy sessions results in an increase of $24.39 to the non-drug component of the weekly bundled payments for HCPCS codes G2067 through G2075 from CY 2022 to 2023. Based on utilization data from Medicare beneficiaries under the OTP benefit through CY 2021, the estimated impact of this policy is an increase in Medicare spending of approximately $25 million in CY 2023. This estimate does not reflect any additional utilization that may occur during CY 2023.

Additionally, as discussed in section III.F. of this final rule, we are finalizing our proposal to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We are also permitting the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. We are also allowing periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2023, to the extent that it is authorized by SAMSHA and DEA at the time the service is furnished and all other applicable requirements are met.

We believe the Part B cost impact of these flexibilities for the use of telecommunications policies will be minimal because we do not expect that these flexibilities will increase the frequency with which medically necessary assessments are furnished.

7. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2022, over 11 million people with Medicare receive care from at least one health care provider in one of the 483 ACOs participating in the Medicare Shared Savings Program (Shared Savings Program), the largest value-based payment program in the country. The policies we are adopting in this final rule for the Shared Savings Program advance Medicare's overall value-based care strategy of growth, alignment, and equity, with many provisions overlapping these categories. These final policies are designed to reverse recent trends where participation has plateaued in the Shared Savings Program, higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to ACOs appears inequitable as evidenced by data indicating underserved populations are less likely to be assigned to a Shared Savings Program. The final policies are also designed to encourage growth of ACOs in underserved communities based, in part, on recent observations where the highest earning ACOs had a higher proportion of beneficiaries who were members of racial and ethnic minority communities and included a greater proportion of ESRD, disabled, and aged/dual eligible beneficiaries than the lowest earning ACOs.

Stagnation in overall participation in the Shared Savings Program in recent years has coincided with increasing total shared savings outlays, driven by sharply higher shared savings payments to ACOs that were already low spending relative to their region electing to transition to risk in the ENHANCED track. While this type of selection was anticipated in estimating the impacts of the December 2018 final rule (83 FR 67816), it was also assumed that: (1) ACOs making the transition to risk would respond with stronger efforts to improve efficiency; and (2) a broader spectrum of relatively higher-spending ACOs would be influenced by the revised benchmarking methodology to drive down spending for their assigned beneficiaries while participating under the BASIC track glide path in order to ultimately achieve sustainable participation under risk in subsequent agreement periods.

As we explained in the CY 2023 PFS proposed rule (87 FR 46400) the increase in shared savings payments to ACOs transitioning to the ENHANCED track appears to be driven largely by favorable regional benchmark adjustments and the ENHANCED track's higher sharing rate, calling into question whether ACOs selecting risk will further improve efficiency or simply be content to collect steady shared savings by maintaining their spending level relative to their region. Meanwhile, ACO Investment Model (AIM) participants—a subset of Track 1 ACOs that meaningfully outperformed peer ACOs in reducing spending and earning shared savings over the period from 2016 through 2018—have also dropped out at an elevated frequency before even attempting the risk-free portion of the BASIC track glide path. The spending reductions achieved by AIM ACOs were found to be similar regardless of an AIM ACO's decision to continue or exit the program. Superior financial performance during an initial agreement period under a one-sided model therefore failed to provide sufficient incentive to overcome a pronounced

aversion to risk demonstrated by this otherwise-effective subset of ACOs.[572]

We noted that without modification, the Shared Savings Program would be at high risk of increasing overall Medicare spending over the coming decade. ACOs serving patients with low spending would likely continue to dominate the roster of ACOs making the transition to risk. Shared savings payments to low-spending ACOs would increase alongside a growing disincentive for ACOs to serve higher spending populations for whom potential savings from care management would likely be greater.[573] We also explained that this selective participation was in response to regional benchmark adjustments that have increased shared savings payments to low spending ACOs and has resulted in higher cost beneficiaries, who have the most need for ACO care management, being increasingly excluded from assignment to ACOs participating in the program. We stated that it appeared very unlikely that selective transition to downside risk under the current participation options and financial methodology would drive down spending enough to offset increased shared savings payments to ACOs with favorable regional benchmarks. Furthermore, we acknowledged that a growing subset of ACOs that elect prospective beneficiary assignment are finding their regional benchmarks to be artificially inflated because of a systematic bias in calculations based on regional FFS expenditures resulting from comparing expenditures for the ACO's own assigned beneficiary population identified based on the offset assignment window, and expenditures for the assignable population of beneficiaries in the ACO's region identified based on the calendar year assignment window. Therefore, the program's baseline trajectory was projected to increase net Medicare spending by approximately $4.2 billion over the period from 2024–2034, which spans two 5-year agreement periods for ACOs renewing or entering in 2024 and 2025. Absent any changes, the program was also projected to violate the statutory requirement that provisions implemented under authority of section 1899(i)(3) of the Act not increase spending.

The policies we are finalizing in this final rule are designed to increase program participation for new ACOs through advance investment payments to promote health equity and provide ACOs greater choice in the pace of progression to performance-based risk; sustain program participation by reducing the effect of ACO performance on benchmark updates and benchmark rebasing; mitigate the bias in regional expenditure calculations that benefits ACOs electing prospective assignment; strengthen incentives for ACOs serving high risk and high dual populations; improve the risk adjustment methodology to better account for medically complex, high cost beneficiaries while continuing to guard against coding initiatives; increase opportunities for low revenue ACOs in the BASIC track to share in savings by allowing ACOs that do not meet the minimum savings rate (MSR) requirement to share in savings at a lower rate; encourage ACOs to transition more quickly to all-payer quality measure reporting; update the ACO beneficiary assignment methodology; and reduce administrative burden on ACOs.

Reducing the cap on negative regional adjustments to high spending ACOs' benchmarks and offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period are expected to significantly re-engage participation for ACOs serving higher cost beneficiaries. While we are uncertain how large the group of new and re-entering ACOs will be and whether they will have a similar savings potential as the first implementation of Track 1, other incentives targeted to low revenue (typically physician-led) ACOs, like advance investment payments and paying partial shared savings to low-revenue ACOs with savings under their MSR, as well as adjusting rebased benchmarks for prior savings are expected to improve the incentive for new ACOs to join the program and reduce spending to a greater extent than the incentive provided under Track 1. Table 151 shows the combined benchmark and the relative impact that 2024/2025 renewing and new ACOs are expected to have on average over the two 5-year agreement periods from 2024–2034. The Baseline columns show these projections under current program rules and the Final columns show the projections for performance under this final rule.

TABLE 151: Projected Impacts on Benchmark and Spending for 2024/2025 Renewing, Re-entering and New ACOs

	Renewing ACOs		New ACOs / Re-entering ACOs	
	Baseline	Final	Baseline	Final
Average Annual Benchmark ($ Billion)	$73	$91	$11	$44
Gross Savings (Impact on Claims, % of Bmark)	-2.7%	-2.8%	-1.3%	-2.7%
AAPM QP Physician Pay Increase (% of Bmark)	0.3%	0.3%	0.3%	0.1%
Shared Savings/(Losses) (% of Bmark)	2.8%	2.1%	2.2%	1.0%
Net Advance Investment (% of Bmark)				0.01%
Net Federal Impact (% of Bmark)	0.4%	-0.4%	1.2%	-1.6%
Net Federal Impact ($Billions)	$2.9	-$3.6	$1.3	-$6.8
10th percentile	-$1.4	-$10	$0.5	-$11
90th percentile	$7.0	$3.0	$2.0	-$3.2

[572] Trombley, MJ, et al. ACO Investment Model Produced Savings, But the Majority of Participants Exited when Faced with Downside Risk. *Health Affairs.* 2020; 138–146. doi:10.1377/hlthaff.2020.01819.

[573] McWilliams, JM, et al. Early Performance of Accountable Care Organizations in Medicare. *New England Journal of Medicine.* June 2016. 374:2357–2366. DOI: 10.1056/NEJMsa1600142.

b. Impacts for Renewing ACOs

Renewing ACOs for the projected two 5-year agreement periods are anticipated at baseline to generate higher net shared savings earnings (2.8 percent of benchmark) than actual reductions in spending on claims (2.7 percent of benchmark). After also accounting for higher physician fee schedule payments to qualifying practitioners (QPs), totaling on average 0.3 percent of benchmark over 10 years, this cohort of ACOs is projected to increase net program spending by 0.4 percent of benchmark on average, or $2.9 billion over 10 years. For existing ACOs, the changes we are finalizing will help to retain more of the otherwise shrinking subset of ACOs that serve higher spending populations, will remove the bias favoring benchmarks for ACOs electing prospective assignment, and will marginally improve the incentive for efficiency via the use of a three-way blend of the Accountable Care Prospective Trend (ACPT)/national-regional growth rates to update benchmarks and the prior savings adjustment. As a result, overall savings on claims are projected to increase by a small margin to 2.8 percent of benchmark while average shared savings payments will be reduced to an average of 2.1 percent of benchmark. The total 10-year impact for this cohort will flip from a $2.9 billion cost at baseline (range of $1.4 billion savings to $7.0 billion cost at 10th and 90th percentiles) to a $3.6 billion savings under the final policies (range of $10 billion savings to $3 billion cost at the 10th and 90th percentiles).

c. Impacts for New ACOs and Re-Entering ACOs

At baseline without the finalized changes, the cohort of new ACOs and re-entering ACOs starting in 2024 would be relatively small (only $11 billion in annual benchmark) and skewed toward ACOs serving beneficiary populations that are already low cost at baseline. Shared savings payments to this group would also be elevated by the bias inflating benchmarks for ACOs electing prospective assignment. At baseline this cohort would increase net program spending by an estimated 1.2 percent of benchmark or $1.3 billion over 10 years (ranging from an increase of $0.5 to $2.0 billion at the 10th and 90th percentiles). In contrast, under the changes in this final rule, the cohort of new and re-entering participants starting in 2024 is estimated to increase to $44 billion in combined benchmark per year. An anticipated influx of low revenue physician-led ACOs serving higher cost patients is expected to allow this cohort to produce significantly greater savings on claims (2.7 percent of benchmark) than will be paid out in shared savings (1.0 percent of benchmark) because these ACOs will be starting with lower relative benchmarks than existing low-spending ACOs and they will predominantly be paid under the lower 40 percent sharing rate offered in the BASIC track's one-sided models. After accounting for slightly higher physician fee schedule payments to QPs and the nominal net cost of advance investment payments, this cohort is projected to reduce net program spending about 1.6 percent of benchmark or $6.8 billion over a 10-year period (net savings range from $3.2 billion to $11 billion at the 90th and 10th percentiles).

Average gross savings for this cohort (2.7 percent of benchmark) are projected to roughly match average gross savings for renewing ACOs (2.8 percent of benchmark) despite being less-experienced and heavily concentrated in the BASIC track both because they are serving higher-spending patients presenting greater savings opportunities and because they are anticipated to predominantly include low-revenue ACOs for whom sharing-only incentives are relatively strong despite not being pushed toward risk in their first agreement period. As a percentage of benchmark, these projected gross savings rates are consistent with the savings range estimated for historical performance for the Shared Savings Program detailed in Regulatory Impact Analysis for the December 2018 final rule (83 FR 68047 through 68050) and represent modest progression from the 1.3 to 2 percent savings estimated by MEDPAC using an ''intent to treat'' approach for evaluating performance through 2016, which was dominated by participation in Track 1.[574]

d. Annual Combined Impacts 2023–2034

As described in Table 152, relative to baseline projections, the combined cohort entering or renewing for agreement periods beginning in 2024 and 2025 is projected to add roughly $50 billion in annual benchmark, reduce claims costs by $15.5 billion, and on net increase aggregate shared savings payments by about $650 million. The changes in this final rule are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare. Approximately 80 percent of advance investment payments are anticipated to be recovered from shared savings payments by the middle of the second agreement period; the estimate shows $40 million in outstanding advance investment payments by the end of the projection period after an initial $210 million in initial funding. Approximately $60 million in net savings for 2023 is projected for retaining existing higher-spending ACOs that would otherwise have dropped out of the program if not offered the ability to remain in one-sided risk for the remainder of their current agreement period.

More importantly, the Shared Savings Program will increase participation from ACOs serving higher-spending beneficiaries by reducing the negative regional adjustment cap and creating a sharing-only option covering an entire agreement period plus the first 2 years of the succeeding agreement period for eligible ACOs. Advance investment payments and partial shared savings payments for certain ACOs in the BASIC track with savings below their MSR will only marginally increase payments to ACOs while increasing overall program savings by drawing new participation from low revenue ACOs (typically physician-led ACOs), the type that performed well under Track 1. Including a prior savings adjustment as part of benchmark rebasing will broaden the incentive for ACOs to drive down spending over multiple agreement periods by mitigating the ratchet effect for high-spending ACOs, for ACOs in competitive markets with collectively low trend, and for ACOs under prospective assignment that may be concerned about the provision to remove the favorable bias in regional benchmark calculations. Modifications to the quality scoring system through adding a sliding scale approach to determining shared savings and offering bonus points to higher performing ACOs with a high proportion of underserved populations may increase shared savings payments marginally overall depending on how ACOs may otherwise have progressed in future years against what is still a relatively new quality rubric. The finalized changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in

[574] Report to Congress: Medicare and the Health Delivery System (Chapter 6). MEDPAC publication dated June 2019. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch6_medpac_reporttocongress_sec.pdf.*

absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare. The impact estimate ranges from a reduction of $8.2 billion to a reduction of $21.4 billion at the 10th an 90th percentiles.

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TABLE 152: Final Rule Projected Impact Relative to Current SSP Baseline (Financial Impacts in $Millions)

Program Year	ACO Participation	ACO Benchmark	Claims	Net ACO Sharing	Advance Investment Cash Flow*	Comb. Fed Impact
2023	34	10,940	-80	20	N/A	-60
2024	128	40,040	-490	70	210-70	-420
2025	140	43,490	-760	-200	-40	-960
2026	137	44,110	-950	-120	-20	-1,070
2027	138	45,800	-1,170	-70	-10	-1,240
2028	143	49,060	-1,370	-40	-10	-1,410
2029	155	54,930	-1,700	-10	-10	-1,710
2030	146	53,700	-1,990	310	-10	-1,680
2031	144	55,210	-2,110	310	0	-1,800
2032	144	57,130	-2,100	220	0	-1,880
2033	138	56,820	-2,120	250	0	-1,870
2034			-670	-90	0	-760
12Y Total			**-15,510**	**650**	**40**	**-14,810**
Low (10th Ptile)				-3,710		-21,410
High (90th Ptile)				820		-8,200
*Total advance investment payments in 2024 shown with first year repayment amount in same row for 2024						

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e. Discussion of Key Provisions and Related Assumptions

The stochastic model and associated assumptions previously described in the December 2018 final rule (83 FR 67816) were updated to produce this estimate. The model continues to assume that high-revenue ACOs are on average only 50 percent as effective as low-revenue ACOs at reducing spending because high-revenue ACOs include a more comprehensive mix of hospitals and other providers and suppliers for whom the incentive to potentially share in a fraction of savings from preventing utilization is weak compared to the immediate revenue from utilization—an expectation that has been supported by evaluation of actual program performance.[575] Updates included accounting for the current mix of participating ACOs in constructing the potential ACOs making up the renewing cohort and considering the population of exiting ACOs to build a sample of higher spending populations that may be added to the program under the provisions that are expected to boost interest in the program from potential ACOs associated with average and higher spending populations. New low-revenue ACOs were assumed to always prefer the extended glidepath unless they expected a regional benchmark at least 3 percent higher than baseline spending, in which case a one-third probability was assigned for the entrant to opt for higher potential earnings under Level E of the BASIC track. The model was also updated to first decrease the baseline savings potential for existing and new ACOs under the current program rules by about 25 to 50 percent (to better match emerging actual performance from selective low-spending ACO participation) which was then scaled up to estimate the impacts of the final policies to account for new incentives driven mainly by the ACPT and prior savings adjustment, taking the form of a 0 to 50 percent increase in gross savings for low and average spending ACOs and a zero to 100 percent increase for new ACOs serving markedly high spending populations at baseline (at least 10 percent higher than their regional average benchmark spending level). The resulting savings ranges produced by the modeled participation are supported by the proximity to previous estimates of program savings under more balanced participation in Track 1, as noted previously in this section. Savings are expected to increase because of the many new features that will improve the incentive for ACOs to drive down spending over multiple agreement periods. Below is a further discussion of these factors.

Introducing a prospective 5-year growth rate to be blended with the existing retrospective benchmark trend will help to address the so-called 'rural glitch' complaint from ACOs and other interested parties and should at least marginally improve the incentive for ACOs to reduce spending, in particular when multiple ACOs are present in the same market and collectively driving

[575] McWIlliams JM, et al. Medicare Spending After 3 Years of the Medicare Shared Savings Program. *New England Journal of Medicine.* Sept. 2018. 379:1139–1149. DOI: 10.1056/NEJMsa1803388.

down regional spending. The approach that interested parties have floated for mitigating ACOs' effects on their region—effectively removing ACO assigned beneficiaries from the regional calculation—has multiple problems that would increase program spending. It would amplify the benefit to ACOs for selecting lower cost patients and avoiding higher needs groups and drive market consolidation, and still fail to mitigate the cited problem for cases where multiple ACOs work in combination to drive down regional spending. Furthermore, it would increase program spending to such a degree that compliance with the requirements of section 1899(i)(3) of the Act, to use other payment models, would be violated.

We acknowledge a potential elevated risk; however, that uncertainty around external conditions related to the end of the PHE for COVID–19 and economic conditions like emerging inflation could cause a prospective trend to differ materially from actual program-wide growth in per capita spending. Blending the ACPT as one-third of the overall update helps lower the risk that projection error will create problems with appropriateness of spending targets. Risk-bearing ACOs will have extra protection against exposure to ACPT projection error because they will be held harmless on the downside if the new method will charge them more in losses than the prior retrospective trend method. Modeling indicates this safeguard will reduce shared losses owed by ACOs by about $100 million over 10 years, but the net impact of this provision is likely to save several times that amount by retaining ACOs that would otherwise have dropped out of the program.

The most important factor returning the program to net savings is attracting more ACOs into the BASIC track that serve higher spending populations, particularly low revenue physician-led ACOs for whom a 40 percent sharing rate is a strong incentive for efficiency even absent downside risk. The most important provision for growing this participation is the policy change to allow ACOs to stay in a one-sided model (that is, Level A or Level B of the BASIC track) for a full 5-year agreement period. Advance investment payments and the opportunity to receive partial shared savings payments for savings under the MSR will help to increase the share of these new ACOs that are low revenue. These exclusive provisions for low revenue ACOs are estimated to drive $3 billion in net savings over the projection period notwithstanding marginal increases in shared savings outlays. This analysis highlights that the savings gained from increasing participation from this type of ACO will greatly exceed the marginal increase in program outlays from paying partial shared savings under the MSR and advance investment payments, as combined incentive payments (consisting mainly of shared savings payments combined with slightly higher payments to clinicians achieving QP status) to new and reentering ACOs are only projected to reach about 1.1 percent of benchmark over the projection period in return for savings on benefits of 2.7 percent (as detailed in Table 151).

Another key provision for improving the financial impact of the program is establishing a separate ratebook to calculate county-level expenditures for ACOs selecting prospective assignment using an assignable population of beneficiaries that is identified based on the offset assignment window. This final policy will remove a bias that would otherwise artificially boost benchmarks and thereby account for $3.7 billion of the total savings projected above. Most existing ACOs currently benefiting from this bias will still expect to receive favorable regional adjustments at rebasing despite removal of the bias. The new adjustment to benchmarks for prior savings will help restore a positive benchmark adjustment for the subset of ACOs for whom removal of the prospective assignment bias will minimize their regional adjustments at rebasing. However, because the prior savings adjustment will only be applied if it produces a higher adjustment than the regional benchmark adjustment, it will not further increase benchmarks for ACOs already benefiting from the existing regional adjustment.

Modifications to the quality scoring system through the addition of a sliding scale approach to determining shared savings for ACOs to allow for payment of scaled shared savings and a health equity adjustment under which ACOs that perform well on at least one or more measures while serving a high proportion of beneficiaries enrolled in the Medicare Part D low-income subsidy or dually eligible for Medicare and Medicaid or beneficiaries in areas with high Area Deprivation Index scores may earn health equity bonus points are projected to increase shared savings payments marginally overall depending on how ACOs may otherwise have progressed in future years against what is still a relatively new quality rubric. The costs of adding these new methods for improving quality performance scores and paying scaled shared savings are projected to add about $1.3 billion in program spending over 10 years. Other provisions related to assignment and risk adjustment are expected to have relatively nominal financial impacts on the program.

f. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the new policies described in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following provisions require the use of our authority under section 1899(i) of the Act: allowing for advance investment payments; the modifications to the loss sharing rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard; use of the ACPT/national-regional three-way blended benchmark update factor; expanding the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act; and exclusion of the new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program. These changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

A comparison was constructed between the projected impact of the payment methodology that incorporates all changes adopted in this final rule and a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority. The hypothetical baseline was assumed to be limited to a 50 percent upside-only track rebased every three years but including adjustments allowed under section 1899(d)(1)(B)(ii) of the Act including the up to 50

percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark (capped on the upside or downside as detailed in this final rule) and the prior savings adjustment if producing a higher benchmark (also as detailed in this final rule). The stochastic model and associated assumptions described previously in this section were adapted to reflect a marginally reduced participation from low-revenue ACOs because the hypothetical baseline would lack advance investment payments and partial shared savings payments for certain BASIC track ACOs with savings under their MSR. Such analysis estimated approximately $4.9 billion greater average net program savings under the alternative payment model (with the modifications in this final rule) that includes all policies that require the authority of section 1899(i)(3) of Act than would be expected under the hypothetical baseline in total over the 2023 to 2034 projection period.

Participation in performance-based risk in the ENHANCED track and the higher levels of the BASIC track is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to the assumptions used in the modeling of the impacts, described previously). Such added savings are partly offset by lower participation associated with the requirement to transition to performance-based risk. Despite the higher maximum sharing rate of 75 percent in the ENHANCED track under the alternative payment model that includes all policies adopted under section 1899(i)(3) of the Act, relative to the 50 percent maximum sharing rate assumed for the single one-sided risk track under the hypothetical baseline, shared savings payments are expected to be reduced relative to the hypothetical baseline because of lower expected participation resulting from the eventual requirement to transition to risk in the second agreement period under the BASIC track and generally more accurate benchmarks due to the incorporation of regional factors into the calculation of benchmark updates for all ACOs.

We will reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets the requirements of section 1899(i)(3), we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

8. Medicare Part B Payment for Preventive Vaccine Administration Services

In section III.H.2.c of this final rule, for CY 2023, we finalized our proposal to annually adjust the payment amount for administration of preventive vaccines to reflect geographic locality cost differences. That is, we will use the Geographic Adjustment Factor (GAF) described in § 414.26 to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas. Additionally, in section III.H.2.d of this final rule, for CY 2023, we finalized our proposal to annually update the payment amount for the administration of preventive vaccines based upon the Medicare Economic Index (MEI). In section III.H.3.c. of this final rule, we finalized our proposal to continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances. Further, we will adjust and update the $35.50 by the GAF and MEI as we proposed for the preventive vaccine administration services.

The estimated impact of updating the payment amount for the administration of preventive vaccines based upon the MEI (3.8%) in CY 2023 is an increase in spending of roughly $40 million. Approximately $30 million of the increase represents the administration of the COVID–19 vaccine, and the remaining $10 million represents the other preventive vaccines. The provision to adjust the payment amount for the administration of preventive vaccines by the GAF and the provision to continue the additional payment for at-home COVID–19 vaccinations will have a negligible impact on Medicare spending.

9. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

In section III.I. of this final rule, we proposed to clarify § 410.40(e)(2)(ii) by reorganizing existing language and stating that the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is required. We are also clarifying that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance. Finally, we are clarifying that coverage includes observation or other services rendered by qualified ambulance personnel. While we believe that clarification of the regulatory provisions is needed and will be well received by interested parties, we do not believe that these clarifications will have any substantive monetary or impact the amount of time needed submit claims. We believe the primary benefit of the clarification will be for providers and suppliers in preparing and submitting claims. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

10. Medicare Provider and Supplier Enrollment Changes

a. Expansion of Revocation Reasons

As explained in section III.J. of this final rule, we proposed changes to two of our existing revocation reasons:

- We proposed to expand § 424.535(a)(2) to permit revocation based on an OIG exclusion of the provider's or supplier's managing organization, corporate officer, or corporate director.
- We proposed to expand § 424.535(a)(3) to permit revocation based on a felony conviction of the provider's or supplier's managing organization, corporate officer, or corporate director.

We believe these two changes will result in an increase in the number of revocations that CMS imposes. However, we believe this number will be rather small. We currently impose only a limited number of revocations under §§ 424.535(a)(2) and (a)(3). Accordingly, since our expansion of these revocation reasons will be fairly modest, we do not foresee more than a very slight increase in revocations thereunder.

Table 153 outlines the number of revocations we estimate will ensue under our proposed revocation expansions. These numbers only account for additional revocations stemming from our changes:

TABLE 153: Additional Revocations

Revocation Reason	Number
§ 424.535(a)(2)	5
§ 424.535(a)(3)	5
Total	**10**

Internal CMS data indicates that the average provider/supplier that will be affected by these regulatory expansions receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in the CY 2022 PFS final rule) (86 FR 64995)). Providers/suppliers revoked under our proposed revocation expansions will thus not receive these payments. Hence, multiplying our $50,000 estimate by the revocation totals in Table 153 results in a projected transfer from these providers/suppliers to the Federal Government of $500,000 ($50,000 × 10 revocations).

b. Expansion of Fingerprinting Requirements

We proposed the following three revisions to § 424.518:

- Adding provider or supplier ownership changes to the types of provider enrollment transactions falling within the scope of § 424.518. (As explained in section III.J. of this final rule, the affected owner(s) will have to submit fingerprints and be subject to a fingerprint-based criminal background check if the provider or supplier is in the ''high'' level of categorical screening.)
- Stating that any screening level adjustment to ''high'' also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier that originally triggered the screening level increase.
- Moving SNFs from the ''limited'' level of categorical screening to the ''high'' screening level.

These changes will result in an increase in the annual number of providers and suppliers that must furnish fingerprints for their 5 percent or greater direct or indirect owners. Based on existing enrollment statistics and our experience, we project that: (1) 29,726 providers and suppliers per year will be required to submit the fingerprints of their owners (new or existing) pursuant to these changes; and (2) 29,726 owners per year will be fingerprinted (or one owner per provider/supplier, which is roughly consistent with prior estimates).

Consistent with previous burden estimates we have made regarding fingerprinting, we estimate that it will take each owner approximately 2 hours to be fingerprinted. According to the most recent BLS wage data for May 2021, the mean hourly wage for the general category of ''Top Executives'' (the most appropriate BLS category for owners) is $57.94. With fringe benefits and overhead, the figure is $115.88. This will result in an estimated annual burden involving our proposed changes to § 424.518 of 59,452 hours at a cost of $6,889,298.

c. DMEPOS Payment Denials

We also proposed to add a new DMEPOS condition of payment to § 424.57(b). It will require the DMEPOS supplier to be in compliance with all conditions of payment in § 424.57(b), as well as with the licensure requirements of § 424.57(c)(1)(ii)(A), at the time the item or service is furnished in order to receive payment. Based on data collected from our experience with the scenario our proposed change seeks to remedy, we project 6,100 claim denials per month associated with our provision involving $1.3 million in denied/unpaid claims. Over a 12-month period, this results in 73,200 claim denials and $15.6 million in unpaid claims, the latter constituting our estimated annual transfer to the federal government. We welcomed comments on this estimate.

We did not receive public comments on our fingerprinting or DMEPOS payment estimates. Therefore, we are finalizing these estimates as proposed.

11. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

We do not anticipate any additional costs or savings associated with our proposed revision to § 455.107(b), for the latter merely involves giving the states somewhat greater flexibility in executing the provisions of § 455.107.

12. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.L. of this final rule, we extended the existing compliance action of sending letters to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024 through December 31, 2024). Additionally, effective January 1, 2023, we are changing the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions (§ 423.160(a)(5)(ii)). We will determine whether a prescriber qualifies for the emergency or disaster exception (§ 423.160(a)(5)(iii)) based on the prescriber's valid address in PECOS (Medicare Provider Enrollment, Chain, and Ownership System), instead of the NCPDP Pharmacy Database address, and for prescribers who are not enrolled or do not have a valid PECOS address, we will use the address in the National Plan and Provider Enumeration System (NPPES) data. We stated in the CY 2023 PFS proposed rule (87 FR 46406) that we understand that with continuing the compliance action of sending letters to non-compliant prescribers for another year, some prescribers may delay EPCS implementation, but we also believe that our education and outreach with these prescribers during this additional year may help increase adoption. Please see section III.L.4.a. of this final rule for our discussion, as we did receive public comment on the concern that a delay of further non-compliance action might delay EPCS adoption. We do not anticipate these provisions to have any incremental impact on the cost or time associated with prescriber compliance of the electronic prescribing for controlled substances requirement or the cost to interested parties. We did not receive any public comments on our impact assumptions.

13. Medicare Ground Ambulance Data Collection System

In section III.K. of this final rule, we are finalizing a series of changes to the Medicare Ground Ambulance Data Collection System including the provision to update § 414.626(d)(1) and (e)(2) to give us the necessary flexibility to specify how ground ambulance organizations should submit the hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational, and proposed revisions to the Medicare Ground Ambulance Data Collection Instrument.

The changes and clarifications aim to reduce burden on respondents, improve data quality, or both. We grouped our proposed changes and clarifications into four broad categories: editorial changes for clarity and consistency; updates to reflect the web-based system; clarifications responding to feedback from interested parties questions and testing and typos and technical corrections.

While we believe that these changes and clarifications will be well received by the ground ambulance interested parties, we do not believe that these changes will have any substantive impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. We note that the overall length of the Medicare Ground Ambulance Data Collection Instrument will be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we proposed to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

14. HCPCS Level II Coding for Skin Substitutes

We proposed several changes to our policies for skin substitute products. In addition to soliciting feedback on our key objectives related to our skin substitute policies, we proposed to change the terminology of skin substitutes to more accurately reflect how clinicians use these products, to treat these products as incident to supplies under section 1861(s)(2)(A) of the Act, and to pay for these products as incident to supplies under the PFS beginning on Jan 1, 2024. Additionally, in section III.N. of this final rule, we discussed our proposal to revise our HCPCS coding procedures, the impacts related to these provisions are in section III.N.

After consideration of public comments, we are not finalizing the proposed revisions to the payment methodology for skin substitutes. We are also not finalizing any change in terminology. Instead, we plan to host a townhall session in early CY 2023 to discuss alternative payment solutions and nomenclature ahead of CY 2024 rulemaking.

15. Effects of Medicare Parts A and B Payment for Dental Policy

In section II.L.2. of the proposed rule, we: (1) proposed to clarify our interpretation of section 1862(a)(12) of the Act, and clarify and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposed and solicited comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup and certain diagnostic and treatment services prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services; and (3) requested comments on other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services, such as the treatment for head and neck cancers.

If finalized, we stated that we did not believe the proposed codification of current payment policy would result in a significant payment impact because it would be a continuation of existing Medicare payment policy. We also stated that if we were to finalize the payment for an oral or dental examination, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, we did not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of organ transplant, cardiac valve replacement and valvuloplasty surgeries.

As discussed further in section II.L.2. of this final rule, we are finalizing effective beginning in CY 2023: (1) a clarification of our interpretation of section 1862(a)(12) of the Act and codification of certain of our current Medicare FFS payment policies for medically necessary dental services; (2) Medicare Parts A and B payment for dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures effective CY 2023; (3) for CY 2024, Medicare Parts A and B payment for dental services, such as dental examinations, including necessary treatments, performed as part of a comprehensive workup prior to the treatment for head and neck cancers which we indicated we may consider finalizing based on comments received on the proposed rule; (4) the establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services, which we indicated we may consider finalizing in this CY 2023 final rule.

In the proposed rule, we noted that if we were to finalize, as discussed in section II.L.2.c.(i) of this final rule, payment in other clinical scenarios for dental services inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we could adjust our estimates that were included in the proposed rule. As such, we are revising our estimated impact analysis to include scenarios where Medicare Parts A and B would provide payment for dental services prior to the treatment for head and neck cancers in CY 2024. This is in addition to the proposals, as discussed in section II.L.2 of the proposed rule, to clarify and codify certain of our current Medicare FFS payment policies for medically necessary dental services that are not subject to the payment preclusion under section 1862(a)(12) of the Act, and to establish additional clinical scenarios under which Medicare payment for dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup and certain diagnostic and treatment services prior to certain medical services such as organ transplant surgery, cardiac valve replacement, or valvuloplasty procedures beginning in CY 2023.

To complete this analysis, and to ensure that we captured dental services that occurred prior to the covered medical service that occurred within CY 2019, we pulled claims data for which Medicare made payment for dental services from June 1, 2018 through December 31, 2019. This allowed us to capture any dental services that were furnished prior to 90 days of a covered medical service and also allowed us to mirror the claims data range that was utilized in the proposed rule estimate. Further, we believed that the use of

these claims data would be more representative of future utilization patterns given the COVID–19 PHE. Based on this analysis, we estimated that there were roughly 190,000 additional services where Medicare could provide payment for dental services prior to organ transplants, cardiac valve replacement, valvuloplasty procedures beginning in CY 2023, and an additional 29,000 services to accommodate the final policy to provide payment for dental services prior to the treatment for head and neck cancers. This represents a total of 219,000 additional services beginning in CY 2024. Based on claims data from this time period, the average cost of care remained the same between the proposed and final rule estimates. Our claims data showed that Medicare provided payment for dental services for 186 patients with an average cost of care of roughly $525 per person. The majority of these claims were for tooth extraction in patients undergoing radiation treatment of the mouth as opposed to transplant patients, and the range in costs was from $33 to $5,711 per patient. Based on a review of claims data for our existing payment policies and our review of current utilization for beneficiaries, we estimated that the effective rate of coverage of current utilization was less than 0.2 percent. We acknowledge that the actual take-up rate of services could be higher due to the clarification and codification of current policy, which may raise awareness that payment is available. Because of this, we also created impact estimates under the utilization assumptions of 0.2 percent and between 1–3 percent. We then applied these utilization ratios to estimate projected payments for dental exams and treatments prior to organ transplants, cardiac valve replacement, valvuloplasty procedures and treatments for head and neck cancers. We found that the estimated yearly impact beginning in CY 2024 to be roughly $230,000 per year with a 0.2 percent utilization assumption, and roughly $1–3 million per year adjusting for the utilization assumptions of 1–3 percent. This represents an increase from CY 2023 to CY 2024 of roughly $30,000–450,000 for the inclusion payment for dental services prior to head and neck cancers beginning in CY 2024 when applying the utilization assumptions of 0.2, 1, 2, and 3 percent. Therefore, we do not anticipate a significant payment impact for these provisions.

We received public comments, which were discussed earlier in this final rule, on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup and certain diagnostic and treatment services prior to organ transplant surgery, prior to cardiac valve replacement, valvuloplasty procedures or the treatment for head and neck cancers, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services; and other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services. In response to our request for information, we received comments on the types of data sources for establishing Medicare payments for these services, the request to consult with medical and dental professional interested parties, the request to produce an impact analysis that is reproducible, and also detail on potential savings for the Medicare program. We thank commenters for the information they provided in response to this request for information and we will continue to contemplate the suggestions as we consider potential future rulemaking. As we receive additional data, we will strive to ensure that such evaluations will be comprehensive and include further information on the rationale and details used to conduct such determinations. Lastly, we will continue to review the comments we received in response to our request for information on the other provisions discussed in section II.L.2 of the proposed rule.

We also received several comments requesting clarification on whether the estimated payment impact of these proposals would be incorporated into the budget neutrality adjustments to the conversion factor. Because we proposed to codify and update existing Medicare payment policies, these estimates were not incorporated in the budget neutrality adjustments to the conversation factor. Additionally, while the impact of access to these services to some individuals enrolled in Medicare may be very significant, we continue to not anticipate significant impact in the context of overall spending and utilization under the PFS nor do we anticipate significant utilization and spending impact of these policies finalized in section II.L.2 of this final rule.

We acknowledge that the actual take-up rate of services could be higher than the utilization assumptions included within our current estimates. As discussed in the proposed rule, we remain open to adjusting any finalized policy through future rulemaking, and conducting further impact analysis while also providing an opportunity for public comment on such analysis once we have additional data. We continue to be open to conducting further impact analysis once we have additional data and input from interested parties.

16. Updates to the Quality Payment Program

In this section, we estimate the overall and incremental impacts due to the Quality Payment Program policies finalized in this rule. We estimate participation, final scores, and payment adjustment for clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also present the incremental impacts to the number of expected QPs and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall MIPS Modeling Approach and Data Assessment

(1) Updating the MIPS Model

In the CY 2023 PFS proposed rule (87 FR 46407 through 46408), we noted that we created two MIPS RIA models: a baseline and proposed policies RIA model. The aim of the baseline model is to reflect participation, final scores, and payment adjustments for the CY 2023 performance period/2025 MIPS payment year based on previously finalized policies for the CY 2023 performance period/CY 2025 MIPS payment year. Examples of previously finalized policies are an increase in the APM qualified participants threshold and the removal of the additional MIPS payment adjustment for exceptional performance and additional performance threshold. The finalized policies model builds off the baseline model and incorporates the MIPS policy provisions for the CY 2023 performance period/2025 MIPS payment year included in this rule. The aim of the baseline and final policy models is to estimate the incremental impacts of the policies in this final rule. There were two major updates to the modeling approach used in this RIA for the baseline and final policy model compared to the CY 2022 PFS final rule (87 FR 4606 through 46407).

First, we changed the MIPS modeling tool that we used in order to incorporate the same scoring engine as the one used to determine actual MIPS payment adjustments. We generally applied the same assumptions as our previous RIA analyses, but this update ensures that

the clinician population and final scores in our model align as much as possible with actual MIPS scoring and minimizes differences between projections and policy implementation. It should be noted, data limitations and assumptions which may impact model results still remain and are described later in this section of the RIA.

Second, we modeled participation, scoring, and payment adjustments for the MIPS Value Pathways (MVPs). The CY 2023 performance period/2025 MIPS payment year is the first year where clinicians can voluntarily submit MVPs. Although we are modeling MVPs, we are not modeling subgroup reporting. A more detailed discussion of the approach used to model MVPs can be found in section VII.E.16.d.(2) of this RIA.

For this final rule, we replaced the ''proposed policies model'' with the ''final policies model'' and as we discuss in the following sections, we updated the methodology to reflect data submitted in the 2021 MIPS performance period.

(2) Assessing Which Data To Use To Estimate Future MIPS Performance

In the 2023 PFS proposed rule (87 FR 46407), we discussed our decision to use 2019 MIPS performance period submissions to estimate eligibility and scoring. We noted that we assessed the use of 2020 performance period submissions for the 2022 PFS final rule (86 FR 65637) and stated in that same rule the reasons why we believed the CY 2019 performance period submissions would be a better data source for estimating future performance for MIPS eligible clinicians. We found that the extreme and uncontrollable circumstances policy combined with the COVID–19 Public Health Emergency (PHE) limit the data's ability to simulate the future MIPS eligible population and associated performance using 2020 data.

In the 2023 PFS proposed rule (87 FR 46407), we stated the CY 2021 performance period submissions data were not available in time to assess whether the data can be used to predict future performance. We also stated that in this final rule we would evaluate whether it is appropriate to use the CY 2021 performance period data and what, if any, adjustments would need to be made in order to use that data.

After review of the finalized CY 2021 performance period submissions data, we believe that it is appropriate to use CY 2021 performance period data to estimate eligibility, final scores and payment adjustments for the CY 2023 performance period with some exceptions described below. First, in the CY 2023 PFS proposed rule (87 FR 46411) we used cost measure testing files from prior to 2019 to estimate the cost performance category scores since several of the cost measures that we modeled were either revised or established after the 2019 performance period. For example, the Medicare Spending Per Beneficiary measure was proposed with modified specifications in the CY 2020 performance period. These measures were not part of the 2019 MIPS production system, which we used to model performance, and so we had to rely on measure testing files which often including data older than 2019 to model these measures. These data are not as current as 2021 data which may model the cost performance category more accurately. Second, the performance threshold for the CY 2019 performance period was 30 points, while the performance threshold was 60 points for the CY 2021 performance period. The CY 2021 performance threshold of 60 points is closer to our modeled performance threshold of 75 points and, therefore, more accurately reflects clinician behavior. Third, using data from 2021 allows us to more accurately estimate the Promoting Interoperability performance category score. In CY 2021 PFS final rule (85 FR 84819), we finalized two options for meeting the Promoting Interoperability Health Information Exchange Objective: (1) Support Electronic Referral Loops by Sending Health Information measure and Support Electronic Referral Loops by Receiving and Reconciling Health Information measure; and (2) Health Information Exchange Bi-Directional Exchange measure. The CY 2021 performance period submission data were the first data which included the Bi-Directional Exchange measure. Finally, the 2021 data is more recent and therefore is more likely to be reflective of current reporting patterns among clinicians and groups.

While we believe that the 2021 data is the best data source for the RIA model, we recognize that 2021 data has some limitations similar to those of the 2020 data. For instance, both 2020 and 2021 data were from years that occurred during the PHE and may reflect practice and billing patterns that differ from the usual practices of clinicians. We also recognize the 2021 cost measure data, which we discuss in section VII.E.16.d.3.(b) of this final rule, may still be impacted by the PHE for some MIPS eligible clinicians but we believe that it is still useful for modeling cost trends in the overall population of MIPS eligible clinicians. Another limitation of using 2021 data is that we are not able to estimate facility-based scores because there are no Hospital Value-Based Purchasing total performance scores calculated due the PHE.

Due to the CY 2021 performance period PHE extreme and uncontrollable circumstances policy, some MIPS eligible clinicians may not have submitted data for MIPS for the CY 2021 performance period when they otherwise would have. To address this, we supplemented the CY 2021 performance period data with CY 2019 performance period data to more accurately model participation for the 2021 performance period. We further discuss this decision in section VII.E.16.c.2.(a) of this final rule.

b. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2024, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs in the applicable QP Performance Period for a year and the corresponding payment year. These QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician will be subject to the MIPS reporting

requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. In addition, MIPS eligible clinicians will receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B covered professional services in a payment year based on performance during a prior performance period.

We incorporated this change into our baseline eligibility determination. In addition, the thresholds to achieve QP status beginning in the 2023 QP Performance Period will increase to 75 percent for payment amount, and 50 percent for patient count. Overall, we estimate that for the 2023 QP Performance Period between 144,700 and 186,000 eligible clinicians will become QPs, and therefore be excluded from MIPS.

In section VII.E.17.a. of this final rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2023 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2023 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2023 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Kidney Care First; Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- Primary Care First (PCF) Model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 81 FR 77444 and 77445 for information on the APM Participant Lists and QP determinations) on the 2021 third snapshot participation file to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2023 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Estimated Number of Clinicians Eligible for MIPS for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

For this final rule, we updated the data sources for this RIA with the more recent 2021 submissions and associated eligibility data and applied the same assumptions as the CY 2023 PFS proposed rule (87 FR 46409 through 46410) unless otherwise noted below. As discussed in section VII.E16.c.2.(a) of this final rule, we made some engagement assumption modifications to mitigate the effect of potential non-engagement due to the extreme and uncontrollable circumstances policies related to the PHE. We use the terms ''engaged'' to refer to clinicians who submitted data to MIPS. The following paragraphs highlight the key assumptions and data updates.

We used the final reconciled eligibility determination file that aligned with the 2021 performance period submission data. In the CY 2023 PFS proposed rule (87 FR 46408), we noted that using the reconciled eligibility determination file was a change from our assumptions used in the CY 2022 PFS final rule RIA model (86 FR 65642). In the CY 2022 PFS final rule RIA model, we used a combination of data from the first determination period for the 2020 MIPS performance period and data from the end of calendar year 2019 to be paired with 2019 performance period submissions. We noted that we used the determination period from the CY MIPS performance period eligibility file because it was the most recent eligibility file available. However, we also stated that as we updated our model for CY 2023 PFS proposed rule (87 FR 46408), we believed that using the final eligibility file from the CY 2021 MIPS submission data period, which reconciles information from two eligibility determination periods, would be a better data source to pair with our performance period submission data and so we used the final reconciled 2019 eligibility determination file which aligned with the 2019 performance period submission data. Similarly, in this final rule we used the final reconciled 2021 eligibility determination file which aligns with 2021 performance period submissions data.

We did not propose any modifications to MIPS eligibility, therefore the same eligibility assumptions apply to both the baseline and final policies models. Our analysis found that 1.7 million clinicians who had PFS claims from October 1, 2020 to September 30, 2021 as well as additional clinicians associated with a group who had at least one PFS claim from October 1, 2021 through December 31, 2021.

(2) Estimation of MIPS Eligible Clinicians After Applying Assumptions Related To Applying the Low-Volume Threshold Exclusion and Considering the Extreme and Uncontrollable Circumstances Policies Related to COVID–19 PHE.

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted to MIPS. A clinician or group that exceeds at least one, but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby being measured on performance and receiving a MIPS payment adjustment.

We describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.7 million clinicians for the final policies model. We applied the same assumptions presented in the CY 2022 PFS final rule (86 FR 65617 through 65660) to apply the low-volume threshold and to determine whether clinicians participate as a group, virtual group, APM entity, or as individuals, but we made an additional adjustment to recognize the automatic extreme and uncontrollable circumstances policy that applied due to the PHE.

(a) Adjustments to Required Eligibility Engagement Assumptions To Account for the PHE

Clinicians who exceed the low-volume threshold as individuals and individuals in an approved virtual group are categorized as ''required eligibility'' because these clinicians are MIPS eligible regardless of whether they participate in MIPS or not. In the CY 2023 PFS proposed rule (87 FR 46409), we separated these MIPS eligible clinicians into ''Engaged'' and ''Did not Engage'' based on whether they submitted data in the CY 2019 performance period.

We are concerned, however, in moving to 2021 submissions data, that we may be overestimating the number of clinicians with ''required eligibility'' and who do not participate in MIPS since some MIPS eligible clinicians may not have submitted data due to the PHE. As discussed in section VII.E.16.c.2.(a) of this final rule, CMS applied the automatic extreme and uncontrollable circumstances (EUC) reweighting policy for the CY 2021 MIPS performance period due to the PHE. One effect of the automatic EUC policy is that individuals who are MIPS eligible in the CY 2021 MIPS performance period but do not submit data would have their performance categories reweighted and receive a final score equal to the performance threshold for the CY 2021 MIPS performance period/2023 MIPS payment year. These MIPS eligible clinicians would not receive a negative payment adjustment if they did not engage in the CY 2021 performance period, but they would receive a negative payment adjustment in our simulation of the CY 2023 performance period. Therefore, to mitigate the potential effect of the PHE on engagement estimates for the CY 2023 performance period, for MIPS eligible clinicians who submitted data for the CY 2019 performance period and did not submit data for the CY 2021 performance period we assigned their participation status and final score data from the CY 2023 PFS proposed rule baseline model (87 FR 46408). This is because the CY 2023 PFS proposed rule baseline model (87 FR 46408) is based on 2019 submissions data and is hereafter called ''2019 data supplement.''

We chose to use the 2019 data supplement instead of the CY 2023 PFS proposed rule policies model scores since the baseline policies are consistent between the proposal rule and this final rule and a baseline model is used in both rules. We believed these clinicians may participate and perform more similarly to the CY 2019 performance period than the CY 2021 performance period during the CY 2023 performance period. We assumed MIPS eligible clinicians that did not participate in either 2021 or in 2019 would not participate in 2023.

We do not have ability to assess the 2019 data supplement clinicians on performance in our model, so we used the final score from the CY 2023 PFS proposed rule baseline model and used that same score for this final rule's baseline and final policies models. Because we used the same score for the baseline and final policies model, we were not able to assess the incremental impact of policies for this group. However, we believe making this adjustment is valuable because it helps mitigate the potential effect of overestimating the required eligibility/non-participants which in turn would affect the MIPS redistribution payment.

We have therefore separated the ''required eligibility'' into three buckets this year: (1) ''Engaged in MIPS''; (2) ''Did not engage in 2021 did engage in 2019''; and (3) ''Did not engage in either 2021 or 2019'' so that we can isolate both the effects of our final policies which are modeled using 2021 data, the effect of the 2019 data supplement, and model the population of clinicians who did not engage in either year. The year refers to which population of data we used (ie the 2021 population of clinicians or the 2019 supplement).

(b) MIPS Eligibility Estimates

Table 154 summarizes our eligibility estimates for the proposed policies model after applying our assumptions.

We estimate approximately 120,887 MIPS eligible clinicians have required eligibility and engage in MIPS in 2019 and 2021, 17,529 MIPS eligible clinicians who did not engage in MIPS based on 2021 MIPS data but did engage based on 2019 MIPS data, and 10,885 MIPS eligible clinicians who did not engage in MIPS in either year. Additionally, 2,483 clinicians did not engage in 2021 and did not have data from 2019. These clinicians are counted in our model as ''did not engage in 2019 or 2021''.

We estimate approximately 560,211 MIPS eligible clinicians as having ''group eligibility'' in Table 154. These clinicians belong to a group that meets the low-volume threshold. If they were not associated with the group submission, these clinicians will not be eligible for MIPS.

Finally, we estimate about 7,442 clinicians will be eligible and participate through ''opt-in eligibility'' through the ''opt-in'' policy. We updated our opt-in policy to reflect that a clinician can elect to opt-in into MIPS and will be scored even if they do not submit data to MIPS. We estimate that about 79 clinicians will opt-in to the program but not engage.

We estimate a total MIPS eligible clinician population of approximately 719,516 with $56 billion PFS allowed charges estimated to be included in the CY 2023 performance period/2025 MIPS payment year.

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TABLE 154: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the CY 2023 PFS Final Rule Assumptions**

		CY 2023 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians**	**Number of Clinicians**	**PFS allowed charges ($ in mil)*** **
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Engaged in MIPS *	120,887	32,372
	Did not engage in 2021 but engaged in 2019	17,529	5,120
	Did not engage in 2021 and did not engage 2019 (or did not have data in 2019)*	13,368	3,499
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	560,211	14,633
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Engaged in MIPS	7,442	$417
	Do not engage in MIPS	79	$4
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**719,516**	**$56,045**
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	475,882	$11,990
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	98,909	$657
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	403,980	$18,506
Total Number of Clinicians Not MIPS Eligible		**978,771**	**$31,153**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,698,287**	**$87,198**

* Engaged means submitting data to MIPS. Participation excludes facility-based clinicians who do not have scores in the 2021 MIPS submission data.

**The 2,483 clinicians who did not engage in 2021 and were not present in 2019 data are included in this category

*** Allowed charges estimated in 2021 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

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Furthermore, we estimate there will be approximately 475,882 clinicians who are not MIPS eligible, but could be if the clinician or their group elects to opt-in. We describe this group as ''Potentially MIPS eligible'' in Table 154. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1,195,398-clinicians. Finally, we estimate approximately 98,909 clinicians will not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 403,980 will not be MIPS eligible because they are categorically excluded

regardless of volume or submission activity.

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we use the estimated population of 719,516 MIPS eligible clinicians described above.

d. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Summary of Approach for MVPs and Traditional MPS

In sections IV.A.3.a. through IV.A.3.F. of this final rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.E.16.d.(3) of this RIA as we describe our methodology to estimate MIPS payments for the CY 2023 performance period/2025 MIPS payment year. We then present the impact of the overall final policies on the CY 2023 performance period/2025 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2023 performance period/2025 MIPS payment year. By comparing the baseline model to the final policies model, we are able to estimate the incremental impact of the final policies for the CY 2023 performance period/2025 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, and MIPS eligible clinicians can participate as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway or through an MVP in the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity but are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. The average percentage change in total revenues that clinicians earn is less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that will not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact for MIPS Value Pathways

In the 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MVPs beginning in the CY 2023 performance period/2025 MIPS payment year. In updating our MIPS RIA model, we have made some assumptions for both the baseline and final policies model to simulate MVP participants and their MVP final score which are described in the following sections.

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup or APM entity) to register prior to submitting an MVP. As we do not yet have information on who will register, we assume for purposes of this model, that MVP Participants are individual clinicians or groups that currently submit at least four quality measures that are in an MVP. For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the scoring hierarchy as finalized in the CY 2022 PFS final rule 86 FR 65537). For the baseline model, we looked for the quality measures finalized for MVPs in the CY 2022 PFS final rule (86 FR 65441 through 65443):

- Advancing Rheumatology Patient Care
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes
- Advancing Care for Heart Disease MVP
- Optimizing Chronic Disease Management MVP
- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine
- Improving Care for Lower Extremity Joint Repair
- Patient Safety and Support of Positive Experiences with Anesthesia MVP

For the final policies model, we incorporate the quality measure revisions for the above MVPs and use the quality measures to model scores for the new MVPs in Appendix X of this final rule:

- Advancing Cancer Care
- Optimal Care for Kidney Health
- Optimal Care for Neurological Conditions
- Supportive Care for Cognitive-Based Neurological Conditions
- Promoting Wellness

Our MVP Participant assumptions have limitations: we are not incorporating subgroups due to lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption, but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to rules finalized in § 414.1365(d) and § 414.1365(e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2021 performance period (upon which our model is based.) Therefore, we scored any improvement activities the MVP Participants submitted in 2021 as if those improvement activities are in the MVP inventory.

(3) Methodology To Assess Impact For Traditional MIPS

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the CY 2021 MIPS performance period submissions data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories. As discussed in section VII.E.16.c.2.(a) of this final rule, we supplemented with 2019 data supplement.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2023 performance period/2025 MIPS payment year for the baseline and final policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where each are described in detail in the following sections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2022 PFS final rule (86 FR 65642 through 65643) for the baseline and final policies RIA models for the CY 2023 performance period/2025 MIPS payment year.

To create the baseline policies RIA model, which does not reflect the policies finalized in this rule, we made the following modifications to the CY 2022 PFS final rule final policies model to reflect the previously finalized quality performance category policies for the CY 2023 performance period/2025 MIPS payment year:

- As discussed in the CY 2022 PFS final rule (86 FR 65440), we finalized the removal of Web Interface measures after the CY 2022 performance period/2024 MIPS payment year for groups and virtual groups using the existing 10 CMS Web Interface measures. To estimate a quality performance category score for clinicians in groups who previously used the CMS Web Interface as a collection type in 2021, we assumed these groups will use the other two other collection types (MIPS CQMs and eCQMs) available in the CY 2023 performance period/2025 MIPS payment year. We then applied the same methodology described in the CY 2021 PFS proposed rule where we discussed the removal of Web Interface as a collection type (85 FR 50387 through 50388).
- As discussed in the CY 2022 PFS final rule (86 FR 65497 through 65498), we finalized removing the 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points starting with the CY 2023 performance period/2025 MIPS payment year. Due to technical limitation we were previously not able to simulate the removal of the special scoring policy of scoring 3 points for class 2 measures for clinicians not in a small practices beginning with the CY 2023 performance period/2025 MIPS payment year in the 2023 PFS Proposed Rule (87 FR 46411). In this final rule, we were able to incorporate the removal of this scoring policy.
- In the CY 2022 PFS final rule (86 FR 65429), we also finalized extending the use of the CMS Web Interface as a reporting option under the APM Performance Pathway into the CY 2024 performance period/2026 MIPS payment year. Under this policy, for the CY 2023 performance period/2025 MIPS payment year, Web Interface reporting would work in the same manner as for the CY 2021 performance period/2023 MIPS payment year, where ACOs would have the option of reporting either the CMS Web Interface or the APP eCQM/MIPS CQM measure set. In integrating the 2021 data, we assumed that ACOs that submitted Web Interface in 2021 would continue to submit Web Interface in 2023 and that ACOs that submitted the APP eCQM/MIPS measures set in 2021 would continue to do so in 2023 and scored the quality performance category based on the way they submitted their quality data.
- Similar to the CY 2022 PFS final rule model (86 FR 65642), we utilized the most recent benchmark file: the CY 2021 MIPS performance period historical benchmarks; however for this baseline model, we calculated a performance period benchmark if a historical benchmark was not available.

For the final policies model, we made the following modifications to the baseline model to reflect the quality performance category policies for the CY 2023 performance period/2025 MIPS payment year:

- As discussed in section IV.A.10.d.(1)(b)(i) of this final rule, we will score administrative claims quality measures using a benchmark calculated from the performance period data. To simulate this policy in our proposed policies model, we used CY 2021 performance period data to score administrative claims measures.
- In Appendix 1 of this final rule, we added 9 new MIPS quality measures, removed 15 MIPS quality measures, partially removed 2 MIPS quality measures that will be removed from traditional MIPS and retained for use in MVPs, and substantially modified 75 MIPS quality measures. Consistent with prior rules, (83 FR 50053), our RIA estimates assume that clinicians who reported Medicare Part B claims, eCQM, MIPS CQM and QCDR measures that are removed would find alternate measures; therefore, we assign points to the measures that were submitted and included them in our scoring model.
- In Appendix A, we included one new administrative claims measure, Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System, for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities that include at least one cardiologist. We included the test data for this measure into our model.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2022 PFS final rule (86 FR 65643) for the baseline and the final policies RIA models. However, we updated the data source to use the cost measures calculated for the CY 2021 MIPS performance period.

The baseline policies RIA model used the same methodology as the final policies model in the CY 2022 PFS final rule (86 FR 65643) since there are no previously finalized cost performance category policies that will apply beginning with the CY 2023 MIPS performance period.

In section IV.A.10.c.(2)(b) of this final rule, we revise the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group. This recategorization of the MSPB measure does not affect the scoring of the cost performance category. Additionally, in section IV.A.10.d.(1)(c)(i) of this final rule, we establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year. Due to data limitations, we do not have multiple years of cost measures to model improvement scoring. Therefore, we did not make any modifications between the final policies and baseline model for the cost performance category scoring.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As discussed in section VII.E.16.c.2.(a) of this final rule, a limitation of using 2021 data is that we are not able to estimate facility-based scores because there are no Hospital Value-Based Purchasing total performance scores calculated due the COVID–19 PHE. However, for clinicians who did not participate in 2021, we did use the 2019 data supplement to identify final scores based on 2019 performance period submission and these scores include facility-based scores.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

For the CY 2023 PFS final rule baseline RIA model, we are using the CY 2021 Promoting Interoperability performance period submissions data to estimate CY 2023 performance for the Promoting Interoperability performance category. By using the 2021 performance period submissions data, we were able incorporate the Health Information Exchange bi-directional exchange

measure option into the Health Information Exchange objective. We did not make additional modifications to the Promoting Interoperability performance category baseline RIA model beyond what we finalized in the CY 2022 final rule (86 FR 64996).

For the final policies model, we considered the following policy provisions as potential modifications to the baseline RIA model:

- Require and modify the Query of PDMP measure for MIPS eligible clinicians participating in the Promoting Interoperability performance category and maintain the associated points at 10 points.
- Expand the Query of PDMP measure to include not only Schedule II opioids but also Schedule III, and IV drugs.
- Change the scoring for the e-Prescribing measure to 10 points available and the maximum total points available for the Electronic Prescribing Objective will remain at 20 points for CY 2023.
- Adding Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure as an optional alternative measure in the Health Information Exchange (HIE) objective.
- Modify the scoring methodology for the Promoting Interoperability performance category. We refer readers to section IV.A.6.c.(4)(g) of this final rule and Table 155: Scoring Methodology for the Performance Period in CY 2023 of this final rule for further information on the scoring.
- Consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective
- Removing the automatic reweighting of NPs, PAs, CRNAs, or CNSs.

Due to limitations in our scoring engine-based model, we are unable to fully incorporate all of these changes into the final policies model. We incorporated into the model the modification to the scoring methodology for the Promoting Interoperability performance category and the removal of the automatic reweighting of NPs, PAs, CRNAs, and CNSs. Due to the high submission rate for the optional Query of PDMP measure and the expansion of the availability of PDMPs in all 50 States and several localities, we anticipate that clinicians who do not currently submit this newly required measure will now submit the measure or submit one of the associated exclusions. Because we lack CY 2021 MIPS submissions data for the Enabling Exchange Under TEFCA measure, we only used past reporting on the existing Health Information Exchange Objective measures and the Health Information Exchange Bi-directional exchange measure to estimate CY 2023 Promoting Interoperability performance for the final policies model.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we modeled the improvement activities performance category score based on CY 2021 performance period data and APM participation identified in section IV.A.10.d.(1)(c)(i) of this final rule. For clinicians and groups not participating in a MIPS APM, we used their CY 2021 improvement activities score. Using the CY 2021 performance period data, we are not able to incorporate the policy finalized in the CY 2020 performance period (84 FR 62980) to require a minimum threshold of 50 percent of clinicians in a group to complete an improvement activity for the group to receive credit. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section VII.F.17.c.(1) of this final rule, we assigned an improvement activity performance category score of 100 percent.

(f) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996). We calculated and applied the separate risk indicator complex patient bonus components methodology with a single overall cap described at section IV.A.10.d.(2)(a) of this final rule. In section IV.A.10.d.(2)(a)(ii) of this final rule, we allow facility-based clinicians to receive a complex patient bonus. As discussed in section VII.E.16.c.2.(a) of this final rule, we are not able to incorporate this provision because, generally, we do not have data for facility-based clinicians.

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and final policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2022 PFS final rule (86 FR 65519 through 65524).

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and final policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold finalized in the 2022 PFS final rule (86 FR 65527) of 75 points finalized at § 414.1405. For the final policies model, we applied the performance threshold of 75 points finalized in section IV.A.10.e.(2) of this final rule. We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Impact of Payments by Practice Size

We noticed minimal changes to the mean and median final score between our baseline and final policies model. In our baseline model, the mean and median final scores are 77.78 and 79.45 points, respectively. In the final policies model, the mean final score is 77.68 and the median final score is 79.98. Many clinicians are only slightly above or slightly below the performance threshold. For instance, in the final policies model, 176,512 clinicians have a final score between 70 and 80 points. We recognize that, because many scores are clustered around the performance threshold of 75, any variation in scoring

or submissions data can have a significant impact on the proportion of clinicians receiving a positive or a negative payment adjustment.

Between the baseline and final policies model we observe little difference in the percentage and distribution of clinicians receiving a negative payment adjustment. Overall, we project 63.34 percent of engaged clinicians [576] would receive a positive or neutral adjustment in our final policies model compared to 62.56 percent in the baseline model.

In this model, we no longer observe large differences in payment adjustments by practice size. All practices sizes saw either minimal change or a modest increase in the percentage of clinicians receiving either a positive or neutral adjustment.

Because many clinicians scores are close to the performance threshold, many of these clinician's payment adjustments are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. In our final policies model, we project a payment adjustment of negative 9 percent for clinicians with a score of 18 points.

[576] We define engaged MIPS clinicians as those who have submitted data for at least one MIPS performance category.

In our baseline model, the average positive payment adjustment among engaged clinicians is 3.78 percent and the average negative payment adjustment is −1.79 percent. In our final policies model, the average positive payment adjustment among engaged clinicians is 3.71 percent and the average negative payment adjustment among engaged clinicians is −1.84 percent. Only 8.46 percent of clinicians receive a score of less than 50 points and therefore a negative payment adjustment of more than 3 percent.

Because there is only a slight difference in the proportion of clinicians receiving a negative payment adjustment between the final policies and baseline model, we anticipate only a modest change in the amount of funds redistributed due to budget neutrality (from $699 million to $698 million) and a modest change in the maximum positive payment adjustment from 6.10 percent in the baseline to 6.09 percent in the final policies model.

We want to highlight we are primarily using CY 2021 performance period submissions data to simulate a CY 2023 performance period final score, and it is likely that there will be changes that we cannot account for at this time. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2023 performance period/2025 MIPS payment year. This is because the PHE may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for the CY 2019 and 2021 performance periods. Therefore, engagement levels in MIPS for the CY 2023 performance period/2025 MIPS payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the CY 2021 performance period/2023 MIPS payment year, which is associated with a performance threshold of 60 points, and that participation may change since the finalized performance threshold is 75 points.

Finally, the combined impact of negative and positive adjustments as a percent of allowed charges among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS.

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TABLE 155: Estimated CY 2023 Performance Period/2025 MIPS Payment Year Impact on Total Estimated Allowed Charges by Participation Status and Practice Size

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments as Percent of Allowed Charges**
Final policy model among engaged clinicians ***				
1) Solo	10,417	55.64	44.36	0.52%
2) 2-15	67,940	65.21	34.79	1.42%
3) 16-99	461,769	66.61	33.39	1.04%
4) 100+	147,824	56.55	43.45	2.25%
Overall	**687,950**	**64.14**	35.86	1.64%
Finalized policy model among clinicians who did not engage in 2021 but engaged in 2019****				
1) Solo	3,800	32.79	67.21	*****
2) 2-15	7,145	35.63	64.37	*****
3) 16-99	1,466	35.27	64.73	*****
4) 100+	5,196	25.92	74.08	*****
Overall	**17,607**	**32.12**	**67.88**	*****
Finalized policy model among non-engaged clinicians who did not engage in 2021 or 2019****				
1) Solo	4,585	0.00	100.00	-9.00%
2) 2-15	4,307	0.00	100.00	-9.00%
3) 16-99	637	0.00	100.00	-9.00%
4) 100+	1,563	0.00	100.00	-9.00%
Overall	11,092	0.00	100.00	-9.00%

*Practice size is the total number of TIN/NPIs in a TIN.

**The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size. Negative payment adjustments fund positive adjustments through the budget neutral pool.

*** 2021 used to estimate CY 2023 performance period/2025 MIPS payment year payment adjustments. Payment estimates trended to 2025 dollars.

**** 2023 proposed rule baseline model (which was based on 2019 submission), if available, is used to estimate CY 2023 performance period/2025 MIPS payment year payment adjustments. We count clinicians who did not engage in 2021 and who are not present in 2019 data as not engaging in either year.

*****. Payment adjustments are not reported for our 2019 supplement population because the payment adjustments were calculated using our 2021 population

TABLE 156: CY 2023 Performance Period/2025 MIPS Payment Year Impact on Total Estimated Allowed Charges among Clinicians Who Submit Data by Practice Size for the Baseline and Final Policies Models****

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments as Percent Allowed Charges***
Baseline model among clinicians who engage with MIPS **				
1) Solo	10,417	55.39%	44.61%	0.50%
2) 2-15	67,932	65.03%	34.97%	1.41%
3) 16-99	147,832	56.64%	43.36%	1.10%
4) 100+	461,769	64.26%	35.74%	2.22%
Overall	687,950	62.56%	37.44%	1.64%
Final **policies model among clinicians who** engage **with MIPS****				
1) Solo	10,417	56.38%	43.62%	0.52%
2) 2-15	67,932	66.04%	33.96%	1.42%
3) 16-99	147,832	56.78%	43.22%	1.04%
4) 100+	461,769	65.21%	34.79%	2.25%
Overall	687,950	63.35%	36.65%	1.64%

*Practice size is the total number of TIN/NPIs in a TIN.

**2021 and 2019 data used to estimate CY 2023 performance period /2025 MIPS payment adjustments. Payment estimates trended to 2025 dollars.

***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we finalized several policies that have an impact on burden in the CY 2023 performance period/2025 MIPS payment year. In section VII.E.16.e. of this final rule, we outline estimates of the costs of data collection that includes both the effect of finalized policy updates and adjustments due to the use of updated data sources. For each provision included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 157. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 157: Incremental Burden from Associated Finalized Policies

Burden Description and associated finalized provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2022 PFS final rule into the CY 2023 performance period/2025 MIPS payment year (as discussed in section V.B.9.p of this final rule).	714,352	$76,092,343
Burden change for MVP registration ICR due to the provision of additional MVPs (as discussed in section V.B.9.e.(7)(a)(i) of this final rule). *	+321	+$31,597
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.9.e.(4) of this final rule). *	-4,757	-$503,424
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.9.e.(5) of this final rule). *	-3,697	-$400,072
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.9.e.(6) of this final rule). *	-4,344	-$475,787
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (as discussed in section V.B.9.e.(7)(a)(iii) of this final rule). *	+8,468	+$912,778
Burden change for Promoting Interoperability Submission ICR due to the requirement for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective (as discussed in section V.B.9.g.(3) of this final rule).	+301	+$29,695
Total change in burden due to policy for CY 2023	-3,708	-$405,213
Total burden set forth in the CY 2023 PFS final rule	710,644	$75,687,130

* The total change in burden due to this provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the finalized addition of 5 new MVPs. Therefore, there will be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.9.e.(7)(a)(i) of this final rule.

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(2) Additional Impacts to Clinicians

(a) MVP Maintenance and Development Process

In section IV.A.8.a. of this rule, we finalized the proposed updates to the previously finalized policies for the MVP development and maintenance process in the CY 2021 and 2022 PFS final rules (85 FR 84849 through 84856 and 86 FR 65410). Specifically, we finalized the proposal to modify the MVP development process such that we will evaluate a submitted candidate MVP through the MVP development process and if we determine it is ''ready'' for feedback, we will post a draft version of the MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. Interested parties and the general public will have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We will review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we will not notify the interested party who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process.

We also finalized that beginning with the CY 2023 performance period/2025 MIPS payment year, to modify the MVP maintenance process such that interested parties and the general public will be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We will then review the submitted recommendations and determine whether any are potentially feasible and appropriate. If we identify any submitted recommendations that are potentially feasible and appropriate, we will host a public facing webinar, open to interested parties and the general public, through which they may offer their feedback on the potential revisions we have identified. We will publish details related to the timing and registration process for the webinar

through our Quality Payment Program Listserv.

We acknowledge that there is administrative burden associated with the monitoring and review of the candidate MVPs. However, we are unable to estimate the impact of these policies and quantify the number of interested parties and members of the general public that will review and submit their feedback for a candidate MVP. Similarly, we are uncertain on the number of interested parties and members of the general public that will submit their recommendations for potential revisions to established MVPs for an applicable performance period and if CMS will be hosting a public webinar based on the review of the recommendations. In summary, we are unable to quantify the impact associated with the finalized changes to the MVP development and maintenance process.

(b) Subgroup Registration

In section IV.A.8.e.(3) of this rule, we finalized the proposed updates to the subgroup registration process. As part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. Under this policy, we will identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text-only field, if the options we provide do not correctly describe the subgroup. We recognize that there may be additional burden associated with the proposed description requirement for subgroup registration. However, we assume that the burden associated with choosing a key scenario will minimize the time required for subgroups to provide a narrative description. Additionally, we anticipate the narratives to be short descriptions of the nature of a group practice and appropriately reflect the subgroup composition. We are unable to quantify the additional impact for the updates to the subgroup description requirement.

(c) Impact on Third Party Intermediaries

In section IV.A.10.g.(3)(a) of this rule, we finalized the proposed revisions to the corrective action plan (CAP) requirement at § 414.1400(e)(1)(i)(B) to address the impact to any affected parties, as appropriate. We also finalized the proposed addition at § 414.1400(e)(1)(i)(E) to require the detailed communication plan for communicating the issues that contributed to the non-compliance and the impact to any affected parties, as appropriate. We anticipate administrative burden associated with the requirement for third party intermediaries to submit a detailed communication plan. Because of the relatively low number (fewer than 10 per year historically) of CAPs that we anticipate receiving from QCDRs for the CY 2023 performance period/2025 MIPS payment year, we are unable to quantify the burden associated with the development of a communication plan for third party intermediaries.

(d) Compare Tools: Public Reporting

In section IV.A.10.h.(1) of this rule, we finalized the proposal to identify clinicians who perform telehealth services using Place of Service Code 02 (indicating telehealth) on paid physician & ancillary service (that is, carrier) claims, or modifier 95 appended on paid claims. Additionally, we finalized the proposal to publicly report Medicare procedural utilization data on the Compare tool clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions. We will begin publicly reporting procedural utilization data no earlier than CY 2023. We will use a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. While the Compare tool provisions do not increase the burden of collections, we note that the PRA package may require relevant modification to reflect the Compare tool's new uses and public display.

(e) Administrative Claims Measure

As discussed in appendix 1, we finalized the proposed addition of one new administrative claims quality measure beginning in the CY 2023 performance period/2025 MIPS payment year and for future performance periods: Risk-standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there are no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(f) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.10.b of this final rule, we finalized the proposed changes to the improvement activities Inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding four new improvement activities; modifying five existing improvement activities; and removing six previously adopted improvement activities. We refer readers to Appendix 2 of this final rule for further details. We do not believe these changes to the improvement activities Inventory will significantly impact time or financial burden on interested parties because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these changes to the improvement activities Inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities under the policies in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2023 performance period/2025 MIPS payment year.

g. Assumptions & Limitations

In section VII.E.16.x of this rule, we outline several limitations in using 2021 submissions data for estimating 2023 performance. In addition, in section VII.E.16.d.(4) of this RIA we noted the limitation that, because many scores are clustered near the performance threshold of 75 points, minor variations in clinicians final scores relative to our estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment. In addition to this

limitation, we note several other limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the CY 2023 performance period/2025 MIPS payment year.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2021 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2023 performance period/2025 MIPS payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the final policies.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 154.

17. Opioid Treatment Programs: CY 2022 Methadone Payment Exception

As discussed in section V. of this final rule, the ''Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception'' interim final rule with comment period (Methadone IFC), established a limited exception to the payment methodology for methadone furnished by Opioid Treatment Programs (OTPs). Specifically, under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) was maintained at the CY 2021 rate of $37.38 on an interim final basis for the duration of CY 2022 (86 FR 66032 through 66033).

In this final rule we are finalizing the interim revisions to the regulation text at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception and to make a conforming change to the reference to 42 CFR part 414, subpart J. There are no impacts to Medicare spending in CY 2023 as a result of finalizing the interim revisions promulgated in the Methadone IFC.

F. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we proposed to exercise agency discretion, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)

As discussed in section II.B. of this final rule, ''(5) PE RVU Methodology,'' Steps 3, 10, and 18, and ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'', we hold the work RVUs constant and adjust the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the Medicare Economic Index (MEI) cost shares are updated, we would typically propose to modify steps 3 and 10 described in section II.B. of this final rule to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 described in section II.B. of this final rule. The most recent recalibration was done for the CY 2014 RVUs, when the MEI was last updated.

As an alternative to adjusting the aggregate pools of direct and indirect PE costs and using a relativity adjustment based on the current CY 2014 MEI update, we considered using the proposed rebased and revised MEI cost share weights for CY 2023, as discussed in detail in section II.M. of the proposed rule, for purposes of adjusting the RVUs to match PE share of the MEI for CY 2023. Although we did not propose to for CY 2023, we considered using the rebased and revised cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, shifting over a 4-year transition to reach the proportions of work, PE, and MP, as explained in in section II.M. of the final proposed rule.

Table 158 illustrates specialty-specific impacts if we were to use the proposed rebased and revised MEI cost share weights to adjust the RVUs to match the PE share of the MEI, as proposed in section II.M. of the proposed rule. Column C represents specialty level impacts of our provisions for CY 2023 without the recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights, shown for comparison to the alternatives considered (same impacts as shown in Table 149). Column E represents the specialty level impacts of our provisions for CY 2023 with Year 1 of a 4-year phased in recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights. Column F represents the specialty level impacts of our provisions for CY 2023 with the recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights, without a 4-year phase in, but rather, a full implementation for CY 2023. We note that, as discussed in detail in section II.M. of this final rule, the finalized rebased and revised cost share weights differ slightly from than the proposed rebased and revised cost share weights used to calculate the specialty-specific impacts in Columns E and F in Table 158 for this alternative considered.

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TABLE 158: CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty using Proposed Rebased and Revised MEI Cost Share Weights for CY 2023

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 149)	(E) Combined Impact Year 1 Proposed MEI Transition	(F) Combined Impact Full Proposed MEI Changes
Estimated Conversion Factor			**$33.0607**	**$33.642**	**$31.834**
TOTAL	***TOTAL***	$91,046	-2%	0%	0%
	Non-Facility	$61,291	-2%	-1%	2%
	Facility	$29,755	-1%	1%	-4%
ALLERGY/IMMUNOLOGY	*TOTAL*	$232	-2%	0%	5%
	Non-Facility	$224	-4%	0%	6%
	Facility	$8	-1%	-1%	-6%
ANESTHESIOLOGY	*TOTAL*	$1,743	-2%	-2%	-6%
	Non-Facility	$367	-2%	-3%	0%
	Facility	$1,376	-2%	-2%	-8%
AUDIOLOGIST	*TOTAL*	$70	-2%	1%	3%
	Non-Facility	$68	-3%	1%	3%
	Facility	$2	-2%	-1%	-4%
CARDIAC SURGERY	*TOTAL*	$197	-1%	-3%	-9%
	Non-Facility	$38	-2%	-2%	4%
	Facility	$159	1%	-3%	-12%
CARDIOLOGY	*TOTAL*	$6,310	0%	-1%	-1%
	Non-Facility	$4,641	0%	-2%	1%
	Facility	$1,669	-1%	-1%	-7%
CHIROPRACTIC	*TOTAL*	$670	-2%	0%	1%
	Non-Facility	$668	-2%	0%	1%
	Facility	$1	-2%	-1%	-3%
CLINICAL PSYCHOLOGIST	*TOTAL*	$785	-2%	-3%	-6%
	Non-Facility	$609	-2%	-3%	-5%
	Facility	$176	-2%	-3%	-8%
CLINICAL SOCIAL WORKER	*TOTAL*	$854	-2%	-3%	-6%
	Non-Facility	$656	-2%	-3%	-5%
	Facility	$198	-1%	-3%	-8%
COLON AND RECTAL SURGERY	*TOTAL*	$155	1%	-2%	-4%
	Non-Facility	$56	-1%	-1%	4%
	Facility	$100	1%	-2%	-8%
CRITICAL CARE	*TOTAL*	$352	-1%	0%	-5%
	Non-Facility	$53	-1%	-1%	2%
	Facility	$298	0%	0%	-6%
DERMATOLOGY	*TOTAL*	$3,758	7%	1%	5%
	Non-Facility	$3,622	7%	1%	5%
	Facility	$136	1%	-1%	-4%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$822	0%	5%	16%
	Non-Facility	$821	-1%	5%	16%
	Facility	$	0%	-2%	-6%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 149)	(E) Combined Impact Year 1 Proposed MEI Transition	(F) Combined Impact Full Proposed MEI Changes
Estimated Conversion Factor			**$33.0607**	**$33.642**	**$31.834**
EMERGENCY MEDICINE	*TOTAL*	$2,531	0%	-1%	-7%
	Non-Facility	$231	-1%	-1%	0%
	Facility	$2,300	2%	-1%	-8%
ENDOCRINOLOGY	*TOTAL*	$532	0%	0%	0%
	Non-Facility	$427	-1%	0%	0%
	Facility	$105	4%	2%	-4%
FAMILY PRACTICE	*TOTAL*	$5,786	-1%	0%	0%
	Non-Facility	$4,637	-1%	0%	1%
	Facility	$1,148	-1%	4%	-1%
GASTROENTEROLOGY	*TOTAL*	$1,591	0%	-1%	-3%
	Non-Facility	$604	-1%	-1%	2%
	Facility	$987	4%	-1%	-6%
GENERAL PRACTICE	*TOTAL*	$371	-2%	0%	0%
	Non-Facility	$301	-1%	-1%	1%
	Facility	$70	-2%	3%	-2%
GENERAL SURGERY	*TOTAL*	$1,760	2%	-2%	-5%
	Non-Facility	$510	0%	0%	3%
	Facility	$1,250	6%	-2%	-9%
GERIATRICS	*TOTAL*	$175	-1%	2%	1%
	Non-Facility	$98	-1%	0%	0%
	Facility	$78	0%	5%	1%
HAND SURGERY	*TOTAL*	$255	-1%	0%	1%
	Non-Facility	$135	-2%	0%	2%
	Facility	$120	1%	0%	-1%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,706	0%	-1%	1%
	Non-Facility	$1,129	0%	-1%	3%
	Facility	$577	-2%	0%	-5%
INDEPENDENT LABORATORY	*TOTAL*	$594	4%	1%	10%
	Non-Facility	$593	-2%	1%	10%
	Facility	$	6%	-2%	-6%
INFECTIOUS DISEASE	*TOTAL*	$586	3%	4%	0%
	Non-Facility	$93	-1%	-1%	2%
	Facility	$493	7%	5%	-1%
INTERNAL MEDICINE	*TOTAL*	$9,813	-2%	3%	1%
	Non-Facility	$5,051	-2%	0%	0%
	Facility	$4,761	0%	6%	1%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$925	-3%	-1%	1%
	Non-Facility	$730	-4%	-1%	3%
	Facility	$196	-1%	-1%	-5%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$465	-1%	-2%	2%
	Non-Facility	$365	-1%	-3%	5%
	Facility	$100	0%	-2%	-9%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$150	1%	0%	-2%
	Non-Facility	$76	-2%	-1%	1%
	Facility	$74	5%	0%	-5%
NEPHROLOGY	*TOTAL*	$2,023	-1%	1%	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 149)	(E) Combined Impact Year 1 Proposed MEI Transition	(F) Combined Impact Full Proposed MEI Changes
Estimated Conversion Factor			**$33.0607**	**$33.642**	**$31.834**
	Non-Facility	$1,282	-2%	-2%	-2%
	Facility	$741	1%	5%	-1%
NEUROLOGY	*TOTAL*	$1,397	-1%	-1%	-1%
	Non-Facility	$942	-1%	-1%	1%
	Facility	$455	-1%	0%	-5%
NEUROSURGERY	*TOTAL*	$727	-2%	-2%	-8%
	Non-Facility	$131	-2%	-1%	1%
	Facility	$596	3%	-2%	-10%
NUCLEAR MEDICINE	*TOTAL*	$53	-2%	-2%	0%
	Non-Facility	$50	-5%	-2%	0%
	Facility	$3	-2%	2%	-4%
NURSE ANES / ANES ASST	*TOTAL*	$1,115	1%	-2%	-8%
	Non-Facility	$25	-1%	-6%	-11%
	Facility	$1,091	5%	-2%	-8%
NURSE PRACTITIONER	*TOTAL*	$5,803	-1%	1%	0%
	Non-Facility	$3,778	-1%	0%	0%
	Facility	$2,024	-1%	4%	0%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$593	-1%	-1%	-1%
	Non-Facility	$409	-1%	0%	2%
	Facility	$183	0%	-1%	-7%
OPHTHALMOLOGY	*TOTAL*	$4,838	-1%	0%	3%
	Non-Facility	$3,447	-1%	1%	4%
	Facility	$1,391	0%	0%	0%
OPTOMETRY	*TOTAL*	$1,308	-2%	0%	4%
	Non-Facility	$1,248	-2%	1%	4%
	Facility	$60	-1%	0%	-1%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$72	-1%	-1%	3%
	Non-Facility	$61	-1%	0%	5%
	Facility	$12	-1%	-1%	-4%
ORTHOPEDIC SURGERY	*TOTAL*	$3,462	-2%	-1%	-2%
	Non-Facility	$1,563	-2%	0%	3%
	Facility	$1,900	0%	-1%	-6%
OTHER	*TOTAL*	$58	-1%	-1%	2%
	Non-Facility	$47	-1%	-1%	3%
	Facility	$11	-1%	0%	-4%
OTOLARNGOLOGY	*TOTAL*	$1,136	-1%	0%	2%
	Non-Facility	$903	-1%	0%	3%
	Facility	$233	-1%	-1%	-5%
PATHOLOGY	*TOTAL*	$1,163	0%	0%	2%
	Non-Facility	$1,138	-1%	0%	2%
	Facility	$26	3%	-1%	-6%
PEDIATRICS	*TOTAL*	$57	2%	0%	-1%
	Non-Facility	$37	-2%	0%	1%
	Facility	$20	7%	2%	-3%
PHYSICAL MEDICINE	*TOTAL*	$1,091	-1%	2%	2%
	Non-Facility	$577	-1%	-1%	2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 149)	(E) Combined Impact Year 1 Proposed MEI Transition	(F) Combined Impact Full Proposed MEI Changes
Estimated Conversion Factor			**$33.0607**	**$33.642**	**$31.834**
	Facility	$514	-2%	6%	1%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$4,991	0%	-1%	2%
	Non-Facility	$4,991	-1%	-1%	2%
	Facility	$	2%	-2%	-6%
PHYSICIAN ASSISTANT	*TOTAL*	$3,168	-1%	0%	0%
	Non-Facility	$2,101	-1%	0%	2%
	Facility	$1,067	-1%	1%	-4%
PLASTIC SURGERY	*TOTAL*	$321	-1%	0%	-2%
	Non-Facility	$142	-2%	0%	2%
	Facility	$179	0%	-1%	-4%
PODIATRY	*TOTAL*	$1,996	1%	-1%	2%
	Non-Facility	$1,778	1%	-1%	3%
	Facility	$218	2%	-1%	-4%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$77	-1%	4%	15%
	Non-Facility	$77	5%	4%	15%
PSYCHIATRY	*TOTAL*	$980	1%	1%	-1%
	Non-Facility	$526	-1%	-1%	-1%
	Facility	$454	3%	4%	-1%
PULMONARY DISEASE	*TOTAL*	$1,397	-1%	1%	-1%
	Non-Facility	$585	-1%	0%	2%
	Facility	$812	-2%	2%	-3%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,608	-2%	1%	6%
	Non-Facility	$1,539	-2%	1%	6%
	Facility	$69	-1%	-2%	-8%
RADIOLOGY	*TOTAL*	$4,712	-2%	-3%	-2%
	Non-Facility	$4,486	-2%	-3%	-1%
	Facility	$226	-1%	-2%	-8%
RHEUMATOLOGY	*TOTAL*	$546	-2%	-1%	1%
	Non-Facility	$489	-3%	-1%	2%
	Facility	$56	-2%	-1%	-6%
THORACIC SURGERY	*TOTAL*	$314	-1%	-2%	-8%
	Non-Facility	$65	-2%	-2%	4%
	Facility	$249	-1%	-3%	-11%
UROLOGY	*TOTAL*	$1,754	-3%	-1%	0%
	Non-Facility	$1,258	-4%	-1%	3%
	Facility	$497	-2%	-2%	-7%
VASCULAR SURGERY	*TOTAL*	$1,095	0%	-2%	1%
	Non-Facility	$810	-1%	-2%	6%
	Facility	$285	2%	-3%	-12%

The majority of specialties would experience shifts of 1 percent or greater if we used the proposed rebased and revised MEI cost share weights, as opposed to the current weights, displayed in Table 158, for proportioning work, PE, and MP RVUs. Several specialties shifted by greater than 3 percent, particularly the specialties with relatively higher PE costs, which are mostly realizing a positive shift, or relatively higher physician work costs, which are realizing a negative shift. As shown in Column F, the shifts are amplified, both negatively and positively, when use of the proposed rebased and revised MEI cost share weights is not phased in over

several years; therefore, we did not consider this a viable alternative for consideration. We note that there are significant shifts in specialty level payments if we used the proposed rebased and revised MEI cost share weights, some of which counter other CY 2023 provisions (that is, changes to Evaluation and Management (E/M) services, chronic pain management, and behavioral health services).

We proposed to delay the adjustments to allow public comment and finalization of the proposed rebased and revised MEI, and to maintain use of the current MEI cost share weights while presenting the information in section II.M. of this final rule and the specialty level impacts in Table 158. We also solicited comment on the use of a transition to phase in use of the proposed rebased and revised MEI cost share weights, if finalized, for potential future rulemaking. Because there are significant proposed methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since the last rebasing and revision of the MEI, we believe it is important to allow public comment and finalization of the MEI changes based on the review of public comment before we incorporate the updated MEI into PFS ratesetting, and we believe this is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Similarly, we proposed to delay the implementation of the rebased and revised MEI for use in the PE geographic practice cost index (GPCI) to allow public comment and finalization of the MEI changes based on the review of public comment before we incorporate the updated MEI into the PE GPCIs.

2. Alternatives Considered for the Practice Expense (PE) Geographic Practice Cost Index (GPCI)

As discussed in section II.G. of this final rule, we use the MEI cost share weights to weight the four components of the PE GPCI: employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses. As the MEI cost shares are updated, we have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI. Instead, we proposed to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 GPCIs, allowing interested parties the opportunity to review and comment on, and for us to respond to comments and finalize, the rebased and revised MEI cost share weights. Because there are significant proposed methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since the last rebasing and revision of the MEI, we believe it is important to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporate the updated MEI into the PE GPCI.

As an alternative to using the current 2006-based cost share weights, we considered using the proposed rebased and revised Medicare Economic Index (MEI) cost share weights for CY 2023, as discussed in detail in section II.M. of this final rule for purposes of weighting the four components of the CY 2023 PE GPCI. Specifically, within the four components of the PE GPCI, we considered proposing to update the employee compensation component from 16.553 percent to 24.716 percent, the office rent component from 10.223 percent to 5.893 percent, the purchased services component from 8.095 percent to 13.914 percent, and the medical equipment, supplies, and other miscellaneous expense component from 9.968 percent to 6.819 percent, as shown in Table 159. We note that, as discussed in detail in section II.M. of this final rule, the finalized rebased and revised cost share weights differ slightly from the proposed rebased and revised MEI cost share weights used for this alternative considered.

TABLE 159: Weighting of the PE GPCI Based on the Cost Share Weights for CY 2023

Expense Category	Current Cost Share Weights	CY 2023 Cost Share Weights	Rebased and Revised Cost Share Weights as Proposed in Section II.M.
Practice Expense	44.839%	44.839%	51.341%
- Employee Compensation	16.553%	16.553%	24.716%
- Office Rent	10.223%	10.223%	5.893%%
- Purchased Services	8.095%	8.095%	13.914%
- Equipment, Supplies, Other	9.968%	9.968%	6.819%

The use of the rebased and revised MEI cost share weights only impacts the PE GPCI. When the PE GPCI was calculated using the proposed rebased and revised MEI cost share weights, 10 of the 112 PE GPCI values remained the same compared to the calculated PE GPCI using the current 2006-based MEI cost share weights. Three of the 112 PE GPCI values differed by ±0.001 and 68 of the 112 PE GPCI values differ less than or equal to ±0.009. Therefore, the provision to maintain the use of the current 2006-based MEI cost share weights has little to no effect on over 70 percent of the localities' PE GPCIs. Of the remaining 31 localities with a difference of greater than ±0.009 between the proposed PE GPCI and the alternative considered, 10 realize an increased PE GPCI when the current 2006-based MEI cost share weights were used, ranging from an increase of 0.010 to 0.012, as compared to the PE GPCI if the proposed rebased and revised MEI cost share weights were incorporated. The remaining 21 localities realize a decrease in PE GPCI when the current 2006-based MEI cost share weights were used, ranging from a decrease of 0.010 to 0.028. We note that we solicited comments in section II.G. of this final rule on the provision to maintain the use of the current 2006-based MEI cost share weights and postpone the implementation of the proposed rebased and revised MEI cost share weights for consideration through potential future rulemaking. See Alternate Addenda D

and E to the proposed rule for the CY 2023 GPCIs and summarized GAFs if the proposed rebased and revised MEI cost share weights discussed in detail in section II.M. of the proposed rule, were incorporated to weight the proposed CY 2023 PE GPCIs (for comparison to Addenda D and E with the provision to maintain the current 2006-based MEI cost share weights for the PE GPCIs). Because the PE GPCIs factor into the GAF equation, we created an Alternate Addendum D to show the recalculated GAFs if the proposed rebased and revised MEI cost share weights were incorporated to weight the CY 2023 PE GPCIs as well. These alternative addenda are available on the CMS website under the supporting documents section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. We note that only the PE GPCI and GAF values differ between Addenda D and E, and Alternate Addenda D and E, as the proposed rebased and revised cost share weights do not impact the work or MP GPCIs.

We received public comments on the provision to maintain the use of the current 2006-based MEI cost share weights and postpone the implementation of the rebased and revised MEI cost share weights for consideration through potential future rulemaking, which were discussed earlier in this final rule. In response to our comment solicitations, we received comments on the timing and implementation strategies for consideration in future rulemaking. We thank commenters for the information they provided and will continue to contemplate the suggestions as we consider future rulemaking.

3. Alternatives Considered Related to Payment for E/M Services

In developing our policies for other E/M visits effective January 1, 2023, we considered a number of alternatives. For reasons discussed in our E/M policy section (section II.F. of this final rule) we considered several refinements for the RUC-recommended work RVUs for several of the codes in the families based on survey time changes to include Hospital Inpatient or Observation Care, Nursing Facility visits, and Home or Residence Services. We proposed to accept the RUC recommendations for the work RVUs because we believe they are more accurate values. For some of these codes the overall times changed and the RUC recommended work RVUs accurately reflect changes based on changes in the times for the service. For some of the codes, changes were noted in the total time and intra-service times which was reflected in the intra-time and total time ratios that led to an increase. Given our interest in maintaining continuity in the overall code set, we proposed to accept the RUC recommendations for the work time values and work RVUs for these codes and sought public comment on our concerns for specific codes.

We received public comments, which were discussed earlier in this final rule, related to revaluation of the Other E/M Visits. Commenters stated that CMS should finalize different values for some of the different families. For hospital inpatient and observation services, we received some comments that we should not accept the RUC-recommended values, especially for values that would decrease. These commenters recommended retaining the historical relative relationship between inpatient/observation and office/outpatient visits. We disagree that changes should never be made to adjust the relative valuation between office/outpatient visits and inpatient/observation care. Observation services are less intense than inpatient services, and the code set merger together with decreases in time, make it appropriate that we accept the RUC recommended values.

For ED visits, a few commenters did not agree with our rejection of the RUC-recommended decrease for one visit level, on the basis that this code would not be properly valued in relationship to the comparable office/outpatient visit. We continue to believe that this particular ED visit should have a higher RVU than the comparable outpatient/office visit, to reflect higher intensity.

For Nursing Facility visits, we received some comments indicating that due to anomalies in code descriptors and decreases in total time, we should retain current values or finalize alternative values, and ask the AMA to review this code family again. We believe this approach would be disruptive, so we are accepting the RUC values and may reconsider this family again in future rulemaking.

For Home and Residence services, a few commenters requested that CMS not finalize RUC-recommended decreases for some of the codes, to help cover costs associated with travel, addressing social determinants of health, and other comprehensive care. Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service. We appreciate the need to account for social determinants of health and other comprehensive care for certain patients during home/residence visits. We are accepting the RUC-recommended values.

Commenters were concerned about the redistributive impacts of Other E/M revaluation under current legislation. Most commenters urged CMS to work with Congress on this issue, and some urged CMS to reactivate the complexity add-on for O/O visits promptly in 2024. Several commenters recommended that CMS continue to consider whether certain Other E/M revaluations disrupt appropriate PFS relativity. After considering the public comments, we are finalizing our proposals for revaluation of Other E/M's as proposed. For the majority of codes, this reflects the consensus reached at the RUC regarding Other E/M valuation. This does not necessarily mean that their valuation will not need to be adjusted in future years, and we will continue to consider appropriate valuation for all E/M visits as we gain experience with them under the new framework. We will also follow CPT proceedings for any additional developments, which we would consider through notice and comment rulemaking.

Regarding prolonged Other E/M services, in our proposed rule, after thoughtful consideration we proposed to develop Medicare-specific coding (three G-codes, one per setting) to avoid potentially substantial overpayment, provide administrative simplification, enable CMS to determine how much time is being spent with patients using claims data, and facilitate program integrity. Allowing for CMS to determine how much time is being spent with patients using claims data is important for future valuation of services on the PFS, and for program integrity. If we proposed to merely accept the CPT prolonged service coding changes, we would not be able to identify the time spent with patients in the claims data alone, because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. We decided to take similar approach as we did for the office/outpatient E/M visits by proposing Medicare-specific coding (G0316 through G0318) for prolonged services for Other E/Ms. We considered two options in coming to our provision. First, we considered using the descriptor time plus 15 minutes, which would allow for prolonged Other E/M services to be reportable once the practitioner spends 15 additional minutes beyond the ceiling time of the

primary service. Or, our second option was to use total time plus 15 minutes, allowing for prolonged Other E/M services to be reportable once the practitioner spends 15 additional minutes beyond the total time of the primary service. Both of these options would allow for time to be counted on any day within the survey period with no frequency limit. We proposed to value the G codes similarly to the parallel CPT code, and require total time to be met before prolonged time starts. Reporting this way, through the use of a G code for each of the specified code families, allows for administrative simplicity and payment accuracy.

We received public comments, discussed earlier in this final rule, related to Medicare-specific coding for prolonged Other E/M services. While some commenters supported our approach, others felt it would result in administrative burden. Some commenters did not believe we should align reported times with survey times. The AMA stated that it would refer prolonged services back to the CPT Editorial Panel for potential further review, if CMS did not adopt the CPT codes for prolonged Other E/M services in the final rule.

We continue to believe that adopting the CPT codes for prolonged services would result in duplicative time counting, and reported times that do not align with work times used for valuation. Having three sets of codes for reporting time associated with a single visit is overly complex, and hinders our ability to assess how much time was spent with patients using claims data, and trends in time under the new framework. However, we agree with commenters that a uniform code set for use by all payers for prolonged services is important to further reduce administrative burden. After consideration of the public comments, we are finalizing our proposals for prolonged Other E/M services as proposed, and will continue to work with the AMA to potentially further refine and standardize this code set, through notice and comment rulemaking. We refer readers to the E/M Visits section of this final rule for a detailed discussion of these issues.

4. Alternatives Considered Related to Provision To Allow Audiologists To Furnish Diagnostic Tests, as Appropriate Without a Physician Order

As discussed in section II.K. of this final rule, interested parties have told us that our regulatory requirement for a physician or NPP order for diagnostic audiology services may be impeding access to audiologists. More recently they have requested that we eliminate the treating physician (or NPP) order requirement for the diagnostic hearing and balance assessment services furnished by audiologists—via notice and comment rulemaking—to enable greater access to these services.

As we also discussed in section II.K. of the final rule, we are concerned that direct access of audiologists' services, that is the removal of the order requirement for these hearing and balance services furnished by audiologists, might lead to payment for services that are not medically necessary because the results are not being used by a treating physician or NPP in the management of the patient's medical condition. Nonetheless, after careful consideration of the interested parties' requests, we proposed to amend the regulation at § 410.32(a)(4) to remove the order requirement for certain audiology services furnished personally by an audiologist once per beneficiary per 12- month period for non-acute hearing conditions. We also proposed to create HCPCS code GAUDX (*Audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids; may be performed on an annual basis*) to describe audiology services furnished without the order of a treating physician or practitioner. However, we did not finalize the use of HCPCS code GAUDX to identify and pay audiology services furnished without a physician/NPP order, due to many commenters' concerns about HCPCS code GAUDX and support for instead establishing a new modifier, which increases the specificity for billing for audiology services and reduces burden for audiologists. As discussed later in this section, we are finalizing the use of a new modifier (AB), along with CPT codes audiologists already use, to identify audiology services furnished without the order of a physician or NPP, and making payment for those services as appropriate using the current CPT codes.

When developing our proposed policy, we considered adding audiologists to § 410.32(a)(2), under the provision that permits nonphysician practitioners to order diagnostic tests. However, unlike audiologists, the practitioners identified in this provision are all required to accept payment on an assignment-related basis under section 1842(b)(18)(C) of the Act and must accept the Medicare payment amount as payment in full. Medicare payment for audiology services provided by audiologists who do not accept assignment will result in higher out-of-pocket expense (that is, the balance billed amount) than if they did accept assignment. In addition, Medicare Part B does not recognize audiologists to treat or manage patients, unlike PAs, NPs or CNSs who may bill for E/M services, and for whom Medicare Part B covers services and supplies incident to their own professional services as provided in the regulation at § 410.26. Rather, because audiology services furnished by audiologists include only diagnostic hearing and balance assessment services, we concluded that adding audiologists with the NPPs listed in § 410.32(a)(2) was inappropriate.

We also considered alternatively removing the requirement for the order of a treating physician or practitioner for audiology services without the annual limitation. However, we had concerns about the possibility of overutilization of HCPCS code GAUDX (which was not finalized) if the results of audiology testing are not used by a treating clinician to manage the patient's medical condition. Additionally, we do not have the ability to predict the behavioral response of audiologists to removal of order requirements. Therefore, we believe that adding an annual limitation will serve to address some of our concerns of overutilization. To monitor for the appropriate use of HCPCS code GAUDX (or modifier AB, as we finalized), we will establish system edits through our usual change management process to ensure that HCPCS code GAUDX (or, as finalized, services billed on the same date of service with modifier AB) is only paid once every 12 months per each beneficiary. This will also help address program integrity concerns about audiologists billing for directly accessed services without an order more frequently, furnishing services that are not reasonable or necessary for the treatment of the beneficiary's illness or injury. Finally, because we are concerned about beneficiaries with acute onset conditions that require immediate medical intervention, and the potential loss of valuable time for medical intervention if the patient sees an audiologist first, we are limiting the direct access to audiology services to non-acute hearing conditions and conditions for which patients' experience disequilibrium symptomology. To help address these safety concerns about direct access to audiologists, we want to stress the importance that such hearing conditions with a rapid onset and balance

conditions with disequilibrium symptoms are to be referred directly to the primary care physician, ENT or other physician or NPP treating the beneficiary.

We received comments on our proposal to allow beneficiaries direct access to audiologists (without an order from the treating physician/NPP) for non-acute hearing conditions and without disequilibrium symptomology once every 12-months using the GAUDX code, as we discussed in Section II.K of this final rule. While a few commenters supported the use of the GAUDX code, including the built-in safeguards, many commenters supported an alternative approach using a new modifier, instead. We agreed with commenters that it would be more transparent to use a modifier alongside the CPT codes that audiologists already use that are paid at PFS rates rather than the proposed GAUDX code and its proposed amount. Although several medical organizations and societies did not support direct access to audiologists of any kind, a couple of commenters, including a medical specialty, agreed with specifically limiting the CPT codes to the same 36 codes we proposed that code GAUDX would encompass, this is, not including the 14 codes we had removed for vestibular function that are used for balance problems; while audiologists favored little or no restraints on which CPT codes they could bill for hearing and balance assessments. In consideration of the comments received, specifically, acknowledging that use of a modifier in this instance would be administratively simpler and transparent for audiologist practitioners, we are finalizing an alternative policy using a new modifier (AB), which still retains the safeguards we proposed to allow beneficiaries to directly access audiologists to provide non-acute hearing assessments, once every 12 months, using new modifier AB.

5. Alternatives Considered Related to the Medicare Shared Savings Program

One purpose of the prior savings adjustment we are adopting in this final rule is to mitigate the rebasing ratchet effect on an ACO's benchmark in order to improve the incentive for higher spending ACOs to reduce spending in advance of eventual rebasing and to encourage their renewal for successive agreement periods. It remains a possibility, however, that even with this provision, higher spending ACOs that are effective in reducing spending may eventually drop out of the Shared Savings Program absent the opportunity to participate in a one-sided model in the succeeding agreement period. While we project only 1 to 5 percent of new ACOs dropping out before the end of their first agreement period, the dropout rate could reach as high as 30 percent during the second agreement period. Signaling that risk will eventually be mandatory could prevent the formation of new low-revenue ACOs for whom a sharing-only incentive has proven to be effective. We considered an alternative in which low revenue ACOs would be permitted to participate in a one-sided model for a second full agreement period and estimate it would further increase program savings by at least $1 billion because it would increase retention for the type of ACO that has favorably responded to a moderate upside-only incentive in the past. This additional savings would result from (1) about a 60 percent reduction in the projected dropout rate by the end of the second agreement period for new and re-entering ACOs and (2) an assumed incremental increase in the share of ACOs that would form as low revenue (a type that is assumed to be more effective at reducing spending). This alternative estimate is likely conservative, as the savings impact could be significantly greater if such signaling regarding the second agreement period were to prove to be a key factor motivating a significant increase in the overall number of ACOs that enter a first agreement period under the Shared Savings Program (instead of just the proportion that form as low revenue versus high revenue).

We also considered adding guardrails for calculating shared savings by limiting the difference the ACPT may be allowed to show (in either direction) from actual national assignable trend. As we discussed in the proposed rule, setting a prospective symmetric threshold for correcting extreme projection error would automatically correct for bias in either direction and prevent the need for CMS to address pressure to correct projection error on an ad hoc basis. Public pressure to correct for projection error would be strongest in situations where actual growth eclipses the ACPT by a significant margin. If CMS were assumed to only update the ACPT in years where such pressures were magnified because a change will favor ACOs, this impact estimate would show $1.3 billion in additional spending over 10 years. This estimate presumes that CMS would limit deviation in ACPT from actual national trend to no more than 2 percent in years where the ACPT understates national trend. The cost of such policy to asymmetrically correct for unfavorable projection error would grow if the threshold for making such adjustments were assumed to move lower than 2 percent.

6. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran separate final policies RIA models based on the actual mean for the CY 2019 performance period/2021 MIPS payment year and the CY 2020 performance period/2022 MIPS payment year with a performance threshold of 86 and 89, respectively which are potential values that may be used for the performance threshold for CY 2023 performance period/2025 MIPS payment year. The models have the same mean and median final score as our final policies RIA model since the performance threshold does not change the final score. In the iteration with a performance threshold of 86, 60.24 percent of MIPS eligible clinicians will receive a negative payment adjustment among engaged clinicians. In the model with a performance threshold of 89 points, 63.84 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data.

We report the findings for the baseline RIA model which describes the impact for the CY 2023 MIPS performance period/2025 MIPS payment year if this regulation did not exist. The baseline RIA model has a mean final score of 77.78 and median final score of 79.45. We estimate that $699 million will be redistributed through budget neutrality. There will be a maximum payment adjustment of 6.1 percent after considering the MIPS payment adjustment. In addition, 38.81 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data.

G. Impact on Beneficiaries

1. Shared Savings Program Provisions

As noted previously, a number of changes in this final rule collectively aim to increase participation in a more sustainable way for ACOs serving medically complex, high cost beneficiaries. The policies we are adopting in this final rule are designed to reverse recent trends where growth has plateaued in the Shared Savings Program, higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to

ACOs appears inequitable as evidenced by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO than their Non-Hispanic White counterparts, and to encourage growth of ACOs in underserved communities.

Additionally, ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management, and will stave off the risk apparent in the previous trajectory of the Shared Savings Program where ACO participants and ACO providers/suppliers may have felt pressure to avoid engaging with beneficiaries in high needs communities in order to avoid assignment of high cost beneficiaries to their ACO and to improve their performance relative to a regional expenditures. In combination with the new participation options that are expected attract a mix of new participants, targeted provisions such as using an offset factor to reduce the negative regional adjustment for ACOs serving high risk and high dual populations, aim to increase the reach of ACO care coordination to more beneficiaries with high needs.

2. Quality Payment Program

There are several changes in this final rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate this will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's final rule will be the number of reviewers of last year's rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the rule. For these reasons we thought that the number of commenters will be a fair estimate of the number of reviewers of this year's final rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it will take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $921.76 (8.0 hours × $115.22). Therefore, we estimated that the total cost of reviewing this regulation is $21,514,800 ($931.35 × 23,341 reviewers on this year's proposed rule).

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 160 through 162 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2021 to CY 2022 based on the FY 2022 President's Budget baseline.

TABLE 160: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2023 Annualized Monetized Transfers	Estimated increase in expenditures of -$2.2 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 161: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2023 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.6 billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 162: Accounting Statement for Provisions for the Medicare Shared Savings Program (CYs 2023-2034)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-1,139 million	-458 million	-1,744 million	Table 152
Annualized monetized: Discount rate: 3%	-1,197 million	-484 million	-1,876 million	

Notes: Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 26, 2022.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health insurance, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.2463 is amended by revising paragraph (b)(3) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(b) * * *

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning 152 days after the end of the COVID–19 public health emergency, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

■ 3. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit

a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning 152 days after the end of the COVID–19 public health emergency, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 5. Amend § 410.10 by revising paragraphs (l) and (p) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(l) Pneumococcal, influenza, and COVID–19 vaccines and their administration.

* * * * *

(p) Hepatitis B vaccine and its administration, as defined in § 410.63(a) of this subchapter.

* * * * *

■ 6. Amend § 410.26 by revising paragraph (b)(5) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 7. Amend § 410.32 by adding paragraph (a)(4) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory test, and other diagnostic tests: Conditions.

(a) * * *

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a modifier CMS designates for this purpose.

* * * * *

■ 8. Amend § 410.37—

■ a. In paragraph (c)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'';

■ b. In paragraph (c)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'';

■ c. In paragraph (e)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'';

■ d. In paragraph (e)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'';

■ e. In paragraph (i)(1), by removing the phrase ''individual age 50'' and adding in its place the phrase ''individual age 45''; and

■ f. By adding paragraph (k).

The addition reads as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(k) *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

■ 9. Amend § 410.40 by revising paragraph (e)(2)(ii) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(e) * * *

(2) * * *

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

* * * * *

■ 10. Amend § 410.57 by—

■ a. Revising the section heading and paragraph (a); and

■ b. Adding paragraph (d).

The revisions and addition read as follows:

§ 410.57 Preventive vaccines.

(a) Medicare Part B pays for the pneumococcal vaccine and its administration.

* * * * *

(d) Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).

§ 410.63 [Amended]

■ 11. Amend § 410.63 in the introductory text by removing the phrase ''vaccines (see § 405.310 of this chapter)'' and adding in its place the phrase ''vaccines (see § 411.15 of this chapter)''.

■ 12. Amend § 410.67 by—
■ a. In the definition of ''Opioid use disorder treatment service'' redesignating paragraphs (1) through (8) as paragraphs (i) through (viii) and revising newly redesignated paragraphs (vi) and (vii);
■ b. Revising (d)(2)(i)(B)(*2*);
■ c. Adding paragraph (d)(2)(iv); and
■ d. Revising paragraph (d)(4)(ii).

The revisions and addition read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service

* * *

(vi) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title. Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, and through the end of CY 2023, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(B) * * *

(*2*) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021. For CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021 and updated by the PPI for Pharmaceuticals for Human Use (Prescription).

* * * * *

(iv) *Increased level of psychotherapy.* For CY 2023 and subsequent years, the payment for the non-drug component of the bundled payment for an episode of care under paragraph (d)(2) of this section is adjusted to reflect the CY 2019 Medicare physician fee schedule non-facility rate for psychotherapy, 45 minutes with patient.

* * * * *

(4) * * *

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

* * * * *

§ 410.78 [Amended]

■ 13. Amend § 410.78 in paragraph (b)(3)(xiv) introductory text, by removing the phrase ''the first day'' and adding in its place the phrase ''the day that is the 152nd day''.

■ 14. Amend § 410.152—
■ a. By revising paragraph (h);
■ b. In paragraph (l)(1), by removing the phrase ''(as specified in paragraph (h) of this section)''.

The revision reads as follows:

§ 410.152 Amounts of payment.

* * * * *

(h) *Amount of payment: Preventive vaccine administration.* For the administration of the preventive vaccines described in paragraph (l)(1) of this section, as furnished by providers described in §§ 409.100 and 410.150 of this subchapter, Medicare Part B pays the following amounts, except as otherwise provided under this subchapter:

(1) Effective January 1, 2022, for administration of an influenza, hepatitis B or pneumococcal vaccine, $30 per dose.

(2) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(3) For services furnished on or after January 1 of the year following the year in which the Secretary ends the Emergency Use Authorization for drugs and biologicals issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1).

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) through (3) of this section is adjusted to reflect geographic cost variations:

(i) For services furnished before January 1, 2023, using the Geographic Practice Cost Indices (GPCIs) established for the year, as described in section 1848(e)(1) of the Act and §§ 414.2 and 414.26 of this subchapter.

(ii) For services furnished on or after January 1, 2023, using the Geographic Adjustment Factor (GAF) established for the year as described in section 1848(e)(2) of the Act and §§ 414.2 and 414.26 of this subchapter.

(5) The payment amount for administration of a preventive vaccine described in paragraphs (h)(1) through (3) of this section is updated annually using the percentage change in the Medicare Economic Index (MEI) as described in section 1842(i)(3) of the Act and § 405.504(d) of this subchapter.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 15. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 16. Amend § 411.15 by revising paragraph (i) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) *Dental services*—(1) *Basic rule. Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.

(2) *Exception. Except f*or inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(i) The individual's underlying medical condition and clinical status; or

(ii) The severity of the dental procedures.[577]

[577] Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient's underlying medical condition and clinical status.

(3) *Inapplicability.* (i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Parts A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

(C) The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(ii) Ancillary services and supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the service is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 17. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 18. Amend § 414.502 by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2023 through March 31, 2023.

* * * * *

§ 414.504 [Amended]

■ 19. Amend § 414.504 in paragraph (a)(1) by removing the reference ''January 1, 2022'' and adding in its place the reference ''January 1, 2023''.

■ 20. Amend § 414.507 by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(5);

■ b. Adding paragraph (d)(8);

■ c. Removing paragraph (f); and

■ d. Redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2025, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(5) 2022—0.0 percent of the payment rate established in 2021.

* * * * *

(8) 2025—15 percent of the payment rate established in 2024.

* * * * *

■ 21. Add § 414.523 to subpart G to read as follows:

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) *Specimen collection fee and travel allowance.* In addition to the payment amounts provided under this subpart for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee, as set forth in paragraph (a)(1) of this section, and a travel allowance, as set forth in paragraph (a)(2) of this section.

(1) *Payment for specimen collection.* Except as provided in paragraph (a)(1)(v) of this section and subject to the annual update in paragraph (a)(1)(iv) of this section, beginning January 1, 2023, CMS pays $8.57 for all specimens collected in one patient encounter, where the specimen(s) is:

(i) Used to perform a CDLT paid under this subpart G;

(ii) Collected by a trained technician from a Medicare beneficiary who is——

(A) Homebound as described in 42 CFR 424.22(a)(1)(ii).

(B) A non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen;

(iii) Of the following type—

(A) Blood specimen collected through venipuncture.

(B) A urine sample collected by catheterization.

(iv) Beginning January 1, 2024, CMS updates the specimen collection fee amount under paragraph (a)(1) of this section for each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year.

(v) For a specimen collected from a Medicare beneficiary.

(2) *Payment for travel allowance*—(i) *General requirement.* CMS pays a travel allowance, as calculated under paragraph (a)(2)(iii) of this section, where the specimen is one for which a specimen collection fee is paid under paragraph (a)(1) of this section.

(ii) *Travel allowance basis.* CMS pays a travel allowance on the following bases:

(A) *Flat-rate travel allowance.* The flat-rate travel allowance applies when the trained technician travels 20 eligible miles or less (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(B) *Per-mile travel allowance.* The per-mile travel allowance applies when:

(*1*) The trained technician travels more than 20 eligible miles (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(*2*) The trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

(iii) *Travel allowance amount*—(A) *Eligible miles.* Eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section, and end at the laboratory or the ending point of the technician's travel for specimen

collection as specified in paragraph (a)(1) of this section. Eligible miles do not include miles traveled for any purpose unrelated to specimen collection as specified in paragraph (a)(1) of this section, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

(B) *Travel allowance mileage rate.* The travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the United States Bureau of Labor Statistics, divided by 40 to represent an average miles-per-hour driving speed.

(C) *Travel allowance amount calculation.* (*1*) For the flat-rate travel allowance basis specified in paragraph (a)(2)(ii)(A) of this section, the travel allowance amount is the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section multiplied by ten, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(*2*) For the per-mile travel allowance basis specified in paragraph (a)(2)(ii)(B) of this section, the travel allowance amount is the number of eligible miles multiplied by the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(b) [Reserved]

§ 414.626 [Amended]

■ 22. Amend § 414.626—

■ a. In paragraph (d)(1) introductory text, by removing the phrase ''must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS'' and adding in its place the phrase ''must submit a request to CMS, in the form and manner specified by CMS,''; and

■ b. In paragraph (e)(2) introductory text, by removing the phrase ''by submitting all of the following information:'' and adding in its place the phrase ''by submitting a request to CMS, in the form and manner specified by CMS, that includes all of the following information:''.

§ 414.707 [Amended]

■ 23. Amend § 414.707 in paragraph (a)(2)(iii), by removing the phrase ''(as determined by the Secretary)'' and adding in its place the phrase ''(as defined in § 410.63(a) of this subchapter).''

■ 24. Amend § 414.902 by adding the definition of ''Refundable single-dose container or single-use package drug'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Refundable single-dose container or single-use package drug means a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information. The term ''refundable single-dose container or single-use package drug'' excludes—

(1) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(2) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(3) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

* * * * *

§ 414.904 [Amended]

■ 25. Amend § 414.904 in paragraph (e)(1), by removing the phrase ''(as determined by the Secretary)'' and adding in its place the phrase ''(as defined in § 410.63(a) of this subchapter).''

■ 26. Section § 414.940 is added to subpart K to read as follows:

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Reports.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts that the manufacturer is liable for pursuant to this paragraph are paid in 12-month intervals, in a manner specified by CMS.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than 30 days following the resolution of the dispute.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(1) The product of:

(i) The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

(ii) The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(2) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the quarter.

(3) For purposes of paragraph (c)(1)(ii) of this section, the term ''applicable percentage'' means 10 percent except where an increased applicable percentage is applied in paragraph (d) of this section.

(d) *Treatment of drugs that have unique circumstances.* For purposes of paragraph (c)(1)(ii) of this section, the term ''applicable percentage'' means

(1) 35 percent for drugs that are reconstituted with a hydrogel and have variable dosing based on patient-specific characteristics

(2) [Reserved]

(e) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(e) *Enforcement.* (1) *Manufacturer audit*s. Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this section shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

■ 27. Section § 414.1305 is amended by—

■ a. Adding the definition of ''Facility-based group'';

■ b. Revising the definitions of ''Facility-based MIPS eligible clinician'', ''High priority measure'', ''Multispecialty group'', ''Single specialty group'', and ''Third party intermediary'' to read as follows:

§ 414.1305 Definitions.

* * * * *

Facility-based group means a group that CMS determines meets the criteria specified in § 414.1380(e)(2)(ii).

Facility-based MIPS eligible clinician means an individual MIPS eligible clinician who CMS determines meets the criteria specified in § 414.1380(e)(2)(i).

* * * * *

High priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure.

* * * * *

Multispecialty group means a group as defined at § 414.1305 that consists of two or more specialty types as determined by CMS using Medicare Part B claims.

* * * * *

Single specialty group means a group as defined at § 414.1305 that consists of one specialty type as determined by CMS using Medicare Part B claims.

* * * * *

Third party intermediary means an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

* * * * *

■ 28. Amend § 414.1318 by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraphs (a)(3) and (4); and

■ c. Revising paragraphs (b) and (c)(2).

The revisions and addition read as follows:

§ 414.1318 Subgroups.

(a) * * *

(1) *General.* Except as provided under paragraph (a)(2) of this section and subject to paragraph (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310.

* * * * *

(3) *Single subgroup per eligible clinician.* An individual eligible clinician (as represented by a TIN–NPI combination) may register for no more than one subgroup within a group's TIN.

(4) *Subgroup determination period.* CMS will apply the low-volume threshold criteria for a subgroup as described under paragraph (a)(1) of this section using information from the initial 12-month segment of the applicable MIPS determination period.

(b) *Final score.* Except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance.

(1) CMS will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period.

(2) [Reserved]

(c) * * *

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with § 414.1365. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b).

■ 29. Amend § 414.1340 by adding paragraphs (a)(4) and (b)(4) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(4) At least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026 and 2027.

* * * * *

(b) * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026 and 2027.

* * * * *

■ 30. Amend § 414.1365 by —

■ a. Adding paragraph (b)(2)(iii);

■ b. Revising paragraph (d)(3)(i)(A)(*1*);

■ c. Adding paragraphs (d)(3)(i)(B)(*1*) and (*2*);

■ d. Adding paragraphs (d)(3)(ii)(A) and (B).

The additions and revisions read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(iii) TINs must provide a description of each subgroup that is registered.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) * * *

(*1*) A subgroup is scored on each selected population health measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

(*2*) [Reserved]

* * * * *

(B) * * *

(*1*) A subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points.

(*2*) [Reserved]

(ii) * * *

(A) A subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).

(B) [Reserved]

* * * * *

■ 31. Amend § 414.1380 by—

■ a. Adding paragraph (b)(1)(ii)(D); and

■ b. Revising paragraphs (b)(2)(iv)(E), (b)(4)(ii)(B) and (C), (c)(2)(i)(A)(*4*)(*i*) and (*iii*), (c)(3) introductory text, (e)(2) introductory text, (e)(2)(ii), (e)(4), (e)(5)(i) and (ii), (e)(6)(iv) and (v), and (e)(6)(vi)(A) and (B).

The addition and revisions read as follow:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(D) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

* * * * *

(2) * * *

(iv) * * *

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. The maximum cost improvement score beginning with the 2024 MIPS payment year is 1 percentage point.

* * * * *

(4) * * *

(ii) * * *

(B) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each required measure is worth 10, 20, or 40 points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each required measure is worth 10, 15, 25 or 30 points, as specified by CMS.

(C) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth five or ten bonus points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five bonus points, as specified by CMS.

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) * * *

(*i*) For the 2021 through 2025 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(*iii*) For the 2024 through 2025 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (iv) of this section. For the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section. Beginning with the CY 2023 MIPS performance period/CY 2025 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, or is a facility-based MIPS eligible clinician, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section.

* * * * *

(e) * * *

(2) *Eligibility for facility-based measurement.* A MIPS eligible clinician is eligible for facility-based measurement for a MIPS payment year if CMS determines the MIPS eligible clinician to be facility-based as an individual clinician or as part of a group, or beginning with the 2023 performance period/2025 MIPS payment year, a virtual group, as follows:

* * * * *

(ii) *Facility-based MIPS eligible group determination.* A facility-based MIPS eligible group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

* * * * *

(4) *Data submission for facility-based measurement.* There are no data submission requirements for a MIPS eligible individual clinician to be scored under facility-based measurement. A MIPS eligible group must submit data in the improvement activities or Promoting Interoperability performance categories in order toto be scored as a facility-based MIPS eligible group.

(5) * * *

(i) A facility-based MIPS eligible clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based MIPS eligible group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) * * *

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category.

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or MIPS eligible group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

* * * * *

(vi) * * *

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a MIPS eligible clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a MIPS eligible clinician or group receives a higher MIPS final score through another MIPS submission.

■ 32. Amend § 414.1400 by—

■ a. Revising paragraphs (b)(4)(i)(B), (b)(4)(iii)(A)(*3*), and (e)(1)(i)(B);

■ b. Adding paragraphs (e)(1)(i)(E);

■ c. Revising paragraph (e)(2) introductory text and (e)(3);

■ d. Adding paragraph (e)(5); and

■ e. Revising paragraph (f)(1).

The revisions and additions read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

* * * * *

(iii) * * *

(A) * * *

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.

* * * * *

(e) * * *

(1) * * *

(i) * * *

(B) The impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

* * * * *

(E) The communication plan for communicating the impact to the parties identified in paragraph (e)(1)(i)(B) of this section.

(2) CMS may immediately or with advance notice terminate a third party intermediary for one or more of the following reasons:

* * * * *

(3) A data submission that contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

* * * * *

(5) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(f) * * *

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

* * * * *

■ 33. Amend § 414.1405 by revising paragraph (b)(9) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) Pursuant to the methodology established at paragraph (g) of this section:

(i) The performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) The performance threshold for the 2025 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

■ 34. Amend § 414.1415 by—

■ a. Revising paragraph (b)(3);

■ b. Adding paragraph (b)(4); and

■ c. Revising paragraphs (c)(3)(i)(A) and (c)(7).

The revisions and addition read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(b) * * *

(3) The quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

(4) A single quality measure that meets the criteria under both paragraphs (b)(2) and (3) of this section may be used to satisfy the requirements of paragraph (b)(1) of this section.

(c) * * *

(3) * * *

(i) * * *

(A) For QP Performance Periods beginning in 2023, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(7) *Medical Home Model 50 eligible clinician limit.* Beginning in the 2023 QP Performance Period, notwithstanding paragraphs (c)(2) and (4) of this section, if an APM Entity participating in a Medical Home Model is comprised of more than 50 eligible clinicians, as determined by that APM Entity's Participation List on any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period), the requirements of paragraphs (c)(1) and (3) of this section apply.

■ 35. Amend § 414.1420 by—

■ a. Revising paragraph (c)(3)(ii);

■ b. Adding paragraph (c)(4); and

■ c. Revising paragraphs (d)(3)(i) and (d)(8).

The revisions and addition read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(c) * * *

(3) * * *

(ii) For QP Performance Periods on or after January 1, 2020, use at least one measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

(4) A single quality measure that meets the criteria under both paragraphs (c)(2) and (3) of this section may be used to satisfy the requirements of paragraph (c)(1) of this section.

(d) * * *

(3) * * *

(i) For QP Performance Periods beginning in 2023, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

* * * * *

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Beginning with the 2023 QP Performance Period, notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is comprised of 50 or more eligible clinicians is comprised of more than 50 eligible clinicians, as determined by the information submitted for any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period) as specified in § 414.1440(e), the requirements of paragraphs (d)(1) and (3) of this section apply.

■ 36. Amend § 414.1430 by—

■ a. Revising paragraphs (a)(2)(iii);

■ b. Removing the second paragraph (a)(3)(ii);

■ c. Adding paragraphs (a)(3)(iii) and (iv);

■ d. Revising paragraph (a)(4)(iii);

■ e. Adding paragraph (a)(4)(iv); and

■ f. Revising paragraphs (b)(3)(i)(A) and (B), and (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(2) * * *

(iii) 2023 and 2024: 40 percent.

* * * * *

(3) * * *

(iii) 2023 and 2024: 35 percent.

(iv) 2025 and later: 50 percent.

(4) * * *

(iii) 2023 and 2024: 25 percent.

(iv) 2025 and later: 35 percent.

(b) * * *

(3) * * *

(i) * * *

(A) 2021 through 2024: 35 percent.

(B) 2025 and later: 50 percent.

* * * * *

(4) * * *

(i) * * *

(A) 2021 through 2024: 25 percent.

(B) 2025 and later: 35 percent.

* * * * *

■ 37. Amend § 414.1440 by revising paragraph (e)(2) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

* * * * *

(e) * * *

(2) To request a QP determination under the All-Payer Combination Option, for each payment arrangement submitted as set forth in paragraph (e)(1) of this section, the APM Entity or eligible clinician must include:

(i) The amount of revenue for services furnished through the payment arrangement, the total revenue received from all payers except those excluded as provided in paragraph (a)(2) of this section, the number of patients furnished any service through the arrangement, and the total number of patients furnished any services, except those excluded as provided in paragraph (a)(2) of this section; and

(ii) In the case of an APM Entity or eligible clinician requesting a QP determination under either a Medicaid Medical Home Model or Aligned Other Payer Medical Home Model pursuant to the criteria in § 414.1420, information specified by CMS for purposes of compliance with the 50 eligible clinician limit specified at § 414.1420(d)(8).

* * * * *

§ 414.1450 [Amended]

■ 38. Amend § 414.1450(c)(8) by removing the reference ''November 1'' and adding in its place the reference ''September 1''.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 39. The authority for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 415.140 [Amended]

■ 40. Transfer § 415.140 from subpart D to subpart C.

■ 41. In § 415.140 in paragraph (a) amend the definition of ''Substantive portion'' by removing the reference ''2022'' and adding in its place the reference ''2022 and 2023''.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 42. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 43. Amend § 423.160 by revising paragraphs (a)(5)(ii) and (iii) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) * * *

(ii) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.

(iii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 44. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 45. Amend § 424.57 by adding paragraph (b)(6) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(b) * * *

(6) The supplier is in compliance with all conditions of payment in paragraph (b) of this section, as well as with paragraph (c)(1)(ii)(A) of this section, at the time the item or service is furnished.

* * * * *

■ 46. Amend § 424.502 by adding the definitions of ''Director'', ''Managing organization'' and ''Officer'' in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Director means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.

* * * * *

Managing organization means an entity that exercises operational or managerial control over, or that directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

* * * * *

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

* * * * *

■ 47. Amend § 424.518 by—

■ a. Revising the introductory text;

■ b. Removing paragraph (a)(1)(xviii);

■ c. Adding paragraph (b)(1)(xiv);

■ d. Revising paragraph (c)(1) introductory text; and

■ e. Adding paragraphs (c)(1)(v) and (vi), and (c)(4).

The revision and additions read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, revalidation applications, change of ownership applications pursuant to 42 CFR 489.18, applications to add a new practice location, and applications to report any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42, based on a CMS assessment of risk and assignment to a level of ''limited,'' ''moderate,'' or ''high.''

* * * * *

(b) * * *

(1) * * *

(xiv) Revalidating skilled nursing facilities (SNFs)

* * * * *

(c) * * *

(1) *High categorical risk: Provider and supplier categories.* CMS has designated the following provider and supplier types as ''high'' categorical risk:

* * * * *

(v) Prospective (newly enrolling) (SNFs).

(vi) Enrolled OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, and SNFs that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

* * * * *

(4) Any screening level adjustment under paragraph (c)(3) of this section also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under paragraph (c)(3) of this section was originally raised.

* * * * *

■ 48. Amend § 424.530 by—

■ a. Revising paragraphs (a)(2) and (a)(3) introductory text;

■ b. Adding paragraph (a)(3)(iii); and

■ c. Revising paragraph (c).

The revisions and addition read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.* The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

* * * * *

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction,

exclusion, debt, felony) of an owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

* * * * *

■ 49. Amend § 424.535 by—
■ a. Revising paragraphs (a)(2) and (a)(3)(i);
■ b. Adding paragraph (a)(3)(iv); and
■ c. Revising paragraphs (a)(12)(ii) and (e).

The revisions and addition read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) * * *

(i) The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(iv) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

* * * * *

(12) * * *

(ii) Medicare may not revoke unless and until a provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal.

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 50. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 51. Amend § 425.20 by—
■ a. In paragraph (2) of the definition of ''Experienced with performance-based risk Medicare ACO initiatives'' by removing the phrase ''prior to the agreement start date'';
■ b. In paragraph (2) of the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives'' by removing the phrase ''prior to the agreement start date'';
■ c. In the definition of ''Performance-based risk Medicare ACO initiative'':
■ i. Revising paragraph (1)(i);
■ ii. Redesignating paragraphs (1)(ii) and (1)(iii) as paragraphs (1)(iii) and (1)(iv); and
■ iii. Adding a new paragraph (1)(ii).

The revision and addition read as follows:

§ 425.20 Definitions.

* * * * *

Performance-based risk Medicare ACO initiative

* * * * *

(1) * * *

(i) For performance years beginning prior to January 1, 2023, BASIC track (Levels A through E).

(ii) For performance years beginning January 1, 2023 and in subsequent years, BASIC track (Levels C through E).

* * * * *

■ 52. Amend § 425.100 by—
■ a. Revising paragraph (b)(1); and
■ b. Adding paragraph (d).

The revision and addition read as follows:

§ 425.100 General.

* * * * *

(b) * * *

(1) The ACO meets or exceeds the applicable minimum savings rate established under §§ 425.604, 425.605 (except as provided under § 425.605(h)), 425.606, 425.609, or 425.610.

* * * * *

(d) An ACO is eligible to receive advance investment payments if it meets the criteria under § 425.630(b).

§ 425.204 [Amended]

■ 53. Amend § 425.204(g) introductory text by removing the references ''§ 425.601, § 425.602, or § 425.603'' and adding in its place the references ''§§ 425.601, 425.602, 425.603, or 425.652''.

§ 425.224 [Amended]

■ 54. Amend § 425.224(a)(4) by removing the phrase '', or a one-sided model of the BASIC track's glide path (Level A or Level B),''.

■ 55. Amend § 425.302 by adding paragraph (a)(3)(iv) to read as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iv) That the ACO has moved all advance investment payments received during that performance year into a designated advance investment payments account established under § 425.630(e) and the advance investment payments have been dispersed only for allowable uses.

* * * * *

■ 56. Amend § 425.308 by adding paragraph (b)(8) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(8) Information, updated annually about the ACO's use of advance

investment payments under § 425.630, for each performance year, including the following:

(i) The ACO's spend plan.

(ii) The total amount of any advance investment payments received from CMS.

(iii) An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under § 425.630(d), and such other information as may be specified by CMS.

* * * * *

■ 57. Section 425.310 is revised to read as follows:

§ 425.310 Marketing requirements.

(a) *Requirements.* Marketing materials and activities must:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304 regarding beneficiary incentives.

(4) Not be materially inaccurate or misleading.

(b) *Monitoring.* (1) CMS may request the submission of marketing materials and activities at any time. If CMS determines that the marketing materials and activities do not comply with the requirements of paragraph (a) of this section, CMS will issue written notice of disapproval to the ACO.

(2) The ACO shall discontinue, and require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue, use of any marketing materials or activities disapproved by CMS.

(c) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

■ 58. Amend § 425.312 by revising paragraph (a)(2) to read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) Notification of the information specified in paragraph (a)(1) of this section must be carried out through the following methods:

(i) By an ACO participant posting signs in all of its facilities.

(ii) By an ACO participant making standardized written notices available upon request in all settings in which beneficiaries receive primary care services.

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each fee-for-service beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all fee-for-service beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

(iv) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished during the performance year for which the beneficiary is prospectively assigned to the ACO.

(v) Following the provision of the standardized written notice to a beneficiary, as specified in paragraphs (a)(2)(iii) and (iv) of this section, the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary.

(A) The follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided.

(B) The ACO must retain a record of all beneficiaries receiving the follow-up communication, and the form and manner in which the communication was made available to the beneficiary. The ACO must make these records available to CMS upon request.

* * * * *

■ 59. Amend § 425.316 by adding paragraph (e) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(e) *Monitoring ACO eligibility for advance investment payments.* (1) CMS monitors an ACO that receives advance investment payments pursuant to § 425.630 for changes in its ACO participants that may cause the ACO to no longer meet the standards specified in § 425.630(b)(3) and (4).

(2) If CMS determines during any performance year of the agreement period that an ACO receiving advance investment payments is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, CMS—

(i) Will cease payment of advance investment payments, starting the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

(ii) May take compliance action as specified in §§ 425.216 and 425.218.

(3) If an ACO remains an ACO experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action under this section, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

■ 60. Amend § 425.400 by—

■ a. Revising paragraph (c)(1)(vi) introductory text; and

■ b. Adding paragraph (c)(1)(vii).

The addition and revision read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(vi) For the performance year starting on January 1, 2022 as follows:

* * * * *

(vii) For the performance year starting on January 1, 2023, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vii)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*9*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*10*) 99439 (code for non-complex chronic care management).

(*11*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*12*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*13*) 99495 and 99496 (codes for transitional care management services).

(*14*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(*14*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 61. Amend § 425.402 by adding paragraph (f) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(f) For performance year 2023 and subsequent performance years, CMS employs the following process to identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of the beneficiary assignment methodology under this section.

(1) Prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status.

(2) CMS uses the CCNs identified in paragraph (f)(1) of this section in determining assignment for the performance year.

(3) CMS accounts for changes in CCN enrollment status during the performance year as follows:

(i) If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS will consider services furnished by that CCN in determining beneficiary assignment to the ACO for the applicable performance year for ACOs under preliminary prospective assignment with retrospective reconciliation.

(ii) Services furnished by a CCN with a deactivated enrollment status that is enrolled under an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.

(iii) If a CCN enrolled under the TIN of an ACO participant at the start of the performance year enrolls under a different TIN during a performance year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

■ 62. Amend § 425.512—

■ a. In paragraph (a)(4)(i)(A), by removing the phrase ''quality performance score'' and adding in its place the phrase ''health equity adjusted quality performance score'';

■ b. By revising paragraph (a)(4)(ii) and adding paragraph (a)(4)(iii);

■ c. By revising paragraphs (a)(5)(i) and (ii) and adding paragraph (a)(5)(iii)

■ d. By adding paragraph (a)(6);

■ e. By redesignating paragraph (b) as paragraph (c);

■ f. By adding new paragraph (b);

■ g. In newly redesignated paragraph (c)(2) introductory text, by removing the reference ''paragraph (b)(1) of this section'' and adding in its place the reference ''paragraph (c)(1) of this section''; and

■ h. By revising newly redesignated paragraph (c)(3).

The revisions and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(4) * * *

(ii) For performance year 2023, CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraphs (a)(2) or (a)(4)(i) of this section, but reports quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.

(iii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

* * * * *

(5) * * *

(i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and the following:

(A) For performance year 2024—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure

set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

(B) For performance year 2025 and subsequent years—Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraphs (a)(2) or (a)(5)(i) of this section, but reports quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.

(iii) An ACO will not meet the quality performance standard or the alternative quality performance standard if:

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP.

(B) For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP.

(6) For performance years 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b).

(b) *Calculation of ACO's health equity adjusted quality performance score for* performance year 2023 and subsequent performance years.

(1) For an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(2) of this section. The sum of these values may not exceed 100 percent.

(2) CMS calculates the ACO's health equity adjustment bonus points as follows:

(i) For each measure in the APP measure set, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(2)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates an underserved multiplier for the ACO.

(A) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of —

(*1*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index national percentile rank of at least 85; or

(*2*) The proportion of the ACO's assigned beneficiaries that are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(B) If the proportion determined in accordance with paragraph (b)(2)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for health equity adjustment bonus points.

(v) Except as specified in paragraph (b)(2)(iv)(B) of this section, CMS calculates the ACO's health equity adjustment bonus points as the product of the measure performance scaler determined under paragraph (b)(2)(iii) of this section and the underserved multiplier determined under paragraph (b)(2)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's health equity adjustment bonus points is set equal to 10.

(3) The ACO's health equity adjusted quality performance score, determined in accordance with paragraphs (b)(1) and (b)(2) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), and (a)(5)(i)(B) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraphs (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i) and (a)(5)(i) of this section or the alternative quality performance standard established in paragraphs (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) and (iii) of this section.

(c) * * *

(3) If the ACO reports quality data via the APP and meets data completeness and case minimum requirements:

(i) For performance years 2021 and 2022, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 and subsequent performance years, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

■ 63. Amend § 425.600—

■ a. By revising the heading of paragraph (a)(4)(i)(B);

■ b. In paragraph (a)(4)(i)(B)(*2*)(*ii*), revise the last sentence.

■ c. In paragraph (a)(4)(i)(B)(*2*)(*iv*), by removing the phrase ''For performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022'' and adding in its place the phrase ''Except as provided in paragraph (a)(4)(i)(B)(*2*)(*vi*) of this section, for performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022'';
■ d. By adding paragraphs (a)(4)(i)(B)(*2*)(*vi*) and (*vii*), and (a)(4)(i)(C);
■ e. In paragraph (a)(4)(ii), by removing the reference ''paragraph (d) of this section'' and adding in its place the references ''paragraph (d) or paragraph (g)(2) of this section, as applicable'';
■ f. In paragraph (d) introductory text, by removing the phrase ''beginning on July 1, 2019, and in subsequent years'' and adding in its place the phrase ''beginning on or after July 1, 2019, and before January 1, 2024'';
■ g. By revising paragraph (e) introductory text;
■ h. In paragraph (f)(4)(ii), by removing the reference ''§ 425.601(f)'' and adding in its place the references ''§§ 425.601(f), and 425.656(d)'';
■ i. In paragraph (f)(4)(iii), by removing the reference ''§ 425.601(e)'' and adding in its place the references ''§§ 425.601(e), and 425.652(c)(2)''; and
■ j. By adding paragraphs (g) and (h).

The revisions and additions read as follows:

§ 425.600 Selection of risk model.

(a) * * *

(4) * * *

(i) * * *

(B) *Glide path progression for agreement periods beginning on or after July 1, 2019 and before January 1, 2024.* * * *

(*2*) * * *

(*ii*) * * * In the case of an ACO that elects to remain in Level B for an additional performance year pursuant to the second sentence of paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section, and except as provided in paragraph (a)(4)(i)(B)(2)(*vi)* of this section, the ACO is automatically advanced to Level E under paragraph (a)(4)(i)(A)(*5*) of this section at the start of performance year 4 (or performance year 5 in the case of ACOs entering an agreement period beginning on July 1, 2019).

* * * * *

(*vi*) For performance year 2023, an ACO in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2022, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2023, the ACO is automatically advanced to the next level of the BASIC track's glide path to which the ACO would have automatically advanced absent any election to maintain its participation level for performance year 2022 under paragraph (a)(4)(i)(B)(*2*)(*iv*) of this section and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*vii*) For performance year 2024, an ACO with an agreement period beginning January 1, 2023 in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2023, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2024, the ACO is automatically advanced to the next level of the BASIC track's glide path, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

* * * * *

(C) *Glide path progression for agreement periods beginning on or after January 1, 2024.* (*1*) *Level of glide path entry.* An ACO eligible to enter the BASIC track's glide path as determined under paragraph (g)(1) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*2*) *Automatic advancement.* An ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except as follows:

(*i*) The ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*ii*) The ACO elects to maintain its level of participation as provided in paragraph (a)(4)(i)(C)(*3*) of this section.

(*iii*) The ACO is automatically advanced to Level E pursuant to paragraph (h)(2)(i) of this section.

(*3*) *Election to remain under a one-sided model.* An eligible ACO that enters the BASIC track's glide path at Level A under paragraph (a)(4)(i)(A)(*1*) of this section and is currently at Level A may elect to remain in Level A under paragraph (a)(4)(i)(A)(*1*) of this section for all subsequent performance years of the agreement period.

(*i*) To be eligible to participate under Level A of the BASIC track as described in this paragraph, the ACO must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track under paragraph (a)(4) of this section, and is not participating in an agreement period under the BASIC track as a renewing ACO (as defined at § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under paragraph (a)(4) of this section; and the ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20).

(*ii*) A voluntary election by an ACO under this paragraph (a)(4)(i)(C)(*3*) must be made in the form and manner and by a deadline established by CMS.

(*iii*) The ACO's election to remain in Level A applies for the entirety of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*4*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*5*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(C)(*4*) of this section, the agreement is terminated.

(*6*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(C)(*2*) of this section applies to all subsequent performance years of the agreement period.

* * * * *

(e) For performance years beginning on or after July 1, 2019 and before January 1, 2024, CMS monitors low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period in the BASIC track, for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. If the ACO meets the definition of a high revenue ACO (as specified in § 425.20)—

* * * * *

(g) For agreement periods beginning on or after January 1, 2024, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(i) An ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of two agreement periods, as specified in paragraph (a)(4)(i)(C) of this section.

(ii) An ACO that enters an agreement under the BASIC track's glide path at either Level A under paragraph (a)(4)(i)(A)(*1*) of this section or Level B under paragraph (a)(4)(i)(A)(*2*) of this section is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following:

(A) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(B) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(iii) An ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path as specified in paragraph (a)(4)(i)(C) of this section may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(h)(1) For performance years beginning on or after January 1, 2024, CMS monitors ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to an election under paragraph (a)(4)(i)(B)(*2*)(*vi*), paragraph (a)(4)(i)(B)(*2*)(*vii*), or paragraph (a)(4)(i)(C)(*3*) of this section for changes to their certified list of ACO participants that would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

(2) If the ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (under § 425.20)—

(i) The ACO is permitted to complete the performance year for which it met the definition of experienced with performance-based risk Medicare ACO initiatives in a one-sided model of the BASIC track, but is ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives. The ACO will be automatically advanced to Level E within the BASIC track under paragraph (a)(4)(i)(A)(*5*) of this section at the start of the next performance year and will remain in Level E for all subsequent performance years of the agreement period; and

(ii) Prior to entering performance-based risk, the ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b), in accordance with paragraph (a)(4)(i)(B)(*2*)(*v*) of this section or paragraph (a)(4)(i)(C)(*4*) of this section, as applicable. If the ACO fails to meet the requirements to participate under performance-based risk, the agreement is terminated in accordance with paragraph (a)(4)(i)(B)(*3*) of this section or paragraph (a)(4)(i)(C)(*5*) of this section, as applicable.

■ 64. Amend § 425.601 by—

■ a. Revising the section heading, and paragraphs (a)(1)(i) and (c)(2)(i);

■ b. In paragraph (d) introductory text, by removing the dash at the end of the paragraph, and adding a colon in its place;

■ c. In paragraph by (d)(1)(iv), by removing the semicolon at the end of paragraph, and adding a period in its place;

■ d. In paragraph (d)(2), by removing ''; and'', and adding a period in its place;

■ e. Removing paragraph (d)(3);

■ f. In paragraph (f)(5)(ii), by removing the reference ''paragraph (f)(4)(i) of this section'', and adding in its place the reference ''paragraph (f)(5)(i) of this section''; and

■ g. In paragraph (f)(5)(iv), by removing the references ''paragraphs (f)(1) and (2) of this section'', and adding in their place the references ''paragraphs (f)(1) through (3) of this section''.

The revisions read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

* * * * *

(a) * * *

(1) * * *

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(c) * * *

(2) * * *

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

* * * * *

■ 65. Amend § 425.605—

■ a. By revising paragraph (a) introductory text, paragraphs (a)(1)(i) and (ii), paragraph(a)(2) introductory text, and paragraphs (a)(5)(i) and (a)(6);
■ b. By adding paragraph (b)(2)(ii)(E);
■ c. By revising paragraphs (b)(3), and (c)(2);
■ d. In paragraph (d)(1) introductory text, by removing the reference ''§ 425.600(d)'' and adding in its place the references ''§ 425.600(d) or § 425.600(g)'';
■ e. By revising the heading of (d)(1)(i)(A)(*2*);
■ f. By adding paragraphs (d)(1)(i)(A)(*3*) and (*4*);
■ g. By revising paragraph (d)(1)(i)(B)(*1*);
■ h. By revising the heading of paragraph (d)(1)(ii)(A)(*2*);
■ i. By adding paragraphs (d)(1)(ii)(A)(*3*) and (*4*);
■ j. By revising paragraph (d)(1)(ii)(B)(*1*);
■ k. By revising the heading of paragraph (d)(1)(iii)(A)(*2*);
■ l. By adding paragraphs (d)(1)(iii)(A)(*3*) and (*4*);
■ m. By revising paragraph (d)(1)(iii)(B)(*1*);
■ n. In paragraph (d)(1)(iii)(D)(*2*), by removing the reference ''§ 425.601'' and adding in its place the references ''§ 425.601 or § 425.652'';
■ o. By revising the heading of paragraph (d)(1)(iv)(A)(*2*);
■ p. By adding paragraphs (d)(1)(iv)(A)(*3*) and (*4*);
■ q. By revising paragraph (d)(1)(iv)(B)(*1*);
■ r. In paragraph (d)(1)(iv)(D)(*2*), by removing the reference ''§ 425.601'' and adding in its place the references ''§ 425.601 or § 425.652'';
■ s. By revising the heading of paragraph (d)(1)(v)(A)(*2*);
■ t. By adding paragraphs (d)(1)(v)(A)(*3*) and (*4*);
■ u. By revising paragraph (d)(1)(v)(B)(*1*);
■ v. In paragraph (d)(1)(v)(D)(*2*), by removing the reference ''§ 425.601'' wherever it appears and adding in its place the references ''§ 425.601 or § 425.652'';
■ w. In paragraph (d)(2), by removing the reference ''§ 425.600(d)'' and adding in its place the references ''§ 425.600(d) or § 425.600(g)''; and
■ x. By adding paragraph (h).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) *General rules.* For each performance year, CMS determines whether the estimated average per capita Medicare Parts A and B fee-for-service expenditures for Medicare fee-for-service beneficiaries assigned to the ACO are above or below the updated benchmark determined under § 425.601 or § 425.652, as applicable. In order to qualify for a shared savings payment under the BASIC track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section except as provided in paragraph (h) of this section.

(1) * * *

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(1)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(2) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(2) of this section exceeds this cap. If the cap described in paragraph (a)(1)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(2) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(1)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(1)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(2) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the historical benchmark expenditures for that enrollment type and the performance year person years for that enrollment type.

(2) In risk adjusting the benchmark as described in §§ 425.601(a)(10) and 425.652(a)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

* * * * *

(5) * * *

(i) These calculations exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(6) In order to qualify for a shared savings payment, the ACO's average per capita Medicare Parts A and B fee-for-service expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section except as provided in paragraph (h) of this section.

(b) * * *

(2) * * *

(ii) * * *

(E) Automatic transition from Level A to Level E of the BASIC track's glide path under § 425.600(h)(2).

(3) Except as provided in paragraph (h) of this section, in order to qualify for a shared savings payment, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below its updated benchmark by at least the MSR established for the ACO.

* * * * *

(c) * * *

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must—

(i) Meet either the minimum savings rate requirement established under paragraph (b) of this section, or the criteria described in paragraph (h) of this section;

(ii) Meet either the quality performance standard or alternative quality performance standard established under § 425.512; and

(iii) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) * * *

(1) * * *

(i) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(i)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(ii) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(ii)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(iii) * *

(A) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iii)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(iv) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by

meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iv)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(v) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(v)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(h) *Calculation of shared savings for certain BASIC track ACOs not meeting MSR requirement.* An ACO that does not meet the minimum savings rate requirement established under paragraph (b) of this section but meets the other criteria described in paragraphs (c)(2)(ii) and (iii) of this section may qualify for a shared savings payment as provided in this paragraph.

(1) To qualify for a shared savings payment under this paragraph, an ACO must meet all of the following criteria:

(i) The ACO has average per capita Medicare Parts A and B fee-for-service expenditures for the performance year below the updated benchmark determined under § 425.652.

(ii) The ACO is a low revenue ACO as defined in § 425.20 as determined at the time of financial reconciliation for the performance year.

(iii) The ACO has at least 5,000 assigned beneficiaries for the relevant performance year as determined at the time of financial reconciliation for the performance year.

(iv) The ACO is participating in an agreement period beginning on January 1, 2024, or in subsequent years.

(2) The ACO's shared savings payment will be calculated as described in paragraph (d) of this section according to the ACO's applicable level of the BASIC track with the exception that the final sharing rate applied will equal one-half of the applicable percentage described in paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), or (d)(1)(v)(A)(*4*) of this section.

■ 66. Amend § 425.610—

■ a. In paragraph (a) introductory text, by removing the references ''§ 425.601, § 425.602 or § 425.603'' and adding in its place the references ''§ 425.601, 425.602, 425.603, or 425.652'';

■ b. By revising paragraphs (a)(2)(i) and (ii), (a)(3) introductory text, (a)(6)(i) and (d)(2) paragraph heading;

■ c. By adding paragraphs (d)(3) and (4);

■ d. By revising the heading of paragraph (f)(2);

■ e. By adding paragraphs (f)(3) and (4); and

■ f. In paragraph (g), by removing the references ''§ 425.601, § 425.602 or § 425.603'' and adding in its place the references ''§ 425.601, 425.602, 425.603 or 425.652''.

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(2) * * *

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(2)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(3) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(3) of this section exceeds this cap. If the cap described in paragraph (a)(2)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3

and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(3) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(2)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(2)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(3) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the historical benchmark expenditures for that enrollment type and the performance year person years for that enrollment type.

(3) In risk adjusting the benchmark as described in §§ 425.601(a)(10), 425.602(a)(9), 425.603(c)(10), and 425.652(a)(10) CMS makes separate adjustments for each of the following populations of beneficiaries:

* * * * *

(6) * * *

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(d) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(3) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(4) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

* * * * *

(f) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(3) *For the performance year beginning on January 1, 2023.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established in § 425.512 applicable for the performance year by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i), or the alternative quality performance standard established in § 425.512(a)(4)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to § 425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(3)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in § 425.512 applicable for the performance year, the shared loss rate is 75 percent.

(4) *For performance years beginning on or after January 1, 2024.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established in § 425.512 applicable for the performance year by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i), or the alternative quality performance standard established in § 425.512(a)(5)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to § 425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(4)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in § 425.512 for the applicable performance year, the shared loss rate is 75 percent.

* * * * *

■ 67. Amend § 425.611—

■ a. In paragraph (c)(2)(i), by removing the references ''§§ 425.601(c) and 425.603(e)'' and adding in its place the references ''§§ 425.601(c), 425.603(e), and 425.654(a)'';

■ b. In paragraph (c)(2)(ii)(A), by removing the references ''§§ 425.601(a)(4), 425.602(a)(4), and 425.603(c)(4)'' and adding in its place the references ''§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4), and 425.652(a)(4)'';

■ c. In paragraph (c)(2)(ii)(B), by removing the references ''§§ 425.601(c)(3) and 425.603(e)(3)'' and adding in its place the references ''§§ 425.601(c)(3), 425.603(e)(3), and 425.654(a)(3)'';

■ d. By revising paragraph (c)(2)(iii);

■ e. In paragraph (c)(2)(v), by removing the reference ''§ 425.601(a)(5)(ii)'' and adding in its place the references ''§§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii)'' and removing the reference ''§ 425.601(b)(2)'' and adding in its place the references ''§§ 425.601(b)(2) and 425.652(b)(2)(i)''; and

■ f. By revising paragraph (c)(4).

The revisions read as follows:

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID–19 pandemic.

* * * * *

(c) * * *

(2) * * *

(iii) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3),

and capping the prior savings adjustment according to § 425.652(a)(8)(iv).

* * * * *

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility for participation options according to § 425.600(d), and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

* * * * *

■ 68. Amend § 425.612 by—

■ a. Revising paragraph (a)(1)(i)(A) introductory text; and

■ b. In paragraph (a)(1)(i)(A)(*1*) by removing the phrase ''The communication plan'' and adding in its place the phrase ''A communication plan''.

The revision reads as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(i) * * *

(A) An attestation that it has established and will make available to CMS upon request the following narratives describing how the ACO plans to implement the waiver:

* * * * *

§§ 425.614 through 425.629 [Reserved]

■ 69. Add and reserve §§ 425.614 through 425.629 to subpart G.

■ 70. Section 425.630 is added to subpart G to read as follows:

§ 425.630 Option to receive advance investment payments.

(a) *Purpose.* Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs in order to support care improvement for underserved beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive advance investment payments as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO is not a renewing or a re-entering ACO.

(2) The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives.

(4) The ACO is a low revenue ACO.

(c) *Application procedure.* To obtain a determination regarding whether an ACO may receive advance investment payments, the ACO must submit to CMS complete supplemental information as part of its application to participate in the Shared Savings Program (filed pursuant to § 425.202) in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review.* (1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive advance investment payments. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The spend plan must:

(i) Describe how the ACO will spend its advance investment payments during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under this section.

(ii) Identify the categories of goods and services that will be purchased with advance investment payment funds (including any allowable uses under paragraph (e) of this section), the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS.

(iii) State that the ACO has established a separate designated account for the deposit and expenditure of all advance investment payments in accordance with paragraph (e)(4) of this section.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements for advance investment payments and will approve or deny the advance investment payment application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of advance investment payments.* (1) *Allowable uses.* An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.

(2) *Prohibited uses.* Advance investment payments may not be used for any expense other than allowable uses under paragraph (e)(1) of this section. In the case of an ACO participating in Level E of the BASIC track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2).

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period.

(4) *Segregation of advance investment payments.* An ACO must segregate advance investment payments from all other revenues by establishing and maintaining a separate account into which all advance investment payments will be deposited immediately and from which all disbursements of such funds are made only for allowable uses in accordance with this paragraph.

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

(1) *Frequency of payments.* An ACO will receive the one-time payment at the beginning of Performance Year 1 of the ACO's agreement period. An ACO will receive quarterly payments each quarter for the first two performance years of the ACO's agreement period. An ACO may receive no more than eight quarterly payments.

(2) *Quarterly payment amount calculation methodology.* CMS does all of the following in determining the quarterly payment amount prior to the start of the quarter.

(i) Determines the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the

quarterly payment amount are the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for an ACO under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for an ACO under prospective assignment), based on the certified ACO participant list for the relevant performance year.

(ii) Assigns each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS applies the following requirements in assigning a risk factors-based score:

(A) The risk factors-based score will be set to 100 if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid.

(B) The risk factors-based score will be set to the Area Deprivation Index national percentile rank matched to the beneficiary's mailing address if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an Area Deprivation Index national percentile rank.

(C) The risk factors-based score will be set to 50 if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is not available to match the beneficiary to an Area Deprivation Index national percentile rank.

(iii) Determines a beneficiary's payment amount. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

TABLE 1 TO PARAGRAPH (f)(2)(iii)

Risk factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	$0	$20	$24	$28	$32	$36	$40	$45

(iv) Calculates the ACO's quarterly payment amount. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii) of this section.

(g) *Recoupment and recovery of advance investment payments, and notice of bankruptcy.* (1) CMS will recoup advance investment payments made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of advance investment payments made to the ACO. For both renewing and re-entering ACOs, CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of advance investment payments made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the advance investment payments previously recouped or otherwise repaid.

(3) Except as provided for in paragraphs (g)(4) of this section and § 425.316(e)(3), for each performance year, CMS will not recover an amount of advance investment payments greater than the shared savings earned by an ACO in that performance year.

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(5) In the event of bankruptcy—

(i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Termination of advance investment payments.* (1) *General.* Except as provided in paragraph (h)(2) of this section, CMS may terminate an ACO's advance investment payments if the ACO—

(i) Fails to comply with the requirements of this section; or

(ii) Meets any of the grounds for ACO termination set forth in § 425.218(b).

(2) *Eligibility sanction.* CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO no longer meets the eligibility requirements specified in paragraphs (b)(3) and (b)(4) of this section.

(3) *No pre-termination actions.* CMS may immediately terminate an ACO's advance investment payments without taking any of the pre-termination actions set forth in § 425.216.

§§ 425.631 through 425.649 [Reserved]

■ 71. Add and reserve §§ 425.631 through 425.649 to subpart G.

■ 72. Section 425.650 is added to subpart G to read as follows:

§ 425.650 Benchmarking methodology.

(a) *Scope and purpose.* The methodology by which CMS establishes, adjusts, updates and resets an ACO's historical benchmark is described within this subpart G. The benchmarking methodology for agreement periods beginning before January 1, 2024, is specified in §§ 425.601, 425.602, and 425.603. The benchmarking methodology for agreement periods beginning on or after January 1, 2024, is specified in §§ 425.652 through 425.660.

(b) [Reserved]

■ 73. Section 425.652 is added to subpart G to read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on January 1, 2024, and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) This calculation includes individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under § 425.654 of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period, if applicable (as specified under § 425.658), or a combination of these two adjustments. CMS does all of the following to determine the adjustment(s) applied to the historical benchmark:

(i) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(ii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), the ACO will receive the regional adjustment to its benchmark as described in § 425.656.

(iii) If an ACO is eligible to receive a prior savings adjustment, CMS compares the pro-rated positive average per capita savings amount calculated in § 425.658(b)(3)(ii) with the regional adjustment described in § 425.656(c), expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

(A) If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings amount.

(*1*) If the sum is positive, the ACO will receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the positive sum and the cap described in paragraph (a)(8)(iv) of this section. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) If the sum is negative, the ACO will receive a reduced negative regional adjustment amount equal to the negative

sum. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) If the regional adjustment, expressed as a single value, is positive, the ACO will receive an adjustment to the benchmark equal to the higher of the following:

(*1*) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings amount described in § 425.658(b)(3)(ii) and the cap described in paragraph (a)(8)(iv) of this section. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(iv) The cap on the prior savings adjustment calculated in either paragraph (a)(8)(iii)(A)(*1*) or paragraph (a)(8)(iii)(B)(*2*) of this section is equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.226(a)(1).

(iii) Redetermines the offset factor used in determining the negative regional adjustment amount under § 425.656(c)(4) and (5).

(iv) Redetermines the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology under subpart E of this part.

(v) In accordance with paragraph (a)(8) of this section, CMS redetermines the adjustment to the historical benchmark based on the redetermined regional adjustment (as specified under § 425.656), or the prior savings adjustment (as specified under § 425.658), or a combination of these two adjustments.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a) and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT).

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) CMS computes the two-way blend of national and regional growth rates as follows:

(i) Computes national growth rates using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(ii) Computes regional growth rates using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(B) Determine the ACO's regional expenditures as specified under § 425.654.

(iii) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year as specified in paragraph (b)(2)(iv) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(iv) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to the performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(3) CMS computes the ACPT as described in § 425.660.

(4) The two-way blend computed under paragraph (b)(2) of this section and the ACPT are blended together by taking a weighted average of the two.

(i) Absent unforeseen circumstances, the weight applied to the components of the blend is as follows—

(A) Two-way blend is equal to two-thirds; and

(B) ACPT is equal to one-third.

(ii) CMS has sole discretion to determine whether an unforeseen circumstance exists that warrants a reduction to the weight of the ACPT and the reduced weight that will apply to the ACPT.

(5) If an ACO's average per capita Medicare expenditures for the performance year are above its updated benchmark for the year determined as described in paragraph (b)(4) of this section by at least the MLR or negative MSR established for the ACO, CMS will compute a recalculated updated benchmark using the two-way blend described in paragraph (b)(2) of this section.

(i) If the ACO's average per capita Medicare expenditures for the performance year are above the recalculated updated benchmark by a smaller amount than the amount by which they are above the updated benchmark determined as described in paragraph (b)(4) of this section, CMS will use the recalculated updated benchmark to determine the following:

(A) The ACO's responsibility for sharing losses with the Medicare program for ACOs in two-sided models as described under §§ 425.605 and 425.610.

(B) The ACO's financial performance for purposes of monitoring ACO financial performance as described under § 425.316(d).

(ii) If the ACO's average per capita Medicare expenditures for the performance year are below the recalculated updated benchmark, the ACO will neither be responsible for sharing losses with the Medicare program nor eligible for sharing in savings.

(c) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on January 1, 2024, and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) and (b) of this section except that rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

■ 74. Section 425.654 is added to subpart G to read as follows:

§ 425.654 Calculating county expenditures and regional expenditures.

(a) *Calculating county expenditures.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to the relevant benchmark or performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(b) *Calculating regional expenditures.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by:

(1) Weighting the risk adjusted county-level fee-for-service expenditures determined under paragraph (a) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (b)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

■ 75. Section 425.656 is added to subpart G to read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This section applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculation of an average per capita expenditure amount for the ACO's regional service area.* To compute an average per capita expenditure amount for the ACO's regional service area, CMS does all of the following:

(1) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(2) Determines the ACO's regional expenditures as specified under § 425.654 for BY3.

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified using the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(c) *Calculation of the adjustment.* To calculate the adjustment, CMS does all of the following:

(1) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (b)(1) of this section and the average per capita amount of the ACO's historical benchmark determined under § 425.652(a)(1) through (7) and (c)(2), for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Applies a percentage, as determined in paragraph (d) of this section.

(3) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary. The cap is applied as follows:

(i) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(ii) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(4) For negative adjustments, CMS will multiply the regional adjustments calculated in paragraphs (c)(2) or (3) of this section by 1 minus an offset factor equal to the sum of the following—

(i) Proportion of the ACO's BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid; and

(ii) The difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and 1. When calculating the weighted average prospective HCC risk score, the weight applied to the prospective HCC risk score for BY3 for each Medicare enrollment type is equal to the product of the BY3 per capita expenditures for that enrollment type and the BY3 person years for that enrollment type.

(5) The offset factor described in paragraph (c)(4) of this section is subject to a minimum value of zero (representing no offset to the negative regional adjustment) and a maximum value of 1 (representing a full offset to the negative regional adjustment).

(d) *Phase-in of weights used in regional adjustment calculation.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(1) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (d)(5)(i) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in § 425.652(a)(9), CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (d)(1) through (3) of this section used in calculating the regional adjustment.

(e) *Special rules for determining the weights used in the regional adjustment calculation for a re-entering ACO.* For a re-entering ACO whose prior agreement period benchmark was calculated according to § 425.603(c), CMS determines the weight used in the regional adjustment calculation described in paragraphs (b) through (d) of this section by considering the agreement period the ACO is entering into according to § 425.600(f) in combination with either of the following—

(1) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under § 425.603(c)(9) in its most recent prior agreement period; or

(2) For a new ACO identified as a re-entering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under § 425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

■ 76. Section 425.658 is added to subpart G to read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an adjustment to the historical benchmark to account for savings generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more performance years in the Shared Savings Program during this period.

(b) *Calculate average per capita savings amount.* (1) Calculate total per capita savings or losses for each performance year during the 3 years prior to the start of the ACO's current agreement period. CMS applies the following requirements in determining the amount of per capita savings or losses for each performance year:

(i) Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with the requirements of this part, per capita savings for that year will be set to zero.

(iii) For a new ACO identified as re-entering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO's ACO participants were participating.

(2) Take the simple average of the per capita savings or losses calculated in paragraph (b)(1) of this section, including values of zero, if applicable.

(3) Determine the ACO's eligibility for the prior savings adjustment as follows:

(i) If the average per capita amount computed in paragraph (b)(2) of this section is less than or equal to zero, the ACO is not eligible to receive an adjustment for prior savings. The ACO will receive the regional adjustment to its benchmark as described in § 425.656.

(ii) If the average per capita amount computed in paragraph (b)(2) of this section is positive, apply a proration factor to account for any upward growth in the ACO's assigned population in the benchmark years of the ACO's current agreement period as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(c) *Applicability of the prior savings adjustment.* CMS compares the pro-rated average per capita savings amount determined in paragraph (b)(3)(ii) of this section with the regional adjustment described in § 425.656(c), to determine the applicability of the prior savings adjustment, the regional adjustment or a combination of these two adjustments in accordance with § 425.652(a)(8).

■ 77. Section 425.660 is added to subpart G to read as follows:

§ 425.660 Accountable Care Prospective Trend (ACPT).

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS incorporates a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period.

(b) *Determination of ACPT.* An ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. In determining the ACPT for an enrollment type for each performance year, CMS does all of the following:

(1) Projects per capita growth in Parts A and B fee-for-service expenditures for benchmark year 3 (BY3) and each performance year of the ACO's agreement period. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Aged/Disabled.

(2) Calculates one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(A) of this section (the ESRD ACPT) and one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(B) of this section (the Aged/Disabled ACPT). These annualized growth rates will remain fixed over the ACO's agreement period. The annualized growth rate is an annual rate of growth in projected expenditures during the ACO's 5-year agreement period relative to BY3, calculated as follows—

(i) Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period; or

(ii) If annualization as specified in paragraph (b)(2)(i) of this section is determined not to reasonably fit the anticipated growth curve, CMS will apply an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period.

(3) For each performance year, multiplies the applicable annualized growth rate described in paragraph (b)(2) of this section by BY3 truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the annualized growth rate as a flat dollar amount as follows:

(i) The ESRD ACPT is used for the ESRD population.

(ii) The Aged/Disabled ACPT is used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) Adjusts the flat dollar amounts described in paragraph (b)(3) of this section for each performance year for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

(5) Divides the risk adjusted flat dollar amounts described in paragraph (b)(4) of this section by the ACO's historical benchmark expenditures described in § 425.652(a) for each Medicare enrollment type to calculate the percent increase to be included in the blended update factor described in § 425.652(b)(4).

■ 78. Amend § 425.702 by adding paragraph (c)(2)(iii) to read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(2) * * *

(iii) As an organized health care arrangement (as defined at 45 CFR 160.103), and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

* * * * *

■ 79. Amend § 425.704 by revising paragraph (b) introductory text and adding paragraph (b)(3) to read as follows:

§ 425.704 Beneficiary-identifiable claims data.

* * * * *

(b) The ACO must certify that it is requesting claims data about any of the following:

* * * * *

(3) The patients of the organized health care arrangement (as defined at 45 CFR 160.103) in which the ACO is participating with its ACO participants and ACO providers/suppliers, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

* * * * *

§ 425.800 [Amended]

■ 80. Amend § 425.800 in paragraph (a)(4) by removing the references ''§§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610'' and adding in its place the references ''§§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652''.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 81. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 82. Amend § 455.107 by revising paragraph (b)(1)(ii) to read as follows:

§ 455.107 Disclosure of affiliations.

* * * * *

(b) * * *

(1) * * *

(ii) *Change of selection.* A State may, in consultation with CMS, change its selection after it has been made from the option in paragraph (b)(2)(ii) of this section to that in paragraph (b)(2)(i) of this section.

* * * * *

Dated: October 28, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty measures sets will continue to apply for the CY 2023 performance period/2025 MIPS payment year and future years. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Finalized for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

A.1. Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	485
Description:	The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Measure Steward:	American Academy of Dermatology
Numerator:	Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.
Denominator:	All patients aged 18 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.
Exclusions:	N/A
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it addresses a gap in care for patients with psoriasis. This measure assesses for improvement of itch severity of symptoms from index visit to follow up visit, with an achieved score reduction of at least 2 points at follow up. This measure will represent another patient-reported outcome measure for interested parties to report within the MIPS Dermatology specialty set. This measure received conditional support for rulemaking from the Measures Application Partnership (MAP) pending Consensus-Based Entity (CBE) endorsement. While we agreed with the MAP that CBE (for example, NQF) endorsement is preferred, we believed this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Here, guidelines of care for the management and treatment of psoriasis established by the Joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) recommend an itch severity assessment to appropriately assess the degree of pruritus when present.[1] We believed patient-reported outcome performance measures such as this measure ensure that patients and families are engaged partners in their care and can be an effective way to measure the quality of care provided by clinicians. Psoriasis is a common condition, with some 7.5 million people affected in the U.S., leading to millions of clinical visits every year (https://www.aad.org/media/stats-numbers). Chronic pruritis, the symptom assessed in this patient-reported outcome-based measure, has a significant impact on quality of life and is associated with depression and global distress, among other effects.[2] We believed that completion of the measure will support the creation of an effective treatment plan for the patient. Though the required assessment score reduction for this new quality measure is lower than current AAD-NPF guidelines, the measure's current implementation as a MIPS Qualified Clinical Data Registry (QCDR) measure shows an aggregate performance score for this measure of 43.3 percent, indicating a gap in care for achieving 2 point or more reduction in itch severity. The denominator for this measure includes an initial index score for the numeric Rating Scale (NRS) and Visual Rating Scale (VRS) and the ItchyQuant assessment score of 4 or greater. This threshold indicates a clinically realistic goal for patients with an index score of 4 or more (minimal

	to moderate severity) and ensures capture of a more complete denominator eligible patient population to assess for an improvement in itch severity with psoriasis treatment. Additionally, the reliability performance score was high at 0.93 for the 2-point improvement from the index score. Therefore, we believed that incorporating this measure into MIPS will encourage measure adoption which will support clinician adherence to the AAD-NPF clinical guidelines, leading to better symptom control and improved quality of life for patients affected by chronic pruritis. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

Comment: Several commenters supported the addition of the Psoriasis – Improvement in Patient-Reported Itch Severity measure to MIPS. Several commenters appreciated CMS' effort to increase the number of PRO-PM measures. Commenters agreed that measures that assess aspects such as quality of life, or care preferences and patient priorities that are aligned to current clinical guidelines can help advance the current standard of care in ways that would meaningfully improve patient health and reduce overall health costs.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter agreed that patient-reported outcomes are important and appreciated the addition of a new dermatology-specific MIPS measure but was concerned that adequate training and education on using an itch-severity scale for psoriasis has not been expanded properly. The commenter heard from multiple practices there is a lack of education on using these tools.

Response: While this measure does require action on the part of the clinician to administer an itch-severity scale, the tools are publicly available and relatively low burden to administer. There are three different tools available for this measure requiring a numerical value regarding itch severity. Data can be collected by the clinician in a manner that compliments their clinical workflow. As clinicians can choose which measures to report, addition of this measure would add additional flexibility for reporting and provide an additional option for an outcome, high priority measure for the dermatology specialty.

Comment: One commenter opposed the addition of this new measure, in addition to the other new measures proposed, stating they will be administratively burdensome to implement. The commenter stated that quality performance requires a full year of data yet constant changes to workflow and data collection hinder accurate reporting and are burdensome.

Response: We believe this patient experience of care outcome measure fulfills an important gap for dermatologists by including consideration of the patient's voice and experience. While this measure does require action on the part of the clinician, the tools are publicly available and relatively low burden to administer. The tools can be incorporated from multiple data sources allowing flexibility in collection to accommodate clinical workflows. As clinicians can choose which measures to report, addition of this measure would add additional flexibility for reporting and provide an additional option for an outcome, high priority measure for the dermatology specialty. While MIPS quality measures require data collection for the full performance year, individual clinicians and groups can set up their internal systems or work with their third-party intermediaries to efficiently collect data and reduce reporting burden. It is the responsibility of the individual clinician, group, or third-party intermediary to ensure data accuracy.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46458), we are finalizing the *Psoriasis – Improvement in Patient-Reported Itch Severity* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] Elmets, C. A., Korman, N. J., Prater, E. F., Wong, E. B., Rupani, R. N., Kivelevitch, D., Armstrong, A. W., Connor, C., Cordoro, K. M., Davis, D., Elewski, B. E., Gelfand, J. M., Gordon, K. B., Gottlieb, A. B., Kaplan, D. H., Kavanaugh, A., Kiselica, M., Kroshinsky, D., Lebwohl, M., Leonardi, C. L., … Menter, A. (2021). Joint AAD-NPF Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures. Journal of the American Academy of Dermatology, 84(2), 432–470. https://www.jaad.org/article/S0190-9622(20)32288-X/fulltext.

[2] Lee, J., Suh, H., Jung, H., Park, M., & Ahn, J. (2021). Association between Chronic Pruritus, Depression, and Insomnia: A Cross-sectional Study. JAAD International, 3, 54-60. https://www.sciencedirect.com/science/article/pii/S2666328721000122.

A.2. Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	486
Description:	The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessments performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Measure Steward:	American Academy of Dermatology
Numerator:	Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.
Denominator:	All patients aged 18 years and older, with a diagnosis of dermatitis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.
Exclusions:	N/A
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it addresses a gap in care for patients with dermatitis. This measure assesses for improvement of itch severity of symptoms from index visit to follow up visit, with an achieved score reduction of at least 2 points at follow up. This measure will represent another patient-reported outcome measure for clinicians to report within the MIPS Dermatology specialty set. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agreed with the MAP that CBE (for example, NQF) endorsement is preferred, we believed this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Chronic pruritis, the symptom assessed in this measure, has a significant impact on quality of life and is associated with depression, global distress, and sleep impairment among other effects.[1] Though the required assessment score reduction for this new quality measure is lower than current AAD guidelines (https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis), the measure's current implementation as a MIPS Qualified Clinical Data Registry (QCDR) measure shows an aggregate performance score for this measure of 54.9 percent, indicating a gap in care for achieving 2 point or more reduction in itch severity. The denominator for this measure includes an initial index score for the numeric Rating Scale (NRS) and Visual Rating Scale (VRS) and the ItchyQuant assessment score of 4 or greater. This threshold indicates a clinically realistic goal for patients with an index score of 4 or more (minimal to moderate severity) and ensures capture of a more complete denominator eligible patient populations to assess for an improvement in itch severity with dermatitis treatment. Additionally, reliability performance score was sufficient at 0.69 for the 2-point improvement from the index score. Therefore, we believed that incorporating this measure into MIPS will encourage measure adoption which will support clinician adherence to the AAD-NPF clinical guidelines, leading to better symptom control and improved quality of life for patients affected by chronic pruritis. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

Comment: Several commenters supported the addition of the Dermatitis – Improvement in Patient-Reported Itch Severity measure to MIPS. Several commenters appreciated CMS' effort to increase the number of PRO-PM measures.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46459), we are finalizing the *Dermatitis – Improvement in Patient-Reported Itch Severity* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] Lee, J., Suh, H., Jung, H., Park, M., & Ahn, J. (2021). Association between Chronic Pruritus, Depression, and Insomnia: A Cross-sectional Study. JAAD International, 3, 54-60. https://www.sciencedirect.com/science/article/pii/S2666328721000122.

A.3. Screening for Social Drivers of Health

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	487
Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Measure Steward:	Physicians Foundation
Numerator:	Number of patients 18 and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Denominator:	Number of patients 18 years and older.
Exclusions:	N/A
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will address health equity, an important topic that is currently not included within MIPS' quality measure inventory. This measure will assess the rate at which providers screen their adult patients for certain social drivers of health (DOHs); specifically, food insecurity, housing instability, transportation needs, utility help needs, and interpersonal safety. Nearly all physicians within a recent survey indicated that their patients' health outcomes are affected by one or more DOH.[1] The most common DOHs experienced by the respondent physicians' patients were financial instability (34 percent) and transportation needs (24 percent).[1] Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health.[2] Thus, systematically screening patients for social determinants of health and referring them to community-based resources as needed can result in improved health outcomes.[2 3] Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being.[2 3] As an example, early findings from the Accountable Health Communities Model shows those patients within the 'Assistance Track' had 9 percent fewer emergency department visits as compared to their "control group counterparts during the first year following screening" (https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt). Adoption of this measure will address a significant performance gap as 84 percent of physician offices do not screen for all five needs.[4] Therefore, we proposed this measure within the specialty sets of all clinician types to support those interested or already gathering DOH data. We believed the measure supports the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who choose to submit this measure. This measure is consistent with our priority to advance health equity throughout our various programs, including the Quality Payment Program. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive (https://www.cms.gov/pillar/health-equity). This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agreed with the MAP that endorsement of measures is preferred, we believed that the inclusion of this measure serves an important purpose in advancing quality measurement in MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Here, the U.S. Preventive Services Task Force (USPSTF), which is charged by section 915 of the Public Health Service Act to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations," specified the screening for key DOHs in its portfolio of recommendations (https://www.acpjournals.org/doi/10.7326/M20-0730). In a cross-sectional study, DOH were associated with 37.7 percent of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017, including both direct contributions and indirect contributions through other factors. DOH's direct contribution accounted for 5.8 percent of the variation after controlling for patient demographic characteristics, clinical risk, and supply of health care resources. These findings suggest that addressing DOH is important for reducing geographic spending variation and improving the value of health care. The evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[5 6] Another cross-sectional study found that screening for all five social needs was reported by 15.6 percent of practices, whereas 33.3 percent of practices reported no screening, suggesting that few US physician practices screen patients for all five key social needs associated with health outcomes.[4] We also proposed a similar measure for the Hospital Inpatient Quality Reporting (IQR) Program. For further information on the Screening for Social Drivers of Health measure finalized for the Hospital IQR Program in the FY2023 IPPS/LTCH PPS final rule (https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf), we refer readers to 87 FR 49202 through 49215. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

Category	Description

Comment: Numerous commenters strongly supported the inclusion of this new health equity measure in MIPS. Several commenters noted this measure's adoption in the Hospital IQR Program and recommended that CMS apply this measure across other programs for alignment. Several commenters agreed this is a high priority measure in MIPS.

Commenters' stated reasons for supporting this new measure included:

- The country cannot improve health outcomes or reduce health care costs without addressing DOH.
- Given the impact of DOH, this measure is a first step in the process of addressing these factors to achieve value and equity.
- CMS uses hundreds of measures to assess the quality of health care and to direct health care spending, but until this new measure, had zero quality measures that capture these drivers of health in federal payment programs.
- Adoption of this measure will improve access and health outcomes for all patients and to maximize the use of limited government resources to help those most in need.
- The measure is a vital step toward collecting standardized data to support a data-driven approach to addressing health-related social need and informing potential future measure development.
- The particular emphasis on food insecurity and risk for malnutrition can help facilitate access to appropriate and timely interventions for patients.
- DOH has a profound impact on patients and the physicians, particularly in the wake of the public health emergency.
- Interpersonal safety is a key domain, since one in four women in their lifetime will experience intimate partner violence.
- All health care interested parties should take a leading role in creating a more inclusive environment and providing accessible care, including through screenings for health-related social needs.

Response: We appreciate commenters' support for this measure. We will continue to work toward alignment of measures across CMS programs. We will take this feedback into consideration during the public notice and comment cycle for possible implementation in future years.

Comment: Several commenters requested that CMS also implement the Screen Positive Rate for Social Drivers of Health measure in MIPS that was recently adopted for the Hospital IQR Program. Commenters stated that this would mitigate the risk of measure fragmentation, physician and patient burden, and would align measures across hospital and provider payment programs.

Response: We thank the commenters for their input and will take this feedback regarding the Screen Positive Rate for Social Drivers of Health measure into consideration during future rulemaking. We will continue to work toward alignment of measures across CMS programs.

Comment: One commenter supported this new measure but indicated that additional steps are needed to lead change, in part through connection to and partnership with community-based organizations. One suggestion by the commenter was to have measures evaluating referral rate and completion rate for receiving services after positive screens. Another commenter urged CMS to consider developing a companion measure to document if the practice coordinates care based on patient responses, such as connecting patients with community resources. Another commenter recommended that CMS consider a more comprehensive measure that required a plan of action or targeted intervention to meet the patients' needs and assess improvements for at-risk populations.

Response: We thank the commenters for their feedback and will take it into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. Additionally, we encourage the commenters to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter supported this new measure and the role nurses play in conducting screening for social drivers of health in any setting. The commenter encouraged CMS to monitor and study implementation to gain a profile of clinical practices that report on the measure, who within the practice is performing the screening itself, and to identify potential implications for promoting team-based care. In addition, the commenter stated that it would be useful to understand if the screening question for utility difficulties is sufficient to capture access to telehealth modalities.

Response: We will monitor data submitted and any trends that may impact scoring or reporting of the measures; however, we do not intend to prescribe each clinician or group's clinical workflow. As the measure steward, we will take this feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. However, at this time, we are not requiring the use of a particular tool to screen for DOH. As such, there is no specific requirement to capture access to telehealth modalities in the screening question for utility difficulties.

Comment: One commenter strongly supported CMS' position that social needs are a significant driver of health, and that greater screening and structured data collection on social needs is critical to more rigorously understand and document that impact. The commenter strongly encouraged CMS to coordinate with other HHS agencies to align protocols and screening across programs. The commenter also requested that CMS coordinate with states, particularly among Medicaid recipients, to reduce burden. The commenter stated that it is critical to share standardized social needs data with providers, community-based organizations, and others to improve efficiency, reduce data collection burden on both providers and recipients, and coordinate efforts among all relevant interested parties within a community.

Response: We believe this measure is an important first step for eligible clinicians to gather DOH data and advance health equity within MIPS and improve health outcomes. As the measure steward, we will take this feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years.

Comment: One commenter supported this new measure in MIPS but urged CMS to delay the implementation of this measure until the end of the public health emergency. The commenter stated practices are suffering under increased regulatory reporting requirements while the public health emergency is still in effect and urged CMS to consider the strain on practices the public health emergency has caused. The commenter, as well as other commenters, were concerned by the data collection burden associated with the measure and encouraged CMS to balance changes to MIPS against the growing data collection burden upon practices.

Response: While we acknowledge the commenters' concerns, we believe this is an important process measure to support the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who chose to implement this measure. We tried to design this measure with flexibility to reduce burden on clinicians. For example, this measure allows the use of any tool to screen for DOH and therefore, we believe the clinician can determine what tool/process works best for their clinical workflow. More generally, because clinicians have the flexibility to choose which measures to report, the adoption of this measure does not place additional burden on clinicians. Clinicians are not required to select this measure to report. Therefore, if the clinician considers this measure overly

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	burdensome, he or she may opt to report a different measure. Instead, the addition of this measure enhances clinician choice when they select which measures to report. We are also committed to lessening the burden of reporting quality measures through Meaningful Measures 2.0. **Comment:** One commenter stated that family physicians play an important role in helping identify health-related social needs of patients. However, clinicians cannot be held accountable for providing resources to address individual health-related social needs when those resources do not exist in the community, and the commenter stated that CMS should incentivize the development and use of community care organization, or other payer and provider referral systems to ease the burden on all parties to address patients' social needs. The commenter urged caution when considering measurement of this activity as an indicator of care quality in a single health care setting and that the measure should address factors within the control of the individuals or organizations being measured. Another commenter agreed that DOH and inequities in health reach far beyond the control of a medical team and are rooted in societal policies impacting equity in education, housing, and income. The commenter firmly believed that healthcare providers and teams must never be accountable for and paid based on the amelioration of patients' DOH. **Response:** This measure is a first step in the process of collecting DOH that will support advancing health equity and improving health outcomes. We believe this measure is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who chose to implement this measure. This measure does not hold clinicians accountable for and paid based on improvements in patients' DOH. This measure purely focuses on the completion of screening for DOH patient information. It does not require a referral to services or any other action on the part of the clinician, nor does it penalize clinicians for those patients who screen positive for any of the social determinants within the measure. We do note, however, that the information that a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Because clinicians have the flexibility to choose measures to report and this measure's performance is just assessing the screening of patients, we do not believe there would be unintended consequences for the clinicians or the patients they serve regarding things such as clinician/patient relationship, patient care, and clinician performance. **Comment:** One commenter had significant concerns about a quality measure to assess clinician referrals to community-based services to address DOH. The commenter stated this measure is more appropriate for Federally Qualified Health Centers (FQHCs) that have funding for hiring staff who will connect patients with external resources. If CMS wants private and public health organizations to measure equity, the commenter stated, they should consider allowing these organizations to apply for the same grants made accessible to FQHCs. Additional commenters agreed that this measure is most appropriate for facility-level accountability since facilities have the capacity, including staff resources, to conduct these assessments on all patients. One commenter indicated that if a clinician or practice has the capacity to screen all patients, then they should have the option to choose this measure. However, clinicians who might find it difficult to conduct these screenings on all patients due to limited time with the patient, lack of resources, and workflow issues should not be required to report this measure. Another commenter believed that while the data collected in this measure will be valuable, this measure may be more appropriate if reported at the system or regional level. **Response:** While we acknowledge the commenters' concerns, we note that no clinician is required to choose to report this measure. We believe this is an important process measure for clinicians that supports the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure will hold clinicians/groups accountable for screening all patients for DOH, a first step towards this becoming a standard of care that drives meaningful impact and quality outcomes for impacted patients. Clinicians choosing to report on this measure would meet the measure's quality action by completing a screening for all patients 18 years and older once during the performance period. As this measure is only assessing that all patients are screened for DOH and it is not prescriptive in an assessment tool, we don't believe that the measure should only be available at the facility-level. Clinicians can enact any clinical workflow and screening tool combination that works best for their practice, and we believe this is an important aspect to consider when assessing a patient's health and implementing a care plan at both at the clinician and facility-levels. **Comment:** One commenter valued the importance of systematically addressing DOH affecting individual patients, which can help improve the early identification or risk and/or need and prompt referral to relevant sources. In the Inpatient Prospective Payment System (IPPS) rule, CMS noted how providers may use a self-selected screening tool and collect these data in multiple ways. The commenter urged CMS to allow clinicians reporting this measure to use a self-selected screening tool and collect these data in ways that best accommodate the populations they serve and their individual needs. In addition, the Hospital IQR Program is a pay-for-reporting program, while payments are tied to performance under MIPS. The commenter requested that CMS clarify how it intends to set benchmarks and evaluate performance under this measure, which, as proposed, requires screening of all patients with no exclusions. Additional commenters also supported flexibility in the selection of screening tools to better understand DOH and their impact before standardizing screening tools across care settings, geographic locations, and patient populations. One commenter stated that over time CMS should require the use of one set of reliable and commonly used tools. **Response:** We will take this feedback into consideration during the annual revisions for possible implementation in future years. The measure allows use of any tool to screen for the DOH and therefore, the clinician can determine what tool/process works best for their clinical workflow. Because clinicians have the flexibility to choose this measure and it only assesses for the screening of patients, we do not believe there would be unintended consequences for the clinicians or the patients they serve regarding things such as clinician/patient relationship, patient care, and clinician performance. As described in the CY 2023 PFS proposed rule, (87 FR 46460 through 46461) performance is based upon screening DOH for all denominator eligible patients. Scoring analytics for data completeness and performance, in order to establish a benchmark, will be consistent with other measures within MIPS, which are established pursuant to 42 CFR § 414.1380(b)(1)(ii). **Comment:** Several commenters were concerned over the lack of standardized and valid tools across all domains included in the measure and agreed that the domains should align with data standards such as the HL7 Gravity Project and USCDI (for example, only food insecurity has been finalized and uses a gold standard tool). Commenters stated that the typical measure development process is needed for this measure rather than "the trial-and-error data submission and reporting approach currently proposed." One commenter recommended utilizing a restructured version of the measure to create a more standardized approach with identified tools to effectively screen for DOH before inclusion into MIPS. **Response:** While we acknowledge the commenters' concerns, the measure allows use of any tool to screen for the DOH and therefore, we believe the clinician can determine what tool/process/data source works best for their clinical workflow. There are standardized validated tools available for these screenings. This measure does not currently require the capture of granular data from all DOH domain screening results; therefore, it is not necessary to require the use of a specific tool or standardized approach beyond the measure specification as clinicians/groups begin the process of incorporating this screening into their clinical workflow. Adoption of screening DOH in all patients is a critical first step in identifying and addressing DOH deficiencies. As

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	noted above, we strongly encourage, but do not require, clinicians to capture and exchange this information in a standardized format so that this data can be made available across the care continuum. **Comment:** Several commenters indicated that the measure as a process measure determines whether the physician screened for these potential barriers but does not drive the providers to take a specific action to address DOH. One of these commenters stated that in the proposed rule, CMS noted that this could prompt physicians and other providers to make referrals as necessary but does not provide details of what is expected or what methods or tools physicians should use to collect this information. **Response:** As proposed (87 FR 46460 through 46461), this measure does not require specific referrals by the clinician to address DOH or require the use of specific tools to collect such information. We believe public input will be valuable in the continuing development of our health equity quality measurement efforts and broader commitment to health equity, and we intend to review data submitted for this measure to help define and determine the future resources necessary to begin addressing DOH. As the measure steward, we will take this feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. We encourage the commenters to reach out to measure developers/stewards to develop new measures based upon this clinical topic for submission to the Call for Measures for possible future implementation. **Comment:** One commenter, in support of this new measure, stated that assessment of social needs for every patient aligns with their goal of advancing equity and well-being by 2030. However, the commenter had concerns about the data required for this measure, stating that the required data elements may not be reliably documented using discrete data fields that can be captured electronically. The commenter further described that this potential gap in electronic feasibility may place an additional burden on health systems as they attempt to capture the required data. Similarly, another commenter indicated that the proposed rule on this measure stated that electronic specifications are not being developed at this time. In general, the commenter supported this measure concept; however, after years of reported physician burden related to quality measures, the commenter cannot support a manually collected and reported measure. The commenter stated that this "regressive proposal" does not support other HHS requirements to reduce paperwork. The commenter urged the agency to create electronic specifications for any measure, including this one, and ensure that the reporting requirements align with the United States Cored Data for Interoperability (USCDI) data element inclusion and vendor adoption to standardize collection and reporting for these important health equity topics. The commenter stated currently USCDI v3 includes data elements that would assist in collecting this information; however, the ONC has yet to mandate the adoption for vendor systems. Another commenter recommended that CMS delay this measure until electronic specifications have been developed and until USCDI v3 is fully adopted by all electronic health record systems. **Response:** While we appreciate the commenters' concerns, we believe this measure is an important first step for eligible clinicians to gather DOH data and advance health equity within MIPS and improve health outcomes. This measure data would then be available for assessment of trends across health systems and may allow for further delineation of health inequities across different regions of the country, which is an important first step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures, however, not all measures are submitted for the eCQM collection type as this is not currently a requirement prior to submitting a measure for consideration into Call for Quality Measures. We endeavor to include different collection types within our quality measure inventory to allow flexibility in reporting. This measure was submitted to the Call for Quality Measures for the MIPS CQM collection type only by a different entity, and we recently assumed stewardship of this measure. Therefore, this measure is not currently available for additional collection types for implementation for the 2023 performance period. However, as the measure steward, we will take this feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. Moreover, we do not believe that electronic specification of this measure is necessary to proceed with implementation at this time; however, we expect and encourage developers to identify ways to automate collection of information about whether a screening has been done. We further appreciate commenters' concerns about the interoperability of DOH data collected as part of screening activities to support this measure. We note that the measure allows use of any tool to screen for the DOH and therefore, the clinician can determine what tool/process/data source works best for their clinical workflow. However, we recommend use of screening instruments that maximize opportunities to collect and analyze standardized, quantifiable, and actionable data. While we did not propose additional requirements for the tools used to collect screening data under this measure, we strongly encourage the use of tools with screening instruments that are validated, widely used, and which support capture of data in a standardized way (that is, tools coded in accordance with health IT vocabulary standards) so that this data can be made available across the care continuum. The use of validated screening instruments that use available health IT coding terminology will enable greater standardization of social needs data and facilitate interoperable exchange of such data. There are currently a number of tools available to eligible clinicians that incorporate coded screening instruments, including the Accountable Health Communities Health Related Social Needs Survey (AHC HRSN) developed for CMMI's Accountable Health Communities Model[7] as well as other tools identified by key stakeholders, such as the Social Interventions Research and Evaluation Network (SIREN).[8] These screening instruments incorporated within these tools use value sets identified by the Gravity Project, a stakeholder-led initiative that evaluates the validity and appropriateness of available assessment instruments to screen for various domains (https://thegravityproject.net/), and are included in the NLM Value Set Authority Center (VSAC).[9] Questions and responses in these screening instruments are mapped to health IT vocabulary standards (that is, have LOINC coding terminology). More information and links to these value sets can be found through the Interoperability Standards Advisory maintained by the Office of the National Coordinator for Health IT (https://www.healthit.gov/isa/representing-social-determinants-health-screening-assessments). Finally, ONC has also identified these value sets for representing SDOH assessment data in certified health IT products as part of the United States Core Data for Interoperability (USCDI) beginning with USCDI Version 2 (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi). While not yet required under the ONC Health IT Certification program, developers of certified health IT may upgrade their certified health IT products to USCDI Version 2[10] to support the availability of information about DOH with other members of the care team. We encourage eligible clinicians to work with their vendors to explore these options. We appreciate the commenters' support for alignment with USCDI Version 3 and encourage review of information about how USCDI is aligned with available tools for capturing coded DOH information, as well as opportunities for health IT developers to use updated versions of USCDI that have not been adopted in regulation.[10] **Comment:** Several commenters expressed concerns related to how the measure was designed and the lack of measure specifications. One commenter stated that the measure does not provide information on what encounters are included and appears to be specified so broadly that there is significant potential for the measure to be attributed to specialists and others for whom requiring this broad screening approach would not be appropriate. Another commenter stated that there was no information provided on requirements for the frequency of data collection or the measure timeframe, how to account for patients who visit the provider or practice multiple times a year, or how the data will be used. Another commenter stated this measure as currently defined does not provide sufficient detail for clinician to understand whether this measure would be applicable to them. The commenter did not know if the measure denominator

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	intended to capture only those patients with an established relationship with primary care or would other encounters or procedures also be counted, and whether patients who reside in a skilled nursing facility included or excluded. **Response:** This is a process measure that would be required once per performance period for patients meeting the denominator criteria. The measure was based on the Accountable Health Communities universal screening protocol (https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf) with the intent to ensure all patients of MIPS-eligible clinicians are screened. Therefore, the intended denominator population is all patients 18 years of age and older with an encounter during the performance period. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. As is the case with all adopted measures, the detailed technical measure specifications for this measure will be posted to the QPP Resource Library at the end of the year and can then be reviewed for applicability and appropriateness to each clinician/group. The measure does not prescribe how a clinician or group should implement this measure into their workflow. **Comment:** Several commenters expressed the lack of alignment of the measure specifications for this measure in MIPS when compared to the specifications for the Hospital IQR Program (87 FR 49202 through 49215). For example, in the 2023 IPPS final rule, the Screening for Social Drivers of Health measure's numerator definition allows a hospital to screen a patient on "one or all" of the five factors, while the measure as proposed for MIPS does not provide this level of detail and is not consistent with previous statements regarding the need to ensure consistency in specifications of related measures across CMS quality programs. In addition, commenters noted the lack of exclusions included in the measure specifications since the inpatient version finalized excludes (1) patients who opt out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay. The commenters believed that these are important exclusions and should be included in the MIPS version of this measure. **Response:** While we acknowledge the commenters' concerns, the DOH measures are not intended to be consistent between the two programs. At this time, we believe that this measure can be implemented into MIPS without the exclusions found within the Hospital IQR Program. The Hospital IQR Program DOH measure exclusions in question are (1) patients who opt out of screening; and (2) patients who themselves are unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay. Since MIPS also includes outpatient and ambulatory settings and includes clinicians that report as individuals and groups, we believe these exclusions are not necessary because the first exclusion would remove these patients from the denominator eligible patient population, removing them from the quality action assessment creating the potential for use of this exclusion in place of screening in addition to not being able to collect any data on these patients. We believe this subset of patients who refuse to do the screening, would be something all clinicians/groups would encounter and it is their responsibility to outline the importance of completing such screening to their care. The second exclusion is specific to the inpatient care setting only and would therefore not apply to outpatient and ambulatory encounters. However, we will monitor feedback received on this measure for possible revisions in future program years. The FY 2023 IPPS/LTCH PPS proposed rule had two instances in the preamble in which a technical error was made by stating screening was for "one or all" of the five HRSNs (87 FR 28502 and 87 FR 28503) This was corrected to "all five HRSNs" in the FY 2023 IPPS/LTCH PPS final rule as per the measure specifications that we referred to throughout the preamble of the CY 2023 PFS proposed rule (87 FR 28497) in which we proposed to adopt a Screening for Social Drivers of Health measure and as was reviewed as part of the MUC review process (87 FR 49208). The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement (87 FR 49193). We believe that each element within a domain is important as together they help clinicians identify, prioritize, and act on health disparities. We will take this feedback into consideration during the annual revisions for possible implementation in future years. **Comment:** Many commenters expressed concern over the lack of adequate measure testing cited in the proposed rule and stated that the measure must be tested for reliability and validity prior to implementation in MIPS. Another commenter indicated that CMS continues to implement costly testing requirements but does not hold MIPS quality measures to the same QCDR measure testing standards. If implemented effectively, the measure could provide meaningful feedback for clinicians to act. One commenter urged CMS to delay adoption of this measure until testing has been completed to ensure the measure is methodologically sound before using this measure in a reimbursement program. Several commenters stated that this measure should not be considered for use in MVPs until best practices and education are widely available and the measure is adequately specified and tested. Several commenters requested this measure remain voluntary in MIPS. Another commenter believed that prior to implementation of this measure in MIPS, concerns regarding necessary specification and testing must be addressed and endorsement by the NQF should be achieved. **Response:** As we have previously stated (83 FR 53636; 84 FR 62954), we request that interested parties consider when submitting a quality measure for possible inclusion whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing." While we consider whether or not a measure is fully tested, it is not the only relevant standard. This is a screening data collection measure. We believe that achieving health equity is a pressing issue which deserves serious focus and rapid action. This measure is an important first step for data collection of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure was not proposed for use within any MVPs, and therefore has not been finalized for use within any MVPs at this time, but we believe that clinicians should still have the choice to report it. If clinicians choose to report this measure, it will allow them to begin assessing health inequities within the scope of MIPS reporting. We believe this is vital to allow further testing and development of additional health equity measures. In addition, the five domains of this measure were adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement and we encourage its use for data analysis to further understand the factors we have highlighted. This provides a scientific basis and use case for the five domains included in this measure to facilitate reliable data collection. We believe this is an important step towards the future development of outcome-based measures within this topic. We agree with the commenter that endorsement of measures is preferred, however this is not required for measures included in MIPS. Additionally, we did not identify any endorsed measures on this topic for MIPS. We believe that the inclusion of this measure serves an important purpose in advancing quality measurement in MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. While we consider whether or not a measure is fully tested, it is not the only relevant standard. This measure supports health equity, a national healthcare priority and is responsive to filling a critical gap in MIPS. This measure does not result in negative unintended consequences as described in the Blueprint (https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection) such as overuse or inappropriate use of care or treatment, or limiting access to care. Therefore, based upon the importance of this topic and need to address this national healthcare priority, we are finalizing the measure. **Comment:** A commenter stated that there is lack of equivalence with the Accountable Health Communities Model leading to excessive burden on physicians and the measure could also harm the patient-provider relationship. Another commenter suggested that CMS begin the DOH process by measuring organizations on health disparities and by collecting a standardized dataset of characteristics until the industry determines which interventions to reduce these disparities are effective.

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Response: The measure was based on the Accountable Health Communities universal screening protocol with the intent to ensure all patients of MIPS-eligible clinicians are screened. The following five domains were selected to screen for social risk factors in Medicare and Medicaid beneficiaries under the Accountable Health Communities Model: food insecurity; housing instability; transportation needs; utility difficulties; and interpersonal safety. In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected because they can be assessed across the broadest spectrum of individuals in a variety of settings. This measure is a first step in the process of collecting data on DOH that will support advancing health equity and improving health outcomes. This measure purely focuses on the completion of screening for DOH patient information. It does not require a referral to services or any other action on the part of the clinician, nor does it penalize clinicians for those patients who screen positive for any of the DOH within the measure. We do note, however, that the information that a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. Because clinicians have the flexibility to choose this measure, for traditional MIPS, as it was not proposed for inclusion within any MVPs, and it only assesses for the completion of screening for DOH, we do not believe there would be unintended consequences, including harm, to the clinicians or the patients they serve. Instead, it measures the collection of important information regarding the patient that can help to achieve quality clinical outcomes. Additionally, screening for DOH may allow clinicians insight into their patients' life that would allow them to create care plans tailored specifically to patient's assessed social limitations that could impede their overall healthcare delivery and status. The current measure does not require intervention or granular data capture of health disparities, and therefore, allows time for continued development of DOH interventions and standardization of this data.

Comment: Several commenters were concerned that clinicians may become focused on screening for DOH without addressing them and suggested coordinated efforts across the health care system including how to best address patients' needs and provide interventions is required first. In addition, prior to holding providers accountable for screening patients and the associated data collection, commenters recommended CMS simultaneously implement an education effort explaining the importance of the information, best practices for collecting the data and intentions for use, as well as education related to privacy and security. Two additional commenters agreed, noting that implementation of this measure is premature until necessary resources and tools to address the individual's needs for any one of the selected DOH are widely available. Another commenter suggested CMS support providers through funding opportunities to have the necessary infrastructure to gather data.

Response: We will take this feedback into consideration for future policymaking. This measure is only looking at the percentage of patients screened and does not require an action to address these needs if screening is positive. As previously mentioned, this measure was based on the Accountable Health Communities universal screening protocol with the intent to ensure all patients of MIPS-eligible clinicians are screened. There are publicly available screening tools, including the Accountable Health Communities screening tool (https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf). While we acknowledge the commenters' concerns, we believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics which would include providing patients with the appropriate resources and interventions. We agree that the data submitted for this measure will be a significant step towards addressing the role of DOHs in improving health equity and is one of our quality improvement goals, which can then be utilized to help define and determine resources necessary to begin addressing DOH. We agree that should screening for DOH become a standard of care, the vital next step would be to work across the healthcare system to ensue resources are in place that address and alleviate identified patient social needs to further drive quality health outcomes in all patients. As with all quality measures, the technical specification provides information on how to implement the measure, including clinical recommendation statements and rationale, and will be posted in the December timeframe for review. There are standardized validated tools available for these screenings. This measure remains optional for traditional MIPS, allowing for clinician choice in choosing measures to report. We believe the information obtained from this measure would be managed with the same level of privacy and security as any other medical data related to the patient.

Comment: One commenter did not support adding this new measure to MIPS, stating that the measure does not address the need for referral and bidirectional communication with community-based services to track outcomes. The commenter urged CMS to examine the challenges to linking data from medical and nonmedical sources and encouraged CMS to streamline and align the collection of data related to equity measures across settings and care providers to reduce administrative burden and to avoid a patient being asked the same sensitive questions repeatedly at various points along the care continuum.

Response: We thank the commenter for their comment. This measure purely focuses on the completion of screening for DOH patient information. It does not require a referral to services or any other action on the part of the clinician, nor does it penalize clinicians for those patients who screen positive for any of the social determinants within the measure. We do note, however, that the information that a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided regardless of the availability of community care organizations and whether patients are referred to such organizations.

While we acknowledge the commenter's concerns, we believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. We agree that should screening for DOH become a standard of care, a vital next step would be to ensure bidirectional communication with community-based services/resources to endeavor to alleviate DOH needs to further drive quality outcomes in all patients. We agree with the commenter's suggestion and continue to work towards data element standardization and alignment of measures across programs, to streamline capture of DOH data, as these are current areas of interest and actively being examined and researched.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46460 and 46461), we are finalizing the *Screening for Social Drivers of Health* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

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[7] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.
[8] See the SIREN project at the University of California San Francisco at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison. The National Committee for Quality Assurance has also developed a list of screening tools in the NCQA Social Need Screening and Intervention measure in HEDIS Volume 2: Technical Specifications for Health Plans, 705-717. The proposed measure is available at: https://www.ncqa.org/wp-content/uploads/2022/02/04.-SNS-E.pdf.
[9] VSAC is a repository for clinical coding vocabularies that define clinical concepts to support interoperable health information exchange and is provided by the National Library of Medicine in collaboration with the Office of the National Coordinator for Health Information Technology and CMS. See https://vsac.nlm.nih.gov/.
[10] Office of the National Coordinator for Health IT. (2022). Standards Version Advancement Process. Available at: https://www.healthit.gov/topic/standards-version-advancement-process-svap.

A.4. Kidney Health Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	488
Description:	Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.
Measure Steward:	National Kidney Foundation
Numerator:	Patients who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.
Denominator:	All patients aged 18-75 years with a diagnosis of diabetes at the start of the measurement period with a visit during the measurement period.
Exclusions:	Denominator Exclusions: 1. Patients with a diagnosis of End Stage Renal Disease (ESRD); 2. Patients with a diagnosis of Chronic Kidney Disease (CKD) Stage 5; 3. Patients who have an order for or are receiving hospice or palliative care.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it focuses on nephrology and the critical condition of diabetes, both identified as gaps within MIPS' quality measure inventory. We identified these gaps as priorities for future quality measures. This measure will replace and improve upon the existing measure Q119: Diabetes Medical Attention for Nephropathy. This measure is more specific than measure Q119 as it requires utilizing multiple tests, estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) tests, to assess a patient's kidney health. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agreed with the MAP that CBE (for example, NQF) endorsement is preferred, we believed this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Approximately 9 percent of American adults currently have CKD,[1] and it is projected that by 2030 approximately 17 percent of Americans aged 30 years and older will have CKD.[2 3] In the U.S. from 2002-2016, the burden of CKD, defined as years of life lost, years living with disability, disability-adjusted life years, and deaths, outpaced changes in the burden of disease for other conditions.[4] Patients with CKD are readmitted to the hospital more frequently than those without diagnosed CKD.[2] This public health issue is driven largely by the impact of diabetes—the most common comorbid risk factor for CKD.[2 4] The intent of this process measure is to improve rates of guideline-concordant kidney health evaluation in patients with diabetes. According to the American Diabetes Association (ADA) 'Standards of Medical Care in Diabetes', "Albuminuria and eGFR should be monitored regularly to enable timely diagnosis of CKD, [and] monitor progression of CKD…".[5] Higher rates of such evaluations are believed to improve the rate identification and, potentially, the treatment or delayed progression of CKD in this high-risk population. Early detection is critical in order to initiate timely care as the disease may silently progress to advanced stages (https://www.aafp.org/afp/2017/1215/p776.html). Annual kidney health evaluation in patients with diabetes to determine risk of CKD using estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) is recommended by clinical practice guidelines and has been a focus of various local and national health care quality improvement initiatives, including Healthy People 2020.[2] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

Comment: Several commenters supported this new measure and removal of measure Q119: Diabetes Medical Attention for Nephropathy measure if finalized. Several commenters agreed that this new measure represents an important opportunity to improve the number of adult patients with diabetes who receive an annual kidney health evaluation as identification of kidney disease is critical to slowing its progression and maintain kidney health.

One commenter stated this measure fills a gap in care and provides a more comprehensive assessment of kidney health. The measure is supported by a strong evidence base and was tested at the individual and clinician group levels and the commenter believed that monitoring of kidney health is very important to confirm correct dosages of medications and evaluation of the progression of CKD. Another commenter supported this new measure stating it is part of the of the Core Quality Measure Collaborative (CQMC) ACO/PCMH/Primary Care core measures set. Another commenter stated adoption of this new measure will incentivize appropriate screening of individuals at risk for CKD and should address the challenge of underdiagnosis that often contributes to missed opportunities to delay progression of kidney disease, dialysis, and preventable cardiovascular events. Another commenter applauded CMS for its efforts to mitigate the impact of CKD among Medicare beneficiaries and its associated complications. Several commenters indicated this measure is concordant with recommendations from both the National Kidney Foundation and the American Diabetes Association.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter supported the inclusion of this measure in MIPS as it should help focus efforts on this critical aspect of care. The commenter believes the measure will help promote awareness about kidney health evaluations to allow early identification and help reduce the current gap in delivery of evidence-based kidney care to patients with diabetes.

Category	Description
However, the commenter believes there should be no upper age limit, especially considering the aging population and the importance of CKD in the older population. The specified denominator exclusions should remove most patients who are less likely to benefit from early identification of CKD and initiation or intensification of treatment, so there is no reason to cap the measure at 75 years. The commenter stated that if patients do not meet the exclusion criteria, they should be regularly screened and appropriately treated if identified as having diabetic kidney disease, regardless of age. **Response:** We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. **Comment:** Several commenters were alarmed to see the proposed new exclusion of those receiving palliative care from this measure. Palliative care seems to be equated with hospice, which is incorrect. Excluding those on hospice, who are at the end of life, is appropriate while those receiving palliative care could live for years longer. According to the commenters, palliative care is appropriate at any point in a serious illness and can be provided along with any curative, disease-modifying treatment. The commenters requested that this exclusion be removed as it perpetuates the harmful misconception that palliative care and hospice are the same thing when they are not. **Response:** We agree that palliative care is appropriate at any point in a serious illness and can be provided with any curative, disease-modifying treatment. It is our expectation that clinicians know the difference between palliative and hospice care and would not equate them. Palliative care is generally provided by an interdisciplinary medical team that focuses on the patient as a whole and would be inclusive of the types of services addressed by this measure as needed. Due to the complexities of care required for this population, clinicians that support patients receiving palliative care may inadvertently not perform well from the aspect of producing quality metrics (https://doi.org/10.1186/s12913-019-3961-0). However, we encourage clinicians to provide care as they determine best supports all patients during their healthcare journey even if the patient population is not included within the targeted denominator of a given measure specification. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46462), we are finalizing the *Kidney Health Evaluation* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] National Kidney Foundation. (2019). About Chronic Kidney Disease. Retrieved October 9, 2019, from https://www.kidney.org/atoz/content/about-chronic-kidney-disease.

[2] Saran, R., Robinson, B., Abbott, K. C., Agodoa, L., Bragg-Gresham, J., Balkrishnan, R., Bhave, N., Dietrich, X., Ding, Z., Eggers, P. W., Gaipov, A., Gillen, D., Gipson, D., Gu, H., Guro, P., Haggerty, D., Han, Y., He, K., Herman, W., Heung, M., … Shahinian, V. (2019). US Renal Data System 2018 Annual Data Report: Epidemiology of Kidney Disease in the United States. *American Journal of Kidney Diseases: the Official Journal of the National Kidney Foundation*, *73*(3 Suppl 1), A7–A8. https://doi.org/10.1053/j.ajkd.2015.05.001.

[3] Hoerger, T. J., Simpson, S. A., Yarnoff, B. O., Pavkov, M. E., Ríos Burrows, N., Saydah, S. H., Williams, D. E., & Zhuo, X. (2015). The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative. *American Journal of Kidney Diseases: The Official Journal of the National Kidney Foundation*, *65*(3), 403–411. https://doi.org/10.1053/j.ajkd.2014.09.023.

[4] Bowe, B., Xie, Y., Li, T., Mokdad, A. H., Xian, H., Yan, Y., Maddukuri, G., & Al-Aly, Z. (2018). Changes in the US Burden of Chronic Kidney Disease From 2002 to 2016: An Analysis of the Global Burden of Disease Study. *JAMA Network Open*, *1*(7), e184412. https://doi.org/10.1001/jamanetworkopen.2018.4412.

[5] American Diabetes Association (2021). 11. Microvascular Complications and Foot Care: *Standards of Medical Care in Diabetes-2021*. *Diabetes care*, *44*(Suppl 1), S151–S167. https://doi.org/10.2337/dc21-S011.

A.5. Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Category	Description
NQF # / eCQM NQF #:	1662 / N/A
Quality #:	489
Description:	Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.
Measure Steward:	Renal Physicians Association
Numerator:	Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period.
Denominator:	All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria.
Exclusions:	Denominator Exclusions: Patients receiving RRT.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this nephrology measure because it focuses on chronic kidney disease and diabetes. We identified both conditions as gaps within MIPS and priority areas for future quality measurement. This measure received support for rulemaking by the MAP and was endorsed by the NQF (https://www.cms.gov/files/document/2022-muc-list-program-specific-measure-needs-and-priorities.pdf). This measure is intended to increase the number of patients receiving high-quality nephrology care by focusing on using clinically recommended CKD therapeutic interventions to treat diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria). Patients with these conditions who are treated with ACE inhibitors or ARB therapy have been shown to have lower rates of kidney failure, better cardiovascular outcomes, and lower mortality (https://pubmed.ncbi.nlm.nih.gov/23732715/). Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

Comment: One commenter supported the inclusion of this new measure, as this measure is aimed at increasing the number of patients with CKD and albuminuria who are prescribed ACE inhibitor or ARB therapy. The commenter stated that ACE inhibitors and ARBs are recommended as preferred agents for diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria), even in the absence of hypertension. In these diseases, they lower blood pressure, reduce proteinuria (albuminuria), slow the progression of kidney disease, and likely reduce CVD risk by mechanisms in addition to lowering blood pressure.

Another commenter supported the adoption of this measure, stating that patients with CKD have an increased risk for cardiovascular disease, primarily due to complications related to the blood vessels; and cardiovascular complications often cause death in patients with CKD. Prescribing ACE or ARB to patients to control blood pressure in patients with CKD can slow the progression of the disease and serve as a protective factor for cardiovascular disease.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46463), we are finalizing the *Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

A.6. Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	490
Description:	Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
Numerator:	Patients with immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Denominator:	Patients, 18 years and older, with a diagnosis of cancer and on immune checkpoint inhibitors and who have grade 2 or above diarrhea and/or grade 2 or above colitis.
Exclusions:	Denominator Exclusions: Patients with pre-existing inflammatory bowel disease (IBD) (for example, ulcerative colitis, Crohn's disease).
Measure Type:	Process
Measure Domain:	Patient Safety (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it addresses a gap in care and focuses on patient safety by enhancing early appropriate intervention for adverse effects experienced by patients diagnosed with cancer. We stated that if this measure was finalized, it will represent the only quality measure in MIPS addressing gastrointestinal adverse effects from the use of immune checkpoint inhibitors as part of cancer treatment. This measure will address a gap in care for specific cancer types, leading to a potential increase in personalized care and informing quality improvement. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agreed with the MAP that CBE (for example, NQF) endorsement is preferred, we believed this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. This measure's intent is to promote and assess for appropriate care for immune-related diarrhea and colitis, in accordance with recommendations by clinical guidelines addressing the topic of toxicities in immunotherapy. The occurrence of diarrhea and colitis can be a normal and treatable toxicity (and is many times not immune-related), but if it is immune-related, it can become life-threatening if not addressed in a timely manner.[1] Diarrhea and colitis are the second-most reported adverse events with immune checkpoint inhibitors. The measure is intended to support compliance with the clinical guidelines[2] by ensuring the eligible clinician is addressing the adverse event of diarrhea or colitis by immediately providing an intervention to prevent the adverse event from worsening. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.
We received no public comments on this new measure. For the reasons stated above and in the proposed rule (87 FR 46464), we are finalizing the *Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Acharya, U.H., & Jeter, J.M. (2013). Use of Ipilimumab in the Treatment of Melanoma. *Clinical Pharmacology: Advances and Applications,* 5, 21 - 27. https://doi.org/10.2147/CPAA.S45884.

[2] Thompson, J. A., Schneider, B. J., Brahmer, J., Andrews, S., Armand, P., Bhatia, S., Budde, L. E., Costa, L., Davies, M., Dunnington, D., Ernstoff, M. S., Frigault, M., Kaffenberger, B. H., Lunning, M., McGettigan, S., McPherson, J., Mohindra, N. A., Naidoo, J., Olszanski, A. J., Oluwole, O., … Engh, A. (2020). NCCN Guidelines Insights: Management of Immunotherapy-Related Toxicities, Version 1.2020. *Journal of the National Comprehensive Cancer Network: JNCCN*, *18*(3), 230–241. https://doi.org/10.6004/jnccn.2020.0012.

A.7. Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma

Category	Description
NQF # / eCQM NQF #:	3661 / N/A
Quality #:	491
Description:	Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.
Measure Steward:	College of American Pathologists
Numerator:	Surgical pathology reports that contain impression or conclusion of or recommendation for testing of MMR by immunohistochemistry, MSI by DNA-based testing status, or both.
Denominator:	All surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection.
Exclusions:	Denominator Exclusions: 1. Patients with an existing diagnosis of Lynch Syndrome. 2. Patients with an existing diagnosis of squamous cell carcinoma of the esophagus. 3. Hospice services provided to patient any time during the measurement period.
Measure Type:	Process
Measure Domain:	Communication and Care Coordination (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will address a gap in care for pathology. The measure will assess for impression/conclusion of or recommendation for biomarker testing for specific cancer types, potentially leading to an increase in the rate of proper diagnosis. This measure will represent a new quality measure clinical concept within the Pathology specialty set. This measure focuses on surgical pathology reports that contain impression or conclusion of or recommendation for testing of MMR by immunohistochemistry, MSI by DNA-based testing status, or both. The measure is fully tested and exhibited definitive reliability testing. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agreed with the MAP that the CBE (for example, NQF) endorsement is preferred, we believed this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. This measure is intended to drive quality care, assessing for the efficient use of resources and promote increased use of personalized patient care and patient choice. Lynch syndrome can be attributed to 2-4 percent of all colorectal carcinomas and has clinical implications for treatment of the affected patient and family members.[1 2] In the Molecular Biomarkers for the Evaluation of Colorectal Cancer guideline from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology it is recommended that mismatch repair status testing in patients with colorectal cancers is necessary for the identification of patients at high risk for Lynch syndrome and/or prognostic stratification.[1] One of two different initial tests can be performed on colorectal specimens to identify individuals who might have Lynch Syndrome: 1) Immunohistochemistry (IHC) for MMR protein expression, which is often diminished because of mutation; or 2) analysis for microsatellite instability (MSI), which results from MMR deficiency. The National Comprehensive Cancer Network (NCCN) guidelines state IHC and MSI on newly diagnosed colorectal and endometrial cancers regardless of family history to determine Lynch Syndrome, is cost effective and has been confirmed for colorectal cancer and endorsed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group at the CDC, the US Multi-Society Task Force on Colorectal Cancer, and the American Gastroenterological Association.[3 4] In 2020, the average performance rate for the colorectal carcinoma only measure was 71.05 percent and the average performance rate for the endometrial carcinoma only measure was 76.63 percent. The detection of defective mismatch repair (MMR) or microsatellite instability (MSI) can assist with the proper diagnoses of cancer.[2 5] Currently, there are no existing guidelines for the use of MMR/MSI for the detection of four cancer types (Colorectal Carcinoma, Endometrial, Gastroesophageal, and Small Bowel Carcinoma) and the potential utilization of Checkpoint Blockade Therapy. There are upcoming guidelines in development that will address these medical topics. This measure was developed to align with these guidelines to ensure it will drive quality outcomes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.
Comment: Several commenters supported the addition of this new quality measure in MIPS. One commenter stated that pathologists play a critical role in communicating information about a tumor's profile that informs patient-provider decision making. The commenter appreciated CMS' recognition on the importance of biomarker testing. Furthermore, the commenter stated that MMR and MMI testing is already recommended in guidelines to identify patients at high risk for Lynch syndrome and agreed that finalizing this measure could lead to an increase in the rate of proper diagnosis and promote increased use of personalized medicine and patient choice.	

Category	Description
	Another commenter indicated this measure is currently in use as a QCDR measure in the Pathologists Quality Registry, where it has seen high levels of use. The commenter also stated that the measure has been designed to work with a CAP Clinical Practice Guideline, released in August of 2022, therefore it represents the most up-to-date clinical information. Another commenter supported this new measure as testing for loss of MMR proteins and microsatellite instability (MSI) has crucial diagnostic, predictive implications to identifying patients at risk for Lynch Syndrome, the most common hereditary colorectal cancer (CRC) syndrome. While gastroenterologists and other clinicians order testing for loss of MMR proteins/MSI for individuals with CRC to screen for Lynch Syndrome, they depend on pathologists' interpretations of the results of these tests and recommendations for further testing to provide high-quality patient care. This measure is applicable to numerous specialties (for example, gastroenterology, pathology, oncology, surgery) and fits the larger paradigm of cross-cutting measures, which are particularly relevant. The commenter stated the measure also promotes effective communication of critical information for the purpose of care coordination and efficient use of resources. Another commenter supported this measure stating that the CQMC Gastroenterology had previously noted the importance of this concept but did not add it to the Gastroenterology core measures set given it is primarily a pathology measure. **Response:** We thank the commenters for supporting this new measure in MIPS. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46465 through 46466), we are finalizing the *Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] Sepulveda, A. R., Hamilton, S. R., Allegra, C. J., Grody, W., Cushman-Vokoun, A. M., Funkhouser, W. K., Kopetz, S. E., Lieu, C., Lindor, N. M., Minsky, B. D., Monzon, F. A., Sargent, D. J., Singh, V. M., Willis, J., Clark, J., Colasacco, C., Bryan Rumble, R., Temple-Smolkin, R., B Ventura, C., & Nowak, J. A. (2017). Molecular Biomarkers for the Evaluation of Colorectal Cancer: Guideline from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology. *Archives of Pathology & Laboratory Medicine*, *141*(5), 625–657. https://doi.org/10.5858/arpa.2016-0554-CP.

[2] Rubenstein, J. H., Enns, R., Heidelbaugh, J., Barkun, A., Adams, M. A., Dorn, S. D., Dudley-Brown, S. L., Flamm, S. L., Gellad, Z. F., Gruss, C. B., Kosinski, L. R., Lim, J. K., Romero, Y., Smalley, W. E., Sultan, S., Weinberg, D. S., & Yang, Y. X. (2015). American Gastroenterological Association Institute Guideline on the Diagnosis and Management of Lynch Syndrome. *Gastroenterology*, *149*(3), 777-782. https://doi.org/10.1053/j.gastro.2015.07.036.

[3] National Comprehensive Cancer Network (2022). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf.

[4] National Comprehensive Cancer Network (2019). NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms. Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf.

[5] Schmeler, K. M., Lynch, H. T., Chen, L. M., Munsell, M. F., Soliman, P. T., Clark, M. B., Daniels, M. S., White, K. G., Boyd-Rogers, S. G., Conrad, P. G., Yang, K. Y., Rubin, M. M., Sun, C. C., Slomovitz, B. M., Gershenson, D. M., & Lu, K. H. (2006). Prophylactic Surgery to Reduce the Risk of Gynecologic Cancers in the Lynch Syndrome. *The New England Journal of Medicine*, *354*(3), 261–269. https://www.nejm.org/doi/full/10.1056/NEJMoa052627.

A.8. Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System

Category	Description
NQF # / eCQM NQF #:	3612 / N/A
Quality #:	492
Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is the number of acute cardiovascular-related admissions per 100 person-years at risk for admission during the measurement year. Time at risk is calculated as the number of days a patient is alive, from the start of the measurement period or first visit, until heart transplantation, LVAD implantation, or home inotropic therapy; enrollment in hospice; death; or the end of the measurement period. Time not considered at risk and excluded: Days spent in a hospital, SNF, or acute rehabilitation facility; 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and Time during and after LVAD implantation, home inotropic therapy, or heart transplantation. Acute cardiovascular-related admissions are defined using individual ICD-10-CM codes and the Agency for Healthcare Research and Quality's (AHRQ) Clinical Classification Software (CCS) diagnosis categories, which group clinically similar codes together. AHRQ CCS diagnosis categories used to define outcome: 55: Fluid and electrolyte disorders; 96: Heart valve disorders; 97: Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease); 98: Essential hypertension; 100: Acute myocardial infarction; 102: Nonspecific chest pain; 104: Other and ill-defined heart disease; 105: Conduction disorders; 106: Cardiac dysrhythmias; 107: Cardiac arrest and ventricular fibrillation; 108: Congestive heart failure; non-hypertensive; 110: Occlusion or stenosis of precerebral arteries; 112: Transient cerebral ischemia; 115: Aortic; peripheral; and visceral artery aneurysms; 116: Aortic and peripheral arterial embolism or thrombosis; 157: Acute and unspecified renal failure; 245: Syncope. Subsets of the following AHRQ CCS diagnosis categories used to define outcome: 99: Hypertension with complications and secondary hypertension; 101: Coronary atherosclerosis and other heart disease; 103: Pulmonary heart disease; 109: Acute cerebrovascular disease; 114: Peripheral and visceral atherosclerosis; 117: Other circulatory disease; 130: Pleurisy; pneumothorax; pulmonary collapse; 131: Respiratory failure; insufficiency; arrest (adult); 133: Other lower respiratory disease; 237: Complication of device; implant or graft. The measure has several outcome exclusions: Planned admissions; Admissions from a skilled nursing facility (SNF) or acute rehab facility; Admissions within 10 days of discharge from a hospital, SNF, or acute rehab; Admissions after patient has entered hospice; Admissions before first visit to provider if no prior year visit; Admissions at time of or following: LVAD implantation, home inotropic therapy, or heart transplant.
Denominator:	The measure includes Medicare FFS beneficiaries ≥65 years of age with at least one inpatient principal diagnosis for heart failure/cardiomyopathy, or at least two outpatient or inpatient heart failure/cardiomyopathy diagnoses in any coding position (for example, primary or secondary position) within the two years prior to the measurement year. • Beneficiaries must be enrolled full-time in Medicare Parts A and B during the year prior to measurement and during the measurement period. Additionally, the cohort excludes: Patients with internalized left ventricular assist devices (LVADs); Patients with heart transplants; Patients on home inotropic therapy; Patients on hospice for any reason; Patients with end-stage renal disease (ESRD) – defined as chronic kidney disease stage 5 or on dialysis. Provider types included for measurement (vetted by TEP and Clinician Committee): Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants; Cardiologists: Cardiologists are covered by the measure because they provide overall coordination of care for patients with HF and manage the conditions that put HF patients at risk for admission due to acute cardiovascular-related conditions. Outcome attribution: We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a cardiologist, a PCP, or can be left unassigned. A patient who is eligible for attribution is assigned to a cardiologist if they have 2 or more visits with a single cardiologist, regardless of how many visits that patient has with a PCP. There are two scenarios where a patient can be assigned to a PCP. • First, if the patient has seen the PCP at least once but has no visits with a cardiologist, the patient is assigned to the PCP. • Second, if the patient has seen the PCP two or more times and has only one visit with a cardiologist, the patient is assigned to the PCP. If the patient has 1 visit each with a cardiologist and a PCP, the patient is assigned to the cardiologist. If the patient has 1 visit with a cardiologist and no visit with a PCP, the patient is assigned to the cardiologist. Finally, the patient will be unassigned if they had no visits with a PCP or cardiologist. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. Patients "follow" their clinician to the TIN designated by the clinician (that is, they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level.
Exclusions:	Numerator Exclusions: The measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of HF patients: Planned admissions (utilizes the adapted planned admission algorithm (PAA) to identify and exclude admissions that are planned); Admissions that likely do not reflect the quality of heart failure management provided by ambulatory clinicians including: Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility ("10-day buffer period"); Admissions that occur while patients are enrolled in Medicare's hospice benefit; Admissions that occur

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	prior to the first visit with the assigned clinician. Admissions on the date or after any of the following: LVAD implantation, home inotropic therapy, or heart transplant (censored at the time of transition to advanced care). Denominator Exclusions: The measure excludes: 1. Patients without continuous enrollment in Medicare Parts A and B for the duration of the measurement period. 2. Patients who (or until death), were ever in hospice during the year prior to the measurement year or in hospice at the start of the measurement period. 3. Patients who have had no Evaluation & Management (E&M) visits to a MIPS eligible clinician. 4. Patients who have had a heart transplant, been on home inotropic therapy, or who have had a left ventricular assist device (LVAD) placed.
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims
Measure-Specific Case Minimum/Performance Period:	MIPS eligible clinicians, groups, subgroups*, virtual groups, and APM Entities containing at least 1 cardiologist / 21 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We proposed this measure because heart failure (HF) is a leading cause of hospitalization in the United States and a major source of disease burden among older adults. There is strong evidence that ambulatory care clinicians can influence admission rates by providing high quality of care to patients with heart failure/cardiomyopathy (https://pubmed.ncbi.nlm.nih.gov/22665827/). We originally proposed this measure in the CY 2022 PFS proposed rule for the CY 2022 performance period/2024 MIPS payment year for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities but did not finalize this proposal or adopt the measure (86 FR 65692 through 65694). Key reasons for not finalizing the measure were concerns related to how beneficiaries are attributed to clinicians and concerns about the appropriateness of risk adjustment for severity of heart failure (86 FR 65692 through 65694). We have subsequently worked to mitigate these concerns, and we re-proposed this measure for the CY 2023 performance period/2025 MIPS payment year to be initially reported only for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities that include at least 1 cardiologist. After CY 2023, we will consider expanding reporting of this measure to include both cardiologists and PCPs. This HF measure was included on the 2020 Measures Under Consideration (MUC) list and evaluated by the MAP, which did not support the measure for rulemaking with potential for mitigation citing NQF endorsement and an analysis of the appropriateness of the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. We agreed that NQF endorsement of measures is preferred, and this measure was subsequently submitted for NQF endorsement as part of the spring 2021 cycle and was endorsed by the NQF in January 2022. NQF currently serves as the CBE regarding certain performance measurement activities performed for CMS pursuant to sections 1890 and 1890A of the Act. We proposed this administrative claims collection type outcome measure as HF is a leading cause of hospitalization in the United States and a major source of disease burden among the elderly population. Approximately 5.7 million adults in the United States have HF, costing the United States $30.7 billion each year, which includes the cost of health care services, medications for treatment, and missed days of work.[1] The toll on patients is also great, with high rates of hospitalization and mortality; nearly half of people with HF die within 5 years of their diagnosis.[2] Patients with chronic HF are vulnerable to a range of complications that may put them at risk for hospitalization, including worsening of HF symptoms and destabilization due to other conditions, such as respiratory disease or infection. To expand the list of available reporting options for clinicians, we proposed this HF measure for use in MIPS, as it is an administrative claims measure, which has no reporting burden. Another version of this measure specified for Accountable Care Organizations (ACOs), "Risk-standardized Acute Admission Rates for Patients with Heart Failure" (ACO-37, NQF ID 2886) was previously used in the CMS Medicare Shared Savings Program, initially for accountability and currently as an informational measure. Although concerns have been raised about the appropriateness of risk adjustment, the measure accounts for patients with more complicated or severe heart failure in several ways: by excluding patients at advanced stages of heart failure, such as those with implanted left ventricular assist device (LVAD), those who receive home inotropic therapy, or those with prior heart transplant or with end stage renal disease; by risk adjusting for AICDs (defibrillators), systolic heart failure, comorbidities (including chronic kidney disease), and for frailty/disability. Moreover, the measure does not include advanced heart failure/transplant specialists for attribution. We conducted analyses of the appropriateness of risk adjustment which demonstrated that the risk adjustment model performed well across deciles of predicted admission risk. Based on this information and the material presented to the MAP and subsequently to the NQF, we believed the measure is evidence-based and will provide important information to drive improvements in clinical practice for heart failure patients. To mitigate concerns about risk adjustment for clinicians with higher caseloads of patients with more complex heart failure, the measure will be initially reported only for MIPS eligible cardiology TINs (that is, MIPS TINs with at least one cardiologist) with a 21-patient case minimum. We believed this approach will allow clinicians and groups who will be scored on the measure to become familiar with the measure. Note: Refer to the 2020 MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.
Comment: One commenter supported the addition of this new measure. **Response:** We thank the commenter for supporting this new measure in MIPS.	

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	Comment: One commenter appreciated that hospitalizations put patients at risk of exposure to adverse events and recognized the importance of continuity of follow-up post-discharge. The commenter also appreciated that the revised version of this measure does not include advanced heart failure/transplant specialists for attribution and continues to exclude planned admissions. The commenter however, continued to have concerns about assigning hospitalization rates per capita to a single clinician. The commenter did not believe this measure was appropriate in its current iteration for physician-level accountability and was more appropriate for facility or system-level accountability (for example, ACOs, the VA, etc.). The commenter also believed that metrics that count hospitalizations focus on utilization without regard to quality. At the hospital level, "success" on the 30-day readmission metric has been found to be associated with excess mortality over the same time frame in some analyses. Outcomes, namely survival, should be measured at the hospital-level. The commenter was concerned that the risk adjustment methodology was inadequate in that it relies exclusively on claims data and on variables that do not fully account for severity of illness, medical complexity, and social determinants of health, all of which are critical drivers of heart failure admissions. The commenter appreciated changes to the measure specifications that address heart failure severity and having the 21-case minimum to mitigate concerns about risk. However, the revised measure still does not adequately adjust for social determinants and other risk factors. **Response:** The overall goals of heart failure therapy are to reduce mortality and morbidity associated with the disease, including decreasing the rate of hospitalizations. This measure is focused on acute unplanned cardiovascular-related admissions, which represents an actionable subset of admissions that can be influenced by primary care providers (PCPs) and cardiologists. In designing this measure, we took into consideration the types of acute hospital admissions that ambulatory providers caring for patients with heart failure could be held accountable for and excluded those that do not reflect the quality of ambulatory care. Because ambulatory providers may not be able to control all the factors that drive cardiovascular-related acute hospital admissions among patients with heart failure, the measure is carefully risk adjusted for comorbid conditions, severity of heart failure, frailty and disability, as well as for the AHRQ Socioeconomic Status (SES) Index (https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/hcbs/findings/index.html), a marker of socioeconomic disadvantage. We note that the target rate of admissions is not "capped" nor is it zero since disease progression often necessitates hospital admission to stabilize and treat cardiovascular complications; rather, the measure assesses whether the admission rate for providers' patients is higher than expected given their risk factors. We agree that some process measures do not capture all the actions that clinicians can take to influence favorable outcomes. Moreover, patients are interested in surviving, avoiding hospital admissions, minimizing symptoms, achieving optimal functioning, and optimizing their quality of life. No set of process measures can be comprehensive enough to serve as a surrogate for these patient outcomes. Thus, we prioritize the use of outcome measures to evaluate quality in MIPS. We will continue to monitor for any unintended consequences of the measure. We note that although thresholds to admit a patient with heart failure from the emergency department (ED) to the hospital can be variable, they are unlikely to be unduly influenced by ambulatory MIPS clinicians. The decision to admit or discharge a patient is generally made by the ED physician. Therefore, it is unlikely that the measure would incentivize changes in thresholds to admit a heart failure patient or create caps on the number of patients admitted. In addition, the measure uses claims codes that are subject to auditing to minimize fraudulent coding. Finally, we note that this measure is adjusted for the AHRQ SES Index, which captures multiple aspects of social deprivation that can impact patients' health and health outcomes, including poverty and median household income; unemployment; education; and housing value and quality. These factors are deeply rooted in societal disparities, and MIPS providers may have little ability to influence their effect. However, ambulatory providers can work with patients to improve on their continuity of care, adherence to prescribed medications, and access to appointments. **Comment:** A few commenters were concerned there is a significant risk for unintended consequences posed by implementation of this measure. Commenters were concerned that the measure still does not adequately consider the competing risk of mortality. One commenter stated that providers with higher mortality rates for more severe heart failure patients could appear to be providing better quality care. Another commenter indicated that there should not be incentives for physicians to select alternative codes, avoid high-risk patients, or fail to admit patients when necessary. The commenter emphasized that metrics should be linked to quality of care and account for any consequences that are tied to rewards and penalties. **Response:** The concern about mortality as a competing outcome was considered during development of the measure since patients with heart failure are at high risk of both hospital admissions and mortality. The measure does not favor providers with higher mortality rates and we will continue to monitor for any unintended consequences of the measure. First, patients who die in the measurement year tend to be admitted more often in that year. Second, when a patient dies, he/she no longer contributes time to the measure denominator (person-years). A better score on the measure is achieved by helping patients stay alive and contribute to the denominator while avoiding hospitalization. With respect to the link between readmissions and mortality, we were concerned about the possibility of unintended consequences of the Hospital Readmissions Reduction Program (HRRP) and commissioned a group of statisticians to undertake an independent study of the relationship between HRRP implementation and mortality rates. The results of the study reassured us that HRRP has not caused an unintended increase in mortality in Medicare patients. **Comment**: A few commenters were concerned about attribution. One commenter stated that heart failure management benefits from close management by both the cardiologist and the primary care clinicians and multiple attribution to all clinicians meeting the attribution criteria would more effectively promote team-based care and care coordination than identifying a single "most responsible" clinician. The proposed algorithm for identifying the most responsible clinician in also problematic and could potentially lead to additional perverse incentives. The commenter stated that CMS specialty indication codes can be unreliable. Second, a cardiologist with a single visit may be more responsible for a patient than a primary care clinician with two visits over the measurement period. In addition, many heart failure patients see multiple cardiologists (for example, electrophysiologist and heart failure specialist). In this case, attributing the patient to the clinician with the most visits or highest charges would be imprecise. A second commenter agreed and believed an attribution to primary care, as opposed to cardiology, is specious and questioned why it needed to be one or the other but not both jointly. Finally, the commenter stated that outpatient evaluation and management codes used in the attribution algorithm are relatively non-specific for heart failure management; therefore, use of Patient Relationship codes would greatly improve the accuracy of attribution of patients to providers. Another commenter noted that it had previously stated that many TINs in large organizations comprise both primary and specialty practices and therefore it is not entirely clear how attribution might be determined. This may be of concern, for example, with Advanced Practice Provider (APP)s who are often considered primary care but may also be in a cardiology practice. The commenter stated that it is not clear if a Cardiology APP visit would count as a primary care visit, or a second visit to the cardiologist. The commenter stated that CMS could explore that possibility that APPs could form subgroups.

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The commenter had other concerns related to attribution, such as how telehealth visits will impact attribution. While MIPS was designed to cater to individual clinicians, attribution of the individual provider for complex conditions and complex systems of care, including heart failure patients, is difficult to achieve and does not accurately reflect patient outcomes. The commenter asked that consideration be given to the fact that operational and clinical processes are increasingly team-based and assessing admission rates via a single clinician (or clinician groups), again elucidates the issue of attribution. Overall, the commenter suggested to CMS that going forward, measures should offer rewards for reduced hospitalization, which would include considerations for team-based care.

Response: The measure is an administrative claims measure and attribution for the measure is determined based upon the pattern of office visits with eligible providers, which reflect opportunities to deliver high-quality care. The patient is attributed to the individual clinician first. We considered multiple attribution for this measure but decided against it given interested party support for identifying and holding accountable the clinician who is "quarterbacking" a patient's care. The aim of attributing patients to an individual provider is to incentivize accountability for care and thus address fragmentation of care for patients with heart failure. We agree there are instances where patients are seeing multiple providers who impact the risk of admission. An underlying premise of our approach to attribution is that ideally there is an individual clinician who is taking responsibility for managing and coordinating the care of a heart failure patient. In most cases, this will be a PCP or a cardiologist. The patient "follows" the individual clinician to which they are assigned to the TIN level assignment. The TIN may be comprised of primary care providers, cardiologists, or it may be a multi-specialty TIN. However, the information about the composition of the TIN is not used for attribution.

Each patient is attributed to the clinician most responsible for the patient's care based on the pattern of outpatient visits with PCPs and relevant specialists. A patient may be assigned to a cardiologist, a PCP, or may be unassigned. We assign a patient who is eligible for attribution to a cardiologist if the patient has 2 or more visits with a single cardiologist, regardless of how many visits that patient has with a PCP. In cases in which a patient has a single visit with a cardiologist and 2 or more visits with a PCP, the patient will be assigned to the PCP to reflect greater opportunity to influence patient management afforded to the PCP. If an electrophysiologist sees a HF patient for an initial visit and a follow-up (2 visits in a year) and the patient does not have visits with another cardiologist, that patient will be assigned to the electrophysiologist over the PCP. Most patients who require electrophysiology consultation and follow-up may be expected to be also under general cardiology care; indeed, <5% of providers in the measure are comprised of electrophysiology specialists.

We acknowledge that non-physician practitioners may practice in primary care or in internal medicine subspecialties, including cardiology. Currently available administrative claims data do not distinguish between non-physician practitioners in primary care versus cardiology. However, if the patient had the most touchpoints with a cardiology APP, they would be assigned to that individual provider. If this provider was part of a cardiology TIN, the patient would follow the APP to the TIN level assignment. Whether or not the TIN is multi-specialty or primary care does not influence the attribution logic.

We appreciate that in some circumstances the attribution algorithm will not always accurately reflect the most responsible clinician. In consultation with the technical expert panel (TEP) and Clinician Committee, we have selected an attribution algorithm that is reasonable under most circumstances. We will consider possible refinements of the attribution algorithm when the measure undergoes reevaluation. We will also explore approaches to attribution that incorporate the Patient Relationship Categories and Codes as they become routinely used and recorded in Medicare claims data.

We also acknowledge that telemedicine visits have increased during the public health emergency. The HCPCS codes used to identify E&M office visits may reflect either in-person or telemedicine appointments. Both types of visits are used for attribution; however, telephone visits are not used for attribution. We also continue to prioritize the use of outcome measures to evaluate quality in MIPS.

Comment: One commenter stated that this measure, like the existing measure Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups, will be triggered for physician extenders that are part of specialty groups (for example, nurse practitioners and physician assistants that are part of radiology, orthopedic, oncology groups, etc.). The commenter also stated that these administrative claims measures should not be applied to physician extenders that are part of specialty groups.

Response: Non-physician practitioners may practice in primary care or in internal medicine subspecialties, including cardiology, or in other specialties. Currently available administrative claims data do not distinguish between non-physician practitioners in primary care versus other specialties. However, if the patient had the most touchpoints with a cardiology advanced practice practitioner (APP), they would be assigned to that provider. If this provider was part of a cardiology TIN, the patient would follow the APP to the TIN level assignment. Please note that the patient would be assigned to the cardiologist over an APP if they had 2 or more visits with the cardiologist. In addition, the measure will only be applied to TINs that contain at least 1 cardiologist, precluding the possibility of a patient being assigned to a TIN of orthopedic specialists. We will continue to evaluate and explore refinements to the attribution algorithm.

Comment: One commenter had concerns about risk adjustment and the methods used for risk model development and whether the model will adequately discriminate good from poor performance on this measure. It was also unclear why age was categorized. It was also not clear why gender and race/ethnicity would be excluded from the model. There is also no adjustment for long term institutionalization or prior nursing facility placement. These are strong markers of frailty and increased risk of admission. The commenter was concerned that the measure does not adequately account for unmeasured patient differences across these specialties. This could bias measure results against those specialties (for example, advanced heart failure specialists) that care for the sickest, most vulnerable patients.

Response: There is indeed growing literature on the advantages of penalized regression, for example Least Absolute Shrinkage and Selection Operator (LASSO) regression analysis, over stepwise methods as a way to select model variables. While the latter method may lead to low prediction accuracy, the measure developer tried to address this by running the stepwise method on bootstrap samples and selecting only the risk factors that consistently entered the final model in at least 90 percent of the bootstrap samples. During measure development, the measure developer explored LASSO and found the method to have a significantly longer run time; however, there was an almost 100 percent overlap in the variables selected between LASSO and stepwise methods.

During measure development, in both univariate and multivariate analyses, we found a monotonic non-linear relationship between age and risk of cardiovascular-related admission. Non-linearity can be addressed in various ways, such as modeling the variable as categorical, or introducing splines. We chose the former method to address non-linearity due to ease of interpretation of the model coefficients. We also tested and included age but not sex or race in the model, consistent with the rationale and approach taken for other CMS outcome measures. Studies suggest that sex- and race-based differences in outcomes are generally driven by age and comorbidities (which are included in the risk adjustment), as well as disparities in care delivery (for example, women with diabetes and HF tend to receive less evidence-based treatment), and not by biological differences.

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	The measure excludes from the outcome hospital admissions that occur when patients are in skilled nursing facility, or acute rehabilitation facilities because, during that time, institutional clinicians have a more direct influence on patients' care and safety as opposed to their primary ambulatory care clinicians. Similarly, the measure excludes time spent in a skilled nursing facility from time at risk for the outcome for the same reasons. The measure is also adjusted for case mix to take into account differences in case mix across providers. However, the measure does not include advanced heart failure specialists for attribution given the sickest patients with most severe heart failure may be concentrated among these provider types. **Comment**: One commenter had concerns related to validity of this measure and stated it remains unclear that hospital readmission rates actually reflect the quality of heart failure care. Admission rates may be modified by providing better quality care or they may be modified by simply raising the threshold to admit patients who would benefit from admission. Thus, they may be measuring differences in admission thresholds or even unmeasured differences in social risk or disease severity and not quality of care. The commenter stated that CMS should focus on measures that address heart failure treatment goals directly (for example, mortality or health status) or on evidence-based process measures that have been shown to improve survival and/or health status. At a minimum, admission rates should be evaluated concurrently with more direct heart failure outcome and process measures. **Response:** The overall goals of heart failure therapy are to reduce mortality and morbidity associated with the disease, including decreasing the rate of hospitalizations. The measure is focused on acute unplanned cardiovascular-related admissions because they represent an actionable subset of admissions that can be influenced by PCPs and cardiologists. In designing this measure, we took into consideration the types of acute hospital admissions that ambulatory providers caring for patients with heart failure could be held accountable for and excluded those that do not reflect the quality of ambulatory care. The measure is carefully risk adjusted for comorbid conditions, severity of heart failure, frailty and disability, as well as for the AHRQ SES Index, a marker of socioeconomic disadvantage. The measure assesses whether the admission rate for providers' patients is higher than expected given their risk factors. We agree that some process measures, for example, those focused on adoption of guideline-directed medical therapy in patients with heart failure or those focused on achievement of blood pressure or glycemic control targets, can be used to incentivize quality improvement for patients with heart failure. However, they do not capture all of the actions that clinicians can take to influence favorable outcomes. Moreover, patients are interested in surviving, avoiding hospital admissions, minimizing symptoms, achieving optimal functioning, and optimizing their quality of life. No set of process measures can be comprehensive enough to serve as a surrogate for these patient outcomes. Thus, we prioritize the use of outcome measures to evaluate quality in MIPS. **Comment:** One commenter requested that CMS hold off on finalizing this measure until the CQMC Cardiology Workgroup has completed its review of the measure. The commenter recognized the importance reducing avoidable readmissions but stated a number of concerns with this measure including a lack of information about outcomes and survival, inadequate adjustment for social risk factors, concerns about appropriate attribution of the measure, and potential carveouts for certain procedures (for example, revascularization, device implantation and ablation). **Response:** We appreciate that the CQMC Cardiology Workgroup is in the process of reviewing the measure. We note that the measure is adjusted for the AHRQ SES Index which captures multiple aspects of social deprivation that can impact patients' health and health outcomes, including poverty and median household income; unemployment; education; and housing value and quality. These factors are deeply rooted in societal disparities, and MIPS providers may have little ability to influence their effect. However, ambulatory providers can work with patients to improve on their continuity of care, adherence to prescribed medications, and access to appointments. We appreciate that in some circumstances the attribution algorithm will not always accurately reflect the most responsible clinician. In consultation with the TEP and Clinician Committee, we have selected an attribution algorithm that is reasonable under most circumstances. The measure outcome includes acute cardiovascular-related hospital admissions. Note that the measure outcome excludes planned admissions, such as those for planned revascularization, device implantation or ablation, as long as they are not accompanied by a discharge diagnosis that is acute or a complication of care. **Comment:** One commenter did not believe that the sole proposed modification to attribute this measure to groups with at least one cardiologist sufficiently addressed their concerns. It is appropriate to attribute these admissions to clinician groups since MIPS participants do not know which patients were assigned to them until well after the reporting period ends (that is, retrospectively), making it impossible for clinicians and practices to implement near real-time interventions. The commenter stated that this measure should not be implemented until MIPS clinicians can actively engage in activities that minimize and prevent those hospitalizations that could be avoided, and the commenter encouraged CMS to explore avenues by which attribution of patients could be done prospectively to allow for such engagement. The commenter is also concerned that while the median reliability score was 0.60 for practices with at least 21 patients, the range was from 0.401 to 0.995. The commenter believes that the minimum sample size must be increased to a higher number to produce a minimum reliability threshold of sufficient magnitude (for example, 0.7 or higher). Ensuring that the resulting performance scores produce information that would not misrepresent the quality of care provided by a group is imperative and while an increase in the sample size would result in a decrease in the number of groups to which the measure would apply, the commenter believes that it would still be a considerable number of patients with heart failure that would continue to be factored into the measure. The commenter appreciated the inclusion of social risk factors within the risk adjustment model and strongly advocated that dual eligibility also be included since it was a strong predictor of whether a patient would be admitted. The commenter also stated all variables that are determined to be predictors that are outside of the control of a group be included. **Response:** We acknowledge that retrospective attribution has the disadvantage that providers do not know who counts as their patients until after they have already provided care. Prospective attribution approaches remove uncertainty on the part of the provider. However, prospective attribution is problematic as it introduces the possibility of gaming or providing differential levels of care to patients based on attribution status. Moreover, patients attributed to a provider may seek care outside of their designation. As a result, prospective attribution may lead to inaccurate assignments of patients. Retrospective attribution makes assignments based on how care is actually delivered. In setting a minimum reliability threshold, we needed to balance measure reliability with the statutory requirement to make performance measures applicable to the broadest number of providers. We typically set a minimum reliability threshold of 0.4 in MIPS for these reasons. This measure is adjusted for the AHRQ SES Index which captures multiple aspects of social deprivation that can impact patients' health and health outcomes, including poverty and median household income; unemployment; education; and housing value and quality. These factors are deeply rooted in societal disparities, and MIPS providers have little influence on their effect. While dual-eligible beneficiaries are likely to have fewer available health/healthcare supports, and may also have other unmeasured social risk factors (for example, low health literacy), we are not adjusting the model for dual eligibility because: adjusting for dual eligibility can mask disparities in care for dual-eligible beneficiaries, the marginal impact of including dual eligibility is attenuated after accounting for demographic, clinical, and frailty risk factors, as well as the AHRQ SES Index, clinicians may have more ability

Category	Description
	to mitigate social risk associated with dual eligibility, especially if a dual-eligible beneficiary is living in a non-socially deprived community, and TEP members supported including only the AHRQ SES Index in the model. **Comment:** One commenter stated that because programs to decrease acute hospitalizations were found beneficial in only 2 of 11 CMS demonstration projects, and only 4 of 11 were effective when the sub-group analysis was limited to high-risk populations, it is evident that this measure should focus on high-risk populations. At first glance, one may think that including low risk patients in the denominator lowers the acute hospitalization utilization and is a good thing, but it actually obfuscates any impact that well-designed programs are having. For organizations without high-risk patients, it is not a meaningful measure. High-risk subgroups had positive effects for the 4 of 11 programs, but 7 still failed. High risk subgroups that saw benefit in all 4 programs were defined by >= 2 hospitalizations in the prior 2 years. The programs had to be directed at the right patients which were high risk patients. The other finding is that these programs had to be offered over multiple years. Therefore, the commenter stated that it is unclear what it means where CMS measures this yearly and thereby give the impression that the measure is valid within a year. **Response**: The goal of the measure is to assess whether the admission rate for providers' patients is higher than expected given their risk factors and thus assess the quality of care delivered to patients with heart failure. The measure is not designed to assess changes in care or to assess the impact of specific programs on outcomes of patients with heart failure. We acknowledge that interventions are most effective when targeted to patients who need them. Although focusing on patients with prior hospitalizations may be an effective strategy for healthcare systems, the purpose of the measure is to evaluate the quality of care of all patients with heart failure, including patients who are well managed and thus avoid hospitalization. We acknowledge that quality improvement programs may require variable time to become effective. The measure evaluates outcomes over a period of 1 year, but this should not dis-incentivize investment in longer-term programs to improve the care of heart failure patients. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46467 through 46469), we are finalizing the *Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] Heidenreich, P. A., Trogdon, J. G., Khavjou, O. A., Butler, J., Dracup, K., Ezekowitz, M. D., Finkelstein, E. A., Hong, Y., Johnston, S. C., Khera, A., Lloyd-Jones, D. M., Nelson, S. A., Nichol, G., Orenstein, D., Wilson, P. W., Woo, Y. J., American Heart Association Advocacy Coordinating Committee, Stroke Council, Council on Cardiovascular Radiology and Intervention, Council on Clinical Cardiology, … Council on Cardiovascular Surgery and Anesthesia, and Interdisciplinary Council on Quality of Care and Outcomes Research (2011). Forecasting the Future of Cardiovascular Disease in the United States: A Policy Statement from the American Heart Association. *Circulation*, *123*(8), 933–944. https://doi.org/10.1161/CIR.0b013e31820a55f5.

[2] Mozaffarian, D., Benjamin, E. J., Go, A. S., Arnett, D. K., Blaha, M. J., Cushman, M., Das, S. R., de Ferranti, S., Després, J. P., Fullerton, H. J., Howard, V. J., Huffman, M. D., Isasi, C. R., Jiménez, M. C., Judd, S. E., Kissela, B. M., Lichtman, J. H., Lisabeth, L. D., Liu, S., … Stroke Statistics Subcommittee (2016). Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. *Circulation*, *133*(4), e38–e360. https://doi.org/10.1161/CIR.0000000000000350.

A.9. Adult Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	493
Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Submission Criteria 1: Patients in Denominator 1 (D1) who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period. Submission Criteria 2: Patients in D2 who received at least 1 Td vaccine or 1 Tdap vaccine between 9 years prior to the encounter and the end of the measurement period. Submission Criteria 3: Patients in D3 who received at least 1 dose of the herpes zoster live vaccine or 2 doses of the herpes zoster recombinant vaccine anytime on or after the patients' 50th birthday. Submission Criteria 4: Patients in D4 who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine, on or after their 60th birthday and before the end of the measurement period.
Denominator:	Submission Criteria 1: Patients 19 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 2: Patients 19 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 3: Patients 50 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 4: Patients 66 years of age or older on the date of the encounter with a visit during the measurement period.
Exclusions:	Denominator Exclusion: All submission criteria: Active chemotherapy during the measurement period; or Bone marrow transplant during the measurement period; or History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time during the patient's history prior to or during the measurement period; or In hospice or using hospice services during the measurement period
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(v) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this multiple performance rate measure because it supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. Evidence provided by the measure steward testing indicates a gap in performance with average performance rates of 24 percent for influenza; 35 percent for Td or Tdap; 28 percent for zoster; and 17 percent for pneumococcal. This robust measure assesses the quality of clinical actions regarding the administration of the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines. The immunizations included within this measure will work to reduce the prevalence of severe diseases that may be associated with hospitalization and potentially lead to a decrease in overall health care costs. We believed the measure will improve overall vaccination rates more effectively than the current individual MIPS measures, Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults because performance is based on the administration of all four vaccinations rather than focusing on just one vaccination per measure. The measure will set a more stringent performance standard by requiring a set of adult immunizations in one composite measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. In connection with the proposal of this measure, we also proposed to remove measures Q110 and Q111 from traditional MIPS, while retaining those two measures for use in relevant MVPs as discussed under Table Group CC and retaining measure Q110 for the purposes of Shared Savings Program ACOs reporting through the APM Performance Pathway (APP) as discussed in section III.G.4.c.(1) of this final rule. We originally proposed this measure in the CY 2020 PFS proposed rule for the CY 2020 performance period/2022 MIPS payment year but did not finalize this proposal due to eminent changes to the pneumococcal vaccination guidelines (84 FR 63207 through 63209). We now proposed this measure for the CY 2023 performance period/2025 MIPS payment year since it reflects the updated guidelines to include any pneumococcal conjugate vaccine or polysaccharide vaccine. Healthy People 2020—an initiative under the Office of Disease Prevention and Health Promotion that provides science-based, 10-year national objectives for improving the health of all Americans—recommends increasing the percentage of adults who are vaccinated against influenza, zoster, and pneumococcal disease.[1] The CDC Advisory Committee in Immunization Practices (ACIP) makes evidence-based recommendations for vaccine use. This measure encourages compliance with the recommendations by showing how many adults within the population receive vaccines per guideline recommendations (https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html). This measure will incentivize higher rates of adoption of the ACIP's recommendations. We proposed that submission of all 4 performance rates will be required for this measure and will be used to determine data completeness. Submission of all 4 performance rates will align with current clinical guidelines as clinicians should attempt to

Category	Description
	administer to the appropriate patient population all vaccines this measure will assess for compliance. By requiring submission of all 4 performance rates, we will capture a complete data set to show performance gaps in vaccine administration. If this measure is finalized for inclusion within MIPS, we proposed to score this measure using a weighted average for the first 2 years of implementation. Beginning with the CY 2025 performance period/2027 MIPS payment year, we will score this measure as an all-or-none composite measure to ensure a more thorough assessment of a patient's vaccination status.

Comment: Several commenters supported adding the Adult Immunization Status (AIS) measure because the measure will improve the capture of routine adult immunizations and fill a critical measure gap. Commenters indicated the measure would provide a strong signal to clinicians of all types, including specialists, about the role of vaccination in driving quality health outcomes and promote adherence to ACIP-recommended vaccinations.

Commenters' stated reasons for supporting this new measure included:

- Given that three out of every four adults in the U.S. are missing one or more routinely recommended vaccines, it is important to employ strategies to ensure individuals are up-to-date on necessary vaccination, and effective performance measures can be a strong tool to drive clinician behavior change, improve quality of care, and address health disparities.
- Increased adult immunizations in Medicare has the potential to reduce health care costs by decreasing the prevalence of vaccine preventable diseases, many of which are associated with hospitalizations and use of other health care services.
- This new measure meets the three core strategies underlying the movement toward a truly patient-centered health care delivery system by: 1) Improving the way clinicians are paid to incentivize quality and value of care over simply quantity of services; 2) improving the way care is delivered by providing clinical practice support, data and feedback reports to guide improvement and better decision-making and; 3) making data more available in real-time at the point of contact and enabling the use of certified Electronic Health Recoher (EHR) technology and other data sources to support care delivery.
- It is imperative for everyone to receive immunizations as vaccines are critical to infectious disease prevention and control. Given the role of nurses in vaccination efforts and their role in advising patients to adhere to recommended vaccination schedules, it is appropriate for CMS to expand immunization reporting with this measure. CMS and the Medicare administration have been critical to public health efforts during the public health emergency and quality measurement.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter was concerned that the new Adult Immunization Status measure that is replacing measures Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults is being proposed as a CQM measure and not an eCQM measure and requested the measure also be allowed to be submitted through eCQMs.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted to the Call for Quality Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We endeavor to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measure steward to the Call for Quality Measures. We encourage the commenter to reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years. However, we believe that this is a more robust measure to drive quality care and ensure appropriate immunization status, as compared to the individual measures Q110 and Q111.

Comment: One commenter indicated it is vital that Medicare payment policies support primary care physicians' ability to offer recommended immunizations in their practices. However, the commenter remained concerned that CMS intends to include the Adult Immunization Status measure in the future. The commenter stated that current immunization registries and health data information sharing systems must first be fixed to more effectively aggregate patient information, including immunization records, to evaluate the quality of the care reliably and accurately. This is particularly true for the influenza vaccine which is frequently received by patients in the community at grocery stores, pharmacies, workplaces, etc. Inadequate data aggregation and information sharing increases the burden of reporting, as physicians and their staff must manually track down and enter information for immunizations received outside of their clinic. The commenter stated there will undoubtedly be data gaps that will inappropriately be identified as care deficiencies under this measure.

The commenter encouraged CMS to explore the use of their regulatory authority to address this long-standing gap in data aggregation and information sharing which results in unnecessary administrative time and burden placed on patients and physician practices. Until these changes are in place, the commenter encouraged CMS to prioritize measures that are supported by more efficient and accurate data sources and do not increase burden to physician practices.

Response: We acknowledge that the measure will set a more stringent performance standard by requiring a set of adult immunizations in one multi-performance measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. This robust measure assesses the administration or patient reported receipt of appropriate adult immunizations.

We believe the measure will encourage improvement in overall vaccination rates more effectively because performance is based on the administration of all four vaccinations rather than focusing on just one vaccination per measure. Additionally, this measure is being proposed as a MIPS CQM and may be supported by Qualified Registries or QCDRs meaning that the data for calculation of this measure may be abstracted from multiple medical resources and not necessarily reliant on immunization registries. We believe these types of measures drive the continued efforts of the interoperability of health data information sharing systems and may ameliorate the data aggregation issues identified by commenter.

Comment: One commenter stated that the new Adult Immunization Status measure is much more difficult to report for many providers, specifically specialists. The commenter was concerned many patients will not be able to accurately recall when or if they received a Td/Tdap, flu, or zoster vaccine, noting clinician reliance on the state's immunization registry for data on flu and pneumonia vaccine administration. The commenter indicated that having providers report on whether patients have received these vaccines is unrelated to compliance with the ACIP recommendation, as they believe clinician reporting does not encourage patients to receive vaccines the patient considers unnecessary. Finally, the commenter stated that if CMS is working toward true interoperability, it does not make sense to create a new quality measure that required reporting of data that should be available via HIE, state immunization registry, or other interoperable mechanisms.

Response: Because clinicians have the flexibility to choose measures to report and this measure's performance is based on a weighted average of those measures, we believe that this measure provides a comprehensive adult immunization measure. Each component measure would allow patient reported vaccination documented in the medical record to meet performance. MIPS measures collect data on all payer sources, and therefore we believe this measure

Category	Description
would capture a more robust representation of performance than the individual components. This measure is being proposed as a MIPS CQM and may be supported by Qualified Registries or QCDRs, which supports data abstraction for calculation of this measure from multiple medical resources and not necessarily reliant on immunization registries. The measure contains denominator criteria that is specific to the targeted patient population for the vaccination represented in the component measures. Additionally, this composite measure contains denominator exclusions, applicable to all four submission criteria, that assist with identifying patients that meet the intent of the measure. We believe patients have the right to choose if the vaccination is appropriate for them although believe this measure will encourage engagement between the patient and clinician regarding clinical reasons to consider vaccination as a preventive health option. **Comment:** One commenter had concerns about the applicability and practicality of the Adult Immunization Status measure. A number of the vaccines covered by this measure currently are reimbursed only when administered at the pharmacy under Medicare Part D (for example, Tdap and zoster) and beneficiaries may choose to receive most of the covered vaccines at the pharmacy. Moreover, provider access to state immunization registry data is uneven at best with some states charging providers for access to such data for their patients. If CMS finalizes the addition of this measure for MIPS, the commenter urged CMS to clarify that eligible clinicians and groups may satisfy this measure by documenting patient-reported immunization status, in lieu of data from the patient's electronic medical record or a state registry. **Response:** Each measure component would be reported as defined individually within the measure, which includes medical record documentation and registry data, while also allowing patient reported receipt of vaccination documented in the medical record to meet performance. MIPS measures collect data on all payer sources, and therefore we believe this measure would capture a more robust representation of performance than the individual components. This measure was proposed as a MIPS CQM and may be supported by Qualified Registries or QCDRs, which supports data abstraction for calculation of this measure from multiple medical resources and not necessarily reliant on immunization registries. We believe these types of measures drive the continued efforts of the interoperability of health data information sharing systems. Because clinicians have the flexibility to choose measures to report and this measure's performance is based on a weighted average of those measures, we believe that this measure provides a comprehensive adult immunization measure. **Comment:** One commenter believed this measure provided an inclusive assessment of adult vaccination status with a strong evidence base. However, the commenter had concerns with feasibility at the individual clinician and clinician group attribution levels, as patients do not always go to the same physician to receive all required vaccinations. **Response:** We believe this measure is a more robust reflection of quality care and the recommended adult immunizations. Each component measure would allow patient reported vaccination documented in the medical record to meet performance by individual clinicians or clinician groups. This measure is being proposed as a MIPS CQM and may be supported by Qualified Registries or QCDRs meaning that the data for calculation of this measure may be abstracted from multiple medical resources and not necessarily reliant on immunization registries. **Comment:** One commenter stated that introduction of this new measure in MIPS prior to introduction in MVPs further misaligns the two programs. The commenter was also concerned that the measure was not supported by the MAP and had not been analytically tested at the clinician level. In addition, combining the separate immunization measures into one single measure reduces the impact of each individual measure. Another commenter expressed that the measure was developed, tested, and endorsed at the health plan level, and the MAP did not support this measure for use at individual clinician and clinician group levels. **Response:** We do not believe there is misalignment between MIPS and MVPs. We, in discussion with interested parties, intend to only include measures within MVPs that are most applicable to the clinical topic being addressed by the MVP. Additionally, clinicians and clinician groups are provided the opportunity to select the measures that are appropriate to their specialties within MIPS and MVPs. Additionally, clinicians and clinician groups are provided the opportunity to select the measures that are appropriate to their specialties within traditional MIPS and MVPs. We believe this measure will encourage improvement in overall vaccination rates more effectively because performance is based on the administration of all four vaccinations rather than focusing on just one vaccination per measure. We acknowledge that the measure will set a more stringent performance standard by requiring a set of adult immunizations in one multi-performance measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. Since this multiperformance measure utilizes components of measures that have been implemented MIPS either currently or in prior MIPS performance years at the individual clinician and group level, we believe it can be successfully implemented into MIPS. While CBE endorsement is preferred, it is not a requirement for measure inclusion in MIPS. We are not aware of a similar composite measure specified for clinicians that is NQF endorsed. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46470 through 46471), we are finalizing the *Adult Immunization Status* measure as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] U.S. Department of Health and Human Services (2017). HealthyPeople.gov 2020 Topics & Objectives: Immunization and Infectious Diseases. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.

TABLE Group B: Previously Finalized Specialty Measures Sets Finalized for Combination and Modifications to Previously Finalized Specialty Measures Sets Finalized for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

In the CY 2023 PFS proposed rule (87 FR 46471), we proposed to add "Psychiatry" to the title of the Mental/Behavioral Health specialty set to create a combined new specialty set: Mental/Behavioral Health and Psychiatry (see Table B.21). We also proposed to add "Optometry" to the title of the Ophthalmology specialty set to create a combined new specialty set: Ophthalmology/Optometry (see Table B.28). For both Ophthalmology/Optometry and Mental/Behavioral Health and Psychiatry Specialty Measures sets, there were no proposed changes to the measures contained within each specialty measures set. However, based upon interested parties' feedback and the overlap in denominator eligibility of both individual specialties, we revised the specialty measures set titles to better reflect the applicable and appropriate MIPS eligible clinician types.

We proposed to modify the below previously finalized specialty measures sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures had proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table Group B as follows: NQF # / eCQM NQF #.

We finalized in section IV.A.6.c.(1)(b)(i) of this final rule an expansion of the definition of a high priority measure at §414.1305 to include health equity measures. Further details of these types of measures are located in the CMS Measures Management System Blueprint Version 17.0 (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf).

NOTE:

- Updates to measure titles and/or measure descriptions under Table Group B in this final rule may or may not be considered substantive in nature and therefore may not be proposed or updated under Table Group D. If the change was considered substantive in nature, it will have been finalized in Table Group D.
- Under Table Group B, we responded to comments that are related to new measures that were proposed for addition to measure sets, and measures that were proposed for removal. Any comments received on previously finalized measures are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B, have been removed from the applicable Removal table, and the reason for their retention was addressed under Table Group C. For some specialty sets, this resulted in the Removal Table being removed in its entirety in this final rule if no measures proposed for removal were finalized for removal. As a result, the Removal Table was removed for the following specialty set: Audiology.

It should be noted that the CMS Web Interface collection type will no longer be available in MIPS, except for the purposes of APM entities reporting through the APM Performance Pathway (APP), starting with the CY 2023 performance period; therefore, this collection type is no longer listed in any specialty sets under Table Group B. The CMS Web Interface collection type will remain through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the APP, see sections III.G.4.b.(9) and III.G.4.c.(1) of this final rule. For information on changes to measures under the CMS Web Interface collection type proposed for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this final rule.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.1. Allergy/Immunology								
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration

B.1. Allergy/Immunology								
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Allergy/Immunology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET									
licator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	NA / N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Allergy/Immunology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter opposed the addition of the Screening for Social Drivers of Health measure to the Allergy/Immunology Specialty Set. They stated that there is a lack of adequate specification and testing. Another commenter opposed including the measure in this set stating there are no standardized screening tools and concerns on the administrative burden related to DOH data collection and what responsibility there would be to act on the data.

Response: This measure does not hold clinicians accountable for improvements in patients' DOH and focuses on the completion of screening for DOH patient information. It does not require a referral to services or any other action on the part of the clinician, nor does it penalize clinicians for those patients who screen positive for any of the social determinants within the measure. We believe that achieving health equity is a pressing issue which deserves serious focus and rapid action. The measure focuses on data collection, data analysis, culture of equity, and quality improvement. Additionally, the measure was based on the Accountable Health Communities universal screening protocol with the intent to ensure all patients of MIPS eligible clinicians are screened for DOH. The following five domains were selected to screen for social risk factors in Medicare and Medicaid beneficiaries under the Accountable Health Communities Model: food insecurity; housing instability; transportation needs; utility difficulties; and interpersonal safety.

We believe this measure is an important step towards the future development of outcome-based measures within this topic. While we consider whether or not a measure is fully tested, it is not the only relevant standard. This measure supports health equity, a national healthcare priority, and is responsive to filling a critical gap in MIPS. This measure does not result in negative unintended consequences as described in the Blueprint (https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection), such as overuse or inappropriate use of care or treatment, or limiting access to care. Therefore, based upon the importance of this topic and need to address this national healthcare priority, we are finalizing the measure.

We designed this measure with flexibility to reduce burden on clinicians. For example, this measure allows the use of any tool to screen for DOH and therefore, we believe the clinician can determine what tool/process works best for their clinical workflow. In addition, this is a screening data collection measure and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, the Allergy/Immunology Specialty Set contains 13 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. While we appreciate the commenters' concerns, we believe this is an important process measure that supports collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who chose to implement this measure. CMS is committed to lessening the burden of reporting quality measures through Meaningful Measures 2.0.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46474 through 46475), we are finalizing the above measures for addition to the *Allergy/Immunology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

Comment: One commenter opposed removal of measures Q110 and Q111 from the Allergy/Immunology Specialty Set. Another commenter stated that measure Q110 is one of the highest reported measures by this specialty because many of its patients are immunocompromised. Considering the performance rate is lower than 50 percent (based on prior year data), they stated there is obvious room for improvement. The commenter stated that CMS should maintain this measure in MIPS, as well as this specialty set.

Response: As mentioned, the new Adult Immunization Status measure is more robust and will help drive care by ensuring complete vaccination status for patients. Measures Q110 and Q111 only focus on the administration of a single immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care. Please note that measure Q110 is not being removed due to a high benchmark or topped out status but is being replaced by a more robust measure, which will still allow for clinicians to report and demonstrate improvement on the administration of vaccines.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46475), we are finalizing the above measures for removal from the *Allergy/Immunology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

MEASURES NOT FINALIZED FOR **ADDITION** TO THE ANESTHESIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Anesthesiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.2. Anesthesiology

MEASURES NOT FINALIZED FOR **ADDITION** TO THE ANESTHESIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter was unable to make a recommendation on whether the Screening for Social Drivers of Health measure should be included in the Anesthesiology Specialty Set. The commenter felt that the measure steward and CMS have not been forthcoming with how the measure can be collected or reported. The commenter also requested but did not receive the measure specifications for this measure. The commenter was concerned that a published survey on the topic, which is the basis for the measure steward's assertions about physicians identifying the importance of social determinants of health, cites multiple medical specialties as participating in the survey, but fails to mention anesthesiology. The commenter mentioned having to wait until the final rule to see measure specifications and be able to assess CPT codes listed in the measure. This limits the commenter's ability to determine whether a measure can be collected and reported via its registry and may create confusion among its registry participants. The commenter cited lack of transparency on this measure and requested that future measure proposals intended to capture health equity throughout a patient's care must demonstrate that physicians can report the measure. The commenter stated that CMS and measure stewards should distribute and make public the measure specifications for any proposed measures. **Response:** As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Anesthesiology Specialty Set would contain six MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than 6 MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Anesthesiology Specialty Set, this measure would thus inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for anesthesiologists to assess within their patient population, we appreciate that the inclusion of such measure within this set would eliminate the option of choice to select and report the measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Anesthesiology Specialty Set. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46477), we are not finalizing the Screening for Social Drivers of Health measure for addition to the *Anesthesiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ANESTHESIOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

Comment: One commenter opposed removal of measure Q076 from the Anesthesiology Specialty Set. The commenter stated that while this measure has topped out, the measure is still useful for monitoring patient safety and the impact of patient outcomes. Another commenter opposed removal of measure Q076 from this set for the same reasons related to quality and patient safety. The commenter stated that removing the measure will limit the opportunities for anesthesiologists from meeting base MIPS quality performance category requirements via the Qualified Registry reporting option.

Response: We agree that reducing infections is an important barometer of patient safety and recognize that the measure is endorsed by NQF. The data shows that both the MIPS CQM and Medicare Part B Claims specifications collection types have reached the end of their topped-out life cycles which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2022 Benchmark File. We acknowledge that removal of this measure decreases the number of available measures for anesthesiology, however, there are policies in place to account for this when working to meet MIPS quality performance category requirements.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46478), we are finalizing the above measure for removal from the *Anesthesiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	2152/ N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We proposed to include this measure in the Audiology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure will help to broaden the patient population being screened for unhealthy alcohol use. There is known risk of adverse effects on the auditory system due to alcohol consumption making this an important aspect of care for audiologists.
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Audiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
Comment: Several commenters were supportive of adding measure Q431 and the new Screening for Social Drivers of Health measure to the Audiology Specialty Set. The commenters thanked CMS for their continued support of the inclusion and expansion of audiology within MIPS. Another commenter recognized that these measures are important drivers of improving health care quality and patient outcomes. Another commenter requested that CMS provide educational resources to facilitate the implementation of the Screening for Social Drivers of Health measure across varied clinical settings. **Response:** We thank the commenters for supporting the addition of these measures to the Audiology Specialty Set. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46481), we are finalizing the above measures for addition to the *Audiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS13 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS14 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association	We proposed to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type. Given the close correlation of cardiovascular diseases and cerebral perfusion, interdisciplinary care is vital. We agreed with interested parties' feedback that this measure will help to incentivize timely initiation of appropriate thrombolytic therapy for patients with stroke, which is an important component of cardiology care.

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Cardiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.4a. Cardiology

MEASURES FINALIZED FOR ADDITION TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Cardiology specialty set as it is generally clinically relevant to this clinician type, for those cardiologists that do not subspecialize. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter did not support the addition of measure Q187 to the Cardiology Specialty Set. The commenter stated this measure is more appropriately aligned with emergency medicine and neurosurgery, rather than cardiology, and it is included in the specialty measure sets for these other specialties. Another commenter disagreed with the addition of measure Q187 to this set because cardiologists do not typically treat acute stroke patients. While both stroke and heart attack have similar risk factors, they differ drastically in presentation, acute evaluation, and acute treatment. Stroke patients and heart attack patients are both initially evaluated by emergency physicians, but in the emergency department their care pathways immediately diverge. For heart attacks the ECG is the diagnostic tool. ST elevation leads to a call to an interventional cardiologist and rapid transfer to a cardiac catheterization lab. For stroke patients, the diagnostic tool is the physical exam, followed by CT scan, followed by a choice between thrombolytic therapy and/or the interventional laboratory for thrombus extraction. Interventional cardiologists do not typically treat acute stroke patients and neurologists do not treat acute heart attack patients. The commenter stated that to rate cardiologists by stroke care is inconsistent with patterns of normal clinical care and would be inappropriate.

Response: We agreed with commenters' feedback that this measure will help to incentivize timely initiation of appropriate thrombolytic therapy for patients with stroke, which is an important component of cardiology care. Up to half of ischemic strokes are directly related to cardiac and large artery diseases and cardiovascular risk factors are involved in most other strokes. Moreover, in an acute stroke direct central brain signals and a consecutive autonomic/vegetative imbalance may account for severe and life-threatening cardiovascular complications. The strong cerebro-cardiac link in acute stroke has recently been addressed as the stroke-heart syndrome that requires careful cardiovascular monitoring and immediate therapeutic measures (https://academic.oup.com/eurheartjsupp/article/22/Supplement_M/M3/6024772). Despite substantial progress in stroke research and clinical care that has been achieved, relevant gaps in clinical evidence remain and cause uncertainties in best practices for the treatment and prevention of stroke (https://academic.oup.com/eurjpc/article/27/7/682/5924645). Currently, the Cardiology Specialty Set contains 25 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care, thus cardiologists who do not consider this measure appropriate for their practice may opt to select another measure.

Comment: One commenter supported the addition of the Screening for Social Drivers of Health measure to determine whether patients' social needs are being assessed. Another commenter agreed with the addition of this measure, but only if all other specialties are also rated by this metric. They stated that it is true that cardiovascular disease is profoundly affected by DOH, but it is also true that virtually every other disease is similarly influenced.

Response: We thank the commenters for supporting the addition of this measure to the Cardiology Specialty Set. This measure has also been added to other specialty sets as appropriate.

Comment: One commenter supported the adoption of Adult Immunization Status measure that will replace the individual component measures for influenza and pneumococcal vaccines. Contracting influenza can be gravely serious for patients with heart failure.

Response: We thank the commenter for supporting the addition of this measure to the Cardiology Specialty Set.

Comment: One commenter stated that retaining measures Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Status for Older Adults for cardiologists is more relevant to this specialty than adding the new Adult Immunization Status to this set. Cardiovascular disease is exacerbated by flu and pneumonia so that immunizations against these diseases are a special concern for cardiovascular specialists. Td, Tdap, and zoster are unrelated to cardiac care and not relevant to cardiologists. They stated that having to report on the status of other unrelated immunizations will also cause undue burden.

Response: We acknowledge that the measure will set a more stringent performance standard by requiring a set of adult immunizations in one multi-performance measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. This robust measure assesses the administration of appropriate adult immunizations. These measures' clinical concept is included within the new Adult Immunization Status measure. We understand that some of these immunizations may not be relevant to, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46488 through 46489), we are finalizing the above measures for addition to the *Cardiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46490), we are finalizing the above measures for removal from the *Cardiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.								

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.4b. Electrophysiology Cardiac Specialist

MEASURES NOT FINALIZED FOR ADDITION TO THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Electrophysiology Cardiac Specialist specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.4b. Electrophysiology Cardiac Specialist

MEASURES NOT FINALIZED FOR **ADDITION** TO THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter supported the addition of the Screening for Social Drivers of Health measure to the Electrophysiology Cardiac Specialist specialty set and stated this measure also aligns with the AHA's 2030 Impact Goal of Advancing Equity and Well-Being. However, the commenter believed this measure may be more appropriate if reported at the system or regional level. The commenter was concerned about data required for this measure and that the potential gap in electronic feasibility may place an addition burden on health systems as they attempt to capture the required data. **Response:** As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Electrophysiology Cardiac Specialist Specialty Set would contain three MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Electrophysiology Cardiac Specialist Specialty Set, this measure would thus inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for electrophysiologists to assess within their patient population, we appreciate that the inclusion of such measure within this set would eliminate the option of choice to select and report the measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Electrophysiology Cardiac Specialist Specialty Set. After consideration of public comments, we are not finalizing the Screening for Social Drivers of Health measure for addition to the *Electrophysiology Cardiac Specialist Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Certified Nurse Midwife specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46495), we are finalizing the above measure for addition to the *Certified Nurse Midwife Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / Ecqm NQF #	Quality #	CMS Ecqm ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

We received no public comments on the measure proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46496), we are finalizing the above measure for removal from the *Certified Nurse Midwife Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Chiropractic Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46500), we are finalizing the above measure for addition to the *Chiropractic Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association /American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association /American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.7. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINCAL SOCIAL WORK SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Clinical Social Work specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the inclusion of the Screening for Social Drivers of Health measure in the Clinical Social Work Specialty Set. The commenter agreed with CMS that social drivers of health can be a key component to a beneficiary achieving health equity within all clinical settings and clinician types and encouraged CMS to continue to include measures pertinent to social work practice such as measures in behavioral health.

Response: We thank the commenter for supporting the addition of this measure to the Clinical Social Work Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46504), we are finalizing the above measure for addition to the *Clinical Social Work Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v11	eCQM Specifications	Outcome	Community /Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v12	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.8. Dentistry

MEASURES NOT FINALIZED FOR ADDITION TO THE DENTISTRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Dentistry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.8. Dentistry

MEASURES NOT FINALIZED FOR **ADDITION** TO THE DENTISTRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Although we did not receive any comments pertaining to the inclusion of the Screening for Social Drivers of Health measure in the Dentistry Specialty Set, we want to clarify how we intended the measure would be implemented as an available MIPS quality measure within the inventory, particularly within a specialty set. As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Dentistry Specialty Set would contain three MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Dentistry Specialty Set, this measure would inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for dentists, to assess within their patient population, the inclusion of such measure within this set would eliminate the option of choice to select and report such measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Dentistry Specialty Set. We received no public comments on the measure proposed for addition to this specialty set; however, we are not finalizing the above measure for addition to the *Dentistry Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
*	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	0028 / 0028e	226	CMS 138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS 50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
* ! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	485	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology	We proposed to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this is an important patient-centered measure that helps to address any changes in the patient's quality of life during treatment of psoriasis. This measure incorporates the patient voice, empowering patients to make the best-informed decisions about their own healthcare while also allowing clinicians to optimally adjust care as needed. See Table A.1 for rationale.
! (Outcome)	N/A/ N/A	486	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessments performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology	We proposed to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this is an important patient-centered measure that helps to address any changes in the patient's quality of life during treatment of dermatitis. This measure incorporates the patient voice, empowering patients to make the best-informed decisions about their own healthcare while also allowing clinicians to optimally adjust care as needed. See Table A.2 for rationale.

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Dermatology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: Several commenters supported the addition of the Psoriasis: Improvement in Patient-Reported Itch Severity and Dermatitis: Improvement in Patient-Reported Itch Severity measures to the Dermatology Specialty Set. They believed the addition of these outcome measures helps clinicians, particularly solo practitioners, in meeting case minimum quality measures for dermatology.

Response: We thank the commenters for supporting the new outcome measures in the Dermatology Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46509 through 46510), we are finalizing the above measures for addition to the *Dermatology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

Comment: One commenter stated that the removal of measure Q265 would reduce the number of available/applicable measures in the Dermatology Specialty Set and decrease MIPS scores, noting that only two measures remaining in the set are applicable to providers who prescribe biologics/DMARD'S (measures Q410 and Q176) and only two measures are not topped out. They stated that across the Dermatology Specialty Set, measure Q265 continues to be helpful with patient follow-up and retention especially with staffing shortages this measure has continued to help and promote effective coordination of care across the specialty.

Response: We thank the commenter for their comment and agree that this is a relevant measure for providers that prescribe biologic/DMARD'S; however, we strive to ensure that all measures align with MIPS' goals and priorities, including the removal of measures that are at the end of the topped-out lifecycle. Topped out status is determined by the data reported to MIPS within the 2022 Benchmark file from individual clinicians, groups, and virtual groups, therefore we would be unable to utilize data from other reporting programs as there may be differences in implementation and/or the level of analysis needed to determine topped out status of a quality measure. When a measure has reached the end of their topped-out life cycles it no longer allows for meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. We encourage the commenter to reach out to measure developers/stewards to develop new biopsy follow-up measures that take into account race, ethnicity, and/or language for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46510), we are finalizing the above measure for removal from the *Dermatology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance

B.10. Diagnostic Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Diagnostic Radiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition. For the reasons stated above and in the proposed rule (87 FR 46513), we are finalizing the above measure for addition to the *Diagnostic Radiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS14 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS16 1v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.11. Emergency Medicine

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0069/ N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance	We proposed to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure will help decrease the overuse of antibiotics for the treatment of upper respiratory infections. The addition of this measure to this specialty set is feasible given the high rates that patients are assessed, treated, and managed for this condition in the emergency care setting.
* §	N/A/ N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that it is imperative to complete depression screenings in the emergency care setting to identify mental health conditions as well as forming appropriate treatment plans. Studies have shown depression to be more widespread in emergency departments than in the general public. Identifying patients with depression and their access to care in the emergency department is important as depression has been associated with poorer patient outcomes from care received in the emergency department, as well as increased length of stay in the emergency department and increased number of repeated emergency department visits (https://pubmed.ncbi.nlm.nih.gov/28007366/).

B.11. Emergency Medicine

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/ 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We proposed to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We proposed to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that it is a significant public health concern, and as emergency medical professionals they can mitigate the consequences of alcohol abuse through screening, intervention, and referral. In turn, this will lower the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs.

B.11. Emergency Medicine

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Emergency Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.11. Emergency Medicine

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter supported the addition of measure Q065 to the Emergency Medicine Specialty Set.

Response: We thank the commenter for supporting the addition of this measure to the Emergency Medicine Specialty Set.

Comment: One commenter supported the addition of measure Q226 to this specialty set and six additional specialty sets. They stated that tobacco use is one of the leading preventable causes of death in the U.S. and globally and is a major risk factor for cardiovascular disease and stroke. Quitting smoking at any age significantly reduces the risk of cardiovascular morbidity and mortality for smokers with and without existing cardiovascular disease, so it is essential that smokers be advised to quit at every visit in every setting and be offered evidence-based interventions to support them in doing so.

Response: We thank the commenter for supporting the addition of this measure to the Emergency Medicine Specialty Set, however, based upon feedback received we are not finalizing measure Q226 for inclusion as the time restraints may not allow for implementation.

Comment: Two commenters did not support the addition of the other measures proposed for addition to this set.

One commenter stated that measure Q134 is not clinically relevant to the practice of emergency medicine, as emergency clinicians do not typically conduct this comprehensive screening in the emergency department. The EHR systems that emergency physicians use in emergency departments do not always receive data from other parts of the hospital. It would be difficult to only rely on data from the emergency department encounter to calculate this measure. Some emergency departments may not have the resources and staffing required to conduct these surveys for every patient and adding additional screenings could delay necessary care for patients.

Another commenter indicated that in addition to requiring the clinician to screen a patient for depression, this measure requires the clinician to document a follow-up plan if the patient screens positive. While the commenter supports the intent and value of these screening measures, they do not believe they are truly reflective of emergency care compared to other measures. They stated that it has long been established through CMS coding policies that time-based codes are not applicable in the emergency setting.

The commenter had a similar concern to adding measure Q226 to this set. They believe cessation counseling would be particularly difficult and time-consuming to document for each patient. Furthermore, they believe it would not be clinically relevant to screen every patient that comes to the emergency department. Also, if the patient is admitted to the hospital, the counseling becomes part of the discharge process which never gets translated to an emergency department chart. The commenter stated that more appropriate measures exist, such as QCDR measure CEDR called "Tobacco Use: Screening Cessation Intervention for Patients with Asthma and COPD."

Regarding measure Q431, one commenter stated the measure is not clinically relevant, will add to administrative burden, and is not meaningful in the emergency department setting. Another commenter questioned why CMS is proposing to re-incorporate measures Q226 and Q431 after it had previously determined that these measures were inappropriate for Emergency Medicine and removed them from the Emergency Medicine specialty set in 2018.

Response: We believe these measures represent important concepts; however, based upon the commenter's feedback, measures Q226 and Q431 may not be appropriate for this setting based upon the time required to complete cessation intervention for those patients identified as a tobacco user and will not be adding these two measures to this set. We will take this feedback to the measure steward for potential revisions for future implementation.

Comment: One commenter supported the overall intent of the Screening for Social Drivers of Health measure but stated this screening is done at the facility level, and it may be difficult for individual physicians to report the measure at the individual reporting level. Many institutions have limited resources to conduct these types of screening on every patient. It may be more feasible to limit the screening to certain patients such as patients who are homeless or lack health insurance.

Response: We thank the commenter for supporting the addition of this measure to the Emergency Medicine Specialty Set and note that the measure does not require a referral to services or any other action on the part of the clinician so should be achievable for reporting at the individual reporting level. Because clinicians have the flexibility to choose this measure and it only assesses for the screening of patients, we do not believe there would be unintended consequences for the clinicians or the patients they serve.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46516 through 46518), we are finalizing the above measures for addition to the *Emergency Medicine Specialty Set* as proposed, except measures Q226 and Q431. For the reasons stated above, we are not finalizing our proposals to add measures Q226 and Q431 to the *Emergency Medicine Specialty Set* for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS34 7v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • • Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS64 5v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Endocrinology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A/ N/A	488	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.12. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measures proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46522 through 46523), we are finalizing the above measures for addition to the *Endocrinology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ENDOCRINOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46523), we are finalizing the above measures for removal from the *Endocrinology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS13 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS14 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica
* §	2372 / N/A	112	CMS125v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Opioid)	N/A / N/A	305	CMS137v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90 v12	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS34 7v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v5	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive interested parties' engagement and comprehensive reviews of the literature.	The American Board of Family Medicine

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We proposed to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration that lies within this specialty's scope of practice. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.
* ! (Outcome)	N/A / N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	We proposed to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that benign prostatic hyperplasia is a common medical condition that is frequently seen in family medicine practices. Including this measure will enhance patient-centered care amongst patients and their family medicine providers. Increasing the quality of comprehensive patient care can also result in the overall improvement of the patient's functional status.

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Family Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A/ N/A	488	CMS95 1v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measures proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46535 through 46537), we are finalizing the above measures for addition to the *Family Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46537), we are finalizing the above measures for removal from the *Family Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	NA / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association

B.14. Gastroenterology

MEASURES FINALIZED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Gastroenterology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46541), we are finalizing the above measure for addition to the *Gastroenterology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTROLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	425	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46542), we are finalizing the above measures for removal from the *Gastroenterology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.15. General Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE GENERAL SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the General Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46545), we are finalizing the above measure for addition to the *General Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

MEASURES FINALIZED FOR ADDITION TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. Depression is a serious medical illness associated with higher rates of chronic disease, increased health care utilization, and impaired patient functioning. For the older patient population, depression is commonly diagnosed with other illnesses or as a side effect to medication. Proper depression assessment and intervention is important for the patients within the geriatric population.
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. Complications from patient falls are the leading cause of death from injury in people over the age of 65. Screening patients for their risk of future falls can help reduce the number of patients falls per year.

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Geriatrics specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A/ N/A	488	CMS95 1v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.16. Geriatrics

MEASURES FINALIZED FOR ADDITION TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure is relevant to this specialist's patient population. Along with the high burden of cardiovascular morbidity and mortality in patients with chronic kidney disease, the fact that kidney function decreases in the normal aging process, and evidence that patients over the age of 60 have a greater likelihood of resistant hypertension without proper ACE or ARB therapy, this is an important and relevant measure for this specialty. See Table A.5 for rationale.
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter opposed the addition of the Kidney Health Evaluation measure to the Geriatrics Specialty Set. The commenter stated that while adults over 60 years of age are more likely to develop kidney disease and more than 50 percent of adults over the age of 75 are believed to have kidney disease, there is strong evidence that the current definition of chronic kidney disease (CKD) leads to overdiagnosis and identifies older adults as having CKD even though they do not have an increased risk for adverse outcomes. The commenter encouraged CMS to reconsider the addition of the Kidney Health Evaluation measure so as not to encourage overdiagnosis, overestimation of the burden of CKD, and unnecessary interventions in older adults.

Response: For the specified patient population who experience decreased kidney functioning due to the normal aging process, it is important to appropriately treat CKD to lower the rates of kidney failure, improve cardiovascular outcomes, and lower mortality. (https://pubmed.ncbi.nlm.nih.gov/23732715/). Currently, the Geriatric Specialty Set contains 19 measures allowing clinicians to choose to submit those measures that are meaningful to their scope of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46541), we are finalizing the above measures for addition to the *Geriatrics Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

Comment: One commenter supported the removal of measures Q110 and Q11 from the Geriatrics Specialty Set.

Response: We thank the commenter for supporting the removal of measures Q110 and Q111 from traditional MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46542), we are finalizing the above measures for removal from the *Geriatrics Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.17. Hospitalists

MEASURES NOT FINALIZED FOR **ADDITION** TO THE HOSPITALISTS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Hospitalists specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.17. Hospitalists

MEASURES NOT FINALIZED FOR ADDITION TO THE HOSPITALISTS SPECIALTY SET									
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title And Description	Measure Steward	Rationale for Inclusion

Comment: One commenter did not support the inclusion of the Screening for Social Drivers of Health measure in the Hospitalists Specialty Set. The commenter stated this measure should not be applied in a one-sized-fits-all approach across MIPS.

CMS has already finalized this measure and an additional measure (Screen Positive Rate for Social Drivers of Health) in the CY 2023 Inpatient Prospective Payment System Rule (87 FR 49202 through 49215), with mandatory reporting beginning in the 2024 reporting/FY2026 payment period. Patients seen by hospitalists and other hospital-based clinicians will already receive screening for these social drivers of health as hospitals begin to report the hospital-level measures. The commenter felt this means the data will already be captured and documented in the medical record used by those hospitalists. Therefore, it would be duplicative and counterproductive to create a requirement for hospitalists and other hospital-based clinicians to screen patients again for these drivers of health and repeated screenings could create distress for patients.

Response: We thank the commenter for their comment. As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Hospitalists Specialty Set would contain five MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Hospitalists Specialty Set, this measure would inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for hospitalists to assess within their patient population, the inclusion of such measure within this set would eliminate the option of choice to select and report such measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Hospitalists Specialty Set.

After consideration of public comments, we are not finalizing the Screening for Social Drivers of Health measure for addition to the *Hospitalists Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE HOSPITALISTS SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

Comment: One commenter supported the removal of measure Q076 from the Hospitalists Specialty Set but requested the measure remain in MIPS because it has served as an important impetus for driving the implementation of bloodstream infection controls and improved systems around CVC insertions.

Response: We thank the commenter for supporting the removal of this measure for the Hospitalists Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46555), we are finalizing the above measure for removal from the *Hospitalists Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS34 9v5	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

B.18. Infectious Disease

MEASURES FINALIZED FOR ADDITION TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure will help decrease the overuse of antibiotics for the treatment of upper respiratory infections. The addition of this measure to this specialty set is feasible given the high rates that patients are assessed, treated, and managed for this condition within this specialty.
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that the appropriate use of antibiotics, including the avoidance of overuse of antibiotics, is an important quality of care consideration for infectious disease providers.
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration relevant to this specialty. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
* §	N/A / N/A	240	CMS117v11	eCQM Specifications	Process	Community/Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that appropriate childhood immunization is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that screening for hepatitis C infection is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that appropriate adolescent immunization is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Infectious Disease specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

Comment: One commenter noted there is a lack of clinically appropriate quality measures in the MIPS program for infectious disease physicians, especially if traditional MIPS is sunset. The commenter made recommendations on how to make improvements for the Infectious Disease Specialty Set.

Response: We encourage the commenter to reach out to measure developers/stewards to develop new infectious disease-related measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46558 through 46560), we are finalizing the above measures for addition to the *Infectious Disease Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INFECTIOUS DISEASE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46560), we are finalizing the above measures for removal from the *Infectious Disease Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161v11	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A / N/A	305	CMS137v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v12	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v5	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive interested parties' engagement and comprehensive reviews of the literature.	The American Board of Family Medicine

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MEASURES FINALIZED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We proposed to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration relevant to this specialty. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.
* ! (Outcome)	N/A / N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	We proposed to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that benign prostatic hyperplasia is a common condition among older men and inclusion of this measure in the internal medicine specialty set will promote patient-centered care with the goal of functional status improvement among primary care providers.

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MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Internal Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A/ N/A	488	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

Comment: One commenter supported the addition of measure Q176 to the Internal Medicine Specialty Set and stated that most often, the measure will apply to rheumatologists, but primary care physicians may also manage rheumatoid arthritis. The commenter also supported the addition of the new Adult Kidney Health measure.

Response: We thank the commenter for supporting the addition of these measures to the Internal Medicine Specialty Set.

Comment: One commenter did not support the addition of the Screening for Social Drivers of Health measure to this set and recommended delayed adoption of this measure until reliability and validity testing has been completed.

Response: We believe that the inclusion of this measure serves an important purpose in advancing quality measurement in MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. While we consider whether or not a measure is fully tested, it is not the only relevant standard. This measure supports health equity, a national healthcare priority and is responsive to filling a critical gap in MIPS. This measure does not result in negative unintended consequences as described in the Blueprint (https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection), such as overuse or inappropriate use of care or treatment, or limiting access to care. Therefore, based upon the importance of this topic and need to address this national healthcare priority, we are finalizing the measure.

While we appreciate the commenter's concerns, we believe this is an important process measure that supports collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who chose to implement this measure. We believe that achieving health equity is a pressing issue which deserves serious focus and rapid action. This is a screening data collection measure and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. Currently, the Internal Medicine Specialty set has 60 measures, which allows clinicians to choose to submit those measures that are meaningful to their scope of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46572 through 46574), we are finalizing the above measures for addition to the *Internal Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

Comment: One commenter did not support the removal of measure Q110 from the Internal Medicine Specialty Set unless the Adult Immunization Status measure was finalized for adoption. The commenter did not support the removal of measure Q119 unless the Kidney Health Evaluation measure was finalized for adoption. The commenter also did support the removal of measure Q111.

Response: We thank the commenter and have finalized the Adult Immunization Status measure under Table A.9 and the Kidney Health Evaluation measure under Table A.4.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46574), we are finalizing the above measure for removal from the *Internal Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Interventional Radiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46576), we are finalizing the above measure for addition to the *Interventional Radiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERVENTIONAL RADIOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46577), we are finalizing the above measure for removal from the *Interventional Radiology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.21. Mental/Behavioral Health and Psychiatry

As indicated in the introductory language of Table Group B of the appendix to this final rule, we finalized adding "Psychiatry" to the title of the Mental/Behavioral Health specialty set to create a combined new specialty set: Mental/Behavioral Health and Psychiatry. The Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	N/A / 0104e	107	CMS161v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	366	CMS13 6v12	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS15 9v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS17 7v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication / Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Opioid)	N/A / N/A	305	CMS137 v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance	We proposed to include this measure in the Mental/ Behavioral Health and Psychiatry specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback and the importance of including measures addressing substance use disorders, which are complex mental and behavioral health challenges. Inclusion of this measure will incentivize the appropriate screening and treatment for substance use disorders.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter had concerns with the proposal to create combined specialty sets of "Psychiatry" to the title of "Mental/Behavioral Health.". They believe this type of combination of specialties could lead to providers who lack the knowledge, licensure, or experience necessary to safely treat patients to the currently expected level of care. The commenter had concerns that, by grouping together fairly divergent levels of caregivers into two larger amalgamations, the distinctions between the specialties will not be addressed clearly, such as differences in patient populations. They stated that this kind of change may have serious long-term implications in terms of the scope of practice which providers in these specialties may attempt to be reimbursed for in the future. The commenter was also concerned about the claims made about having received interested parties' feedback. To the commenter's knowledge, the measure steward for at least one of these specialties was not aware of this consideration prior to its announcement in the 2023 PFS proposed rule. The lack of input from the measure steward in advance of such significant changes sets a precedent that will inevitably lead to future measure harmonization that may be inappropriate or that cannot be smoothly implemented. **Response:** Clinicians should be working within their scope of practice when treating patients. Currently, the Mental Behavioral Health/Psychiatry Specialty Set contains 23 measures allowing clinicians to choose to submit those measures that are meaningful to their scope of practice. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. We understand that the significant changes may be cause for concern, and we strongly encourage the commenter to reach out to the measure developer/stewards to collaborate for measure harmonization and new measure development for future implementation. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46582 through 46583), we are finalizing the above measures for addition to the *Mental/Behavioral Health and Psychiatry Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139 v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
! (Equity)	N/A/N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Nephrology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	488	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association	We proposed to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that considering the high burden of cardiovascular morbidity and mortality in patients with chronic kidney disease, the decrease of kidney function in the normal aging process, and evidence that patients over the age of 60 have a greater likelihood of resistant hypertension without proper ACE or ARB therapy, validates the importance of this measure in the overall management of adult kidney disease. This measure is relevant and lies within the scope of care for this clinician type. See Table A.5 for rationale.

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

Comment: One commenter appreciated the inclusion of the new quality measures in the Nephrology Specialty Set. While the commenter believed the Screening for Social Drivers of Health measure is most appropriate for primary care, there may be instances where social drivers of health are linked to disparities in kidney care, and therefore, supports its inclusion in the set. The commenter also supports the inclusion of the Kidney Health Evaluation measure.

Response: We thank the commenters for supporting the addition of these measures in the Nephrology Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46585 through 46587), we are finalizing the above measures for addition to the *Nephrology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEPHROLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46588), we are finalizing the above measures for removal from the *Nephrology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.23. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Neurology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46593), we are finalizing the above measure for addition to the *Neurology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROSURGICAL SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Neurosurgical specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46596), we are finalizing the above measure for addition to the *Neurosurgical Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROSURGICAL SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46597), we are finalizing the above measures for removal from the *Neurosurgical Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	239	CMS15 5v11	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** • Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that Hemoglobin A1c is an important factor in the determination of risk stratification and management strategies for individuals with prediabetes, and it is a typical clinical indicator in the management of diabetes care.
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Nutrition/ Dietician specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Nutrition/Dietician specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46600), we are finalizing the above measures for addition to the *Nutrition/Dietician Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NUTRITION/DIETICIAN SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	This measure was proposed for removal from the Nutrition/Dietician specialty set. Per the measure specifications, the neurological lower extremity exam must consist of documentation of sensory abilities and should include 10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold; however, the clinician should perform all necessary tests to make the proper evaluation. We agreed with interested parties' feedback that this clinician type lacks the required education and training to properly perform the quality action of this measure and it is out of the scope of their practice.
0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	This measure was proposed for removal from the Nutrition/Dietician specialty set. Per the measure specifications, the proper evaluation of footwear must be completed, including a foot examination documenting the vascular, neurological, dermatological, and structural/biomechanical findings. The foot should also be measured using a standard measuring device, and counseling on appropriate footwear should be based on risk categorization. We agreed with interested parties' feedback that this clinician type lacks the required education and training to properly perform the quality action of this measure and it is out of the scope of their practice.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46601), we are finalizing the above measures for removal from the *Nutrition/Dietician Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v11	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type. Osteoporosis is an important public health issue requiring attention as it can lead to co-morbidities and decreased quality of life. Screenings are typically encouraged for women who are post-menopausal and, therefore, relevant to the patient population of this specialty.
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Obstetrics/Gynecology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measures proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46606 through 46607), we are finalizing the above measures for addition to the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46607), we are finalizing the above measures for removal from the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / 0389e	102	CMS129v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v11	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that depression screening and intervention is an essential care process for patients diagnosed with cancer, including patients with breast cancer. Depression can be a disabling co-morbidity in cancer patients and it's vital to incorporate this assessment and intervention in their comprehensive care.
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM specifications, MIPS CQMs specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance	We proposed to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that medications used for supportive care for patients with cancer diagnoses, such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-effects and toxicity. Cancer care management between specialists heightens the need for closer collaboration of medication management for this patient population.

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality	We proposed to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that the inclusion of this patient-centered CAHPS survey measure can incentivize the evaluation of patient-centered domains relevant to cancer care (for example, timely care, provider communication, access to specialists, health promotion and education, shared decision making, functional status, care coordination).

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Oncology/Hematology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A	490	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)	We proposed to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this patient-centered measure focuses on the appropriate management of adverse events that may reduce unnecessary utilization and improve quality of life (QOL) for patients taking checkpoint inhibitors. See Table A.6 for rationale.

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46611 through 4664), we are finalizing the above measures for addition to the *Oncology/Hematology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46614), we are finalizing the above measures for removal from the *Oncology/Hematology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / 0389e	102	CMS12 9v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS15 7v11	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.27b. Radiation Oncology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE RADIATION ONCOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Radiation Oncology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.27b. Radiation Oncology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE RADIATION ONCOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Radiation Oncology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27b. Radiation Oncology

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE RADIATION ONCOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter noted the two measures for addition to the Radiation Oncology Specialty Set. The commenter supported the development and inclusion of health equity quality measures in MIPS but had concerns with the inclusion of Screening for Social Drivers of Health as it relates to the data availability and standardized capture and wanted the measure delayed under electronic specifications have been developed and until USCDI v3 is fully adopted by all electronic health record systems. **Response:** As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Radiation Oncology Specialty Set would contain five MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Radiation Oncology Specialty Set, this measure would inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for radiation oncologists to assess within their patient population, the inclusion of such measure within this set would eliminate the option of choice to select and report such measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Radiation Oncology Specialty Set. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46616 through 46617), we are finalizing measure Q226 for addition to the *Radiation Oncology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. We are not finalizing the addition of the Screening for Social Drivers of Health measure to this set. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.28. Ophthalmology/Optometry

As indicated in the introductory language of Table Group B of the appendix to this final rule, we finalized adding "Optometry" to the title of the Ophthalmology specialty set to create a combined new specialty set: Ophthalmology/Optometry. The Ophthalmology/Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / 0086e	012	CMS143v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
	0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

MEASURES FINALIZED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Ophthalmology/Optometry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES FINALIZED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter applauded CMS for efforts to expand and streamline the MIPS specialty measure sets. The commenter supported creation of the combined new "Ophthalmology/Optometry" Specialty Set. The commenter appreciated that specialty measure sets are not required to be reported by clinicians participating in MIPS but believe they can be helpful for clinicians to more easily identify measures that can be reported.

Response: We thank the commenter for supporting the combined Ophthalmology/Optometry Specialty Set.

Comment: One commenter sought clarity on the purpose of combining Ophthalmology and Optometry, stating that most outcomes-based measures in the current Ophthalmology specialty set measure surgical outcomes, which would generally apply only to ophthalmologists. However, the commenter supported this proposal to the extent that such change may ease reporting burdens and increases efficiencies for clinically integrated ophthalmology and optometry clinics.

Response: Due to measure overlap for both specialty sets it was determined that combining Ophthalmology and Optometry would reduce burden on providers and staff. We encourage physicians to choose and submit those measures that are meaningful to their scope of practice.

Comment: One commenter strongly opposed grouping optometrists with retina specialists and other ophthalmologists in the same MIPS specialty set. Currently, the Ophthalmology Specialty Set includes measures for delicate ocular surgical procedures such as retinal detachment repair and cataract surgery. Optometrists do not have the same level of training as ophthalmologists and retina specialists and may not perform the intraocular surgeries included in this measure set.

Another commenter expressed concern about combining Optometry and Ophthalmology into one specialty set.

Another commenter had significant concerns with the proposal to add Optometry to this specialty set, due to the possible risks and harms this may cause to patients following implementation. The commenter believed that the combination of the two specialties could lead to providers who lack the knowledge, licensure, or experience necessary to differentiate the care expected from each group of doctors as well as confuse policymakers and beneficiaries about the specialties. While some overlap may exist, currently optometrists serve a much younger population, many of whom are not close to qualifying for Medicare. Placing non-surgical optometrists in the same category as ophthalmologists will blur the distinctions between the two different specialties.

Response: As indicated in our previous response, due to measure overlap for both specialty sets it was determined that combining Ophthalmology and Optometry would reduce burden on providers and staff. The combination of these measure sets in no way affects a physician's obligation to only provide covered services within the scope of their license. Thus, despite the combination of these measure sets, physicians must still choose and submit those measures that are meaningful to their scope of practice.

We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46622), we are finalizing the above measure for addition to the *Ophthalmology/Optometry Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Surgery**: For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	Patient Safety	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Orthopedic Surgery specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that the management and avoidance of surgical and post-surgical complications is a critical component of high-quality, patient-centered care. Post-operative complications after THA/TKA can delay a patient's recovery time, prolong hospitalizations, increase readmission rates, and increase disability or rates of mortality. Effective supportive care management can reduce the risk for complications, improve patient outcomes, and reduce overall healthcare costs. See Table A.8 for rationale.

B.29. Orthopedic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Orthopedic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the addition of measure Q480 to the Orthopedic Surgery Specialty Set. They stated that adding this measure to this set will ensure its use, broader adoption, and relevance for surgeons and patients. The commenter also requested that data from this measure be posted as soon as practicable on Physician Compare or other CMS sites to empower beneficiaries as informed consumers of care.

Response: We thank the commenter for supporting the addition of measure Q480 to the Orthopedic Surgery Specialty Set and acknowledge the recommendation to post data from this measure on Physician Compare or other CMS sites once available.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46630), we are finalizing the above measures for addition to the *Orthopedic Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	375	CMS66v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46632), we are finalizing the above measures for removal from the *Orthopedic Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.								

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Otolaryngology

MEASURES FINALIZED FOR ADDITION TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance	We proposed to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure is specific to chronic pharyngeal diagnoses that are commonly treated by the otolaryngology clinician type.
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM specifications, MIPS CQMs specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance	We proposed to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that medications should be assessed to ensure safe use among the older patient population. Reducing the number of inappropriate prescriptions can lead to improved patient safety and significant cost savings.
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons	We proposed to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that the measure includes specialty-specific coding (that is, thyroid, parathyroid, etc. surgeries) and supports positive outcomes for otolaryngology surgical patients.

B.30. Otolaryngology

MEASURES FINALIZED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Otolaryngology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.30. Otolaryngology

MEASURES FINALIZED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

Comment: One commenter did not support the addition of the Adult Immunization Status measure to the Otolaryngology Specialty Set as the comprehensive immunizations required for this measure "do not apply to this specialty." They stated that the complete quality action would not be attributable to an otolaryngologist as they are not directly responsible for ensuring routine vaccinations are current, resulting in passive reporting.

Response: We disagree. We believe that it is clinically relevant because the clinical concepts found within measures Q110 and Q111 are also included within the new Adult Immunization Status measure. We understand that some of these immunizations may not be a priority for, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Currently, the Otolaryngology Specialty Set contains 24 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46637 through 46639), we are finalizing the above measures for addition to the *Otolaryngology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OTOLARYNGOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0069 / N/A	065	CMS154v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance	This measure was proposed for removal from the Otolaryngology specialty set. Per interested parties' feedback, the patients that fall within this measure's denominator are not typically treated by this clinician type. An otolaryngologist's practice focuses more on specific/chronic diagnosis coding rather than the diagnosis associated with this measure. This measure focuses on the appropriate treatment of the common cold which is not typical care that an otolaryngologist provides.
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46640), we are finalizing the above measures for removal from the *Otolaryngology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.31. Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.31. Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma:** Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both	College of American Pathologists	We proposed to include this measure in the Pathology specialty set as it is clinically relevant to this clinician type. This measure addresses a gap in care regarding biomarker testing for specific cancer types. Biomarker testing is an important part of personalized medicine. It provides vital, individualized pathological data to clinicians utilized necessary for guidance in diagnosing and treating their patients, that can be tailored to the specific biomarkers that are found. See Table A.7 for rationale.

Comment: One commenter supported the addition of Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma to the Pathology Specialty Set. They stated that biomarker testing is an important part of personalized medicine and provides vital, individualized pathological data to clinicians.

Another commenter strongly supported the addition of this new quality measure to this set. This measure is currently in use as a QCDR measure in the Pathologists Quality Registry, where it has seen high levels of use. The measure has been designed to work with pathology clinical guidelines and represents the most up-to-date clinical information.

Response: We thank the commenters for supporting this new measure in the Pathology Specialty Set.

Comment: One commenter did not support the addition of Screening for Social Drivers of Health measure to the Pathology Specialty Set. They stated that non-patient-facing clinicians, pathologists do not regularly interact with patients and are not in a position to screen for social drivers of health. Therefore, the commenter stated that this measure cannot be attributed to pathologists and would create additional confusion and complexity if included in this set.

Response: As we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Pathology Specialty Set would contain over six MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set and that choosing to report this measure would be voluntary. However, due to this specialty being non-patient facing, we agree with the commenter that it would be inappropriate to include this measure in the Pathology Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46642), we are finalizing the Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bower Carcinoma measure for addition to the *Pathology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. We are not finalizing the addition of the Screening for Social Drivers of Health measure to this set. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	239	CMS155v11	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117v11	eCQM Specifications	Process	Community/ Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS137v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v11	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS13 6v12	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS15 9v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS17 7v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication /Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pediatrics

MEASURES FINALIZED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Pediatrics specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46647), we are finalizing the above measure for addition to the *Pediatrics Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PEDIATRICS SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	379	CMS74v12	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from the Pediatrics specialty set beginning with the CY 2023 performance period/2025 MIPS payment year. Specialty specific coding is being removed from this quality measure for the 2023 performance period. Therefore, this measure is no longer relevant to this clinician type.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46648), we are finalizing the above measures for removal from the *Pediatrics Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communicatio n and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.33. Physical Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Physical Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46652), we are finalizing the above measure for addition to the *Physical Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure falls within the scope of care for a physical or occupational therapist to assess patients for urinary incontinence symptoms during their medical history intake. Physical and occupational therapists are trained through their education and experience to assess for and treat various patient symptoms and conditions.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	We proposed to include this measure in the Physical Therapy/ Occupational Therapy specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that functional assessment tools can and should be completed by physical and occupational therapists for patients they are treating who are also diagnosed with rheumatoid arthritis. Physical and occupational therapists work with rheumatoid arthritis patients for physical therapy in both land-based and/or aquatic-based programs. These clinicians help to teach patients energy conservation techniques as well as gait, self-care and activities of daily living (ADL) techniques to reduce the stress and load on one's joints.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter supported the addition of measure Q048 to the Physical Therapy/Occupational Therapy Specialty Set stating that treatment for a urinary infection is within the scope of the occupation therapy practitioner. The commenter recommended adding coding for occupational therapy evaluation and reevaluation visits (CPT codes 97165, 97166, 97167, 97168) as applicable encounters for this measure. The commenter supported the addition of measure Q178 to this set stating that assessment of factors influencing occupational engagement for patients with rheumatoid arthritis is within the scope of the occupational therapy practitioner. The commenter recommended adding coding for occupational therapy evaluation and reevaluation visits (CPT codes 97165, 97166, 97167, 97168) as applicable encounters for this measure. The commenter also supported the addition of the Screening for Social Drivers of Health measure to this set stating that clinicians need to understand social drivers of health and their impact on the individual client and supports the addition of this measure. The commenter recommended adding coding for occupational therapy evaluation and reevaluation visits (CPT codes 97165, 97166, 97167, 97168) as applicable encounters for this new measure. **Response:** We thank the commenter for supporting the addition of measures Q048, Q178, and Screening for Social Drivers of Health to the Physical Therapy/Occupations Therapy Specialty Set. We encourage the commenter to reach out to the measure stewards for Q048 and Q178 to discuss revisions for possible implementation of additional CPT codes in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46659 through 46660), we are finalizing the above measures for addition to the *Physical Therapy/Occupational Therapy Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A/ N/A	128	CMS69v1 1	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v1 2	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v1 1	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.35. Plastic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE PLASTIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Plastic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46663), we are finalizing the above measure for addition to the *Plastic Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Podiatry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter supported the addition of the new Screening for Social Drivers of Health measure to the Podiatry Specialty Set. However, the commenter suggested CMS provide resources that help clearly define what the terms mean "for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety" mean, and resources for clinicians on this measure. The commenter also was concerned about the lack of exclusions in the proposed measure and was unclear how the measure would be scored for MIPS.

Response: We believe public input is very valuable in the continuing development of our health equity quality measurement efforts and broader commitment to health equity. We agree that the data collection for this measure will be a significant first step towards addressing the role of social determinants of health in improving health equity and is one of our quality improvement goals. We will take this feedback into consideration during the public notice and comment cycle for possible implementation in future years. We will also consider this feedback when providing educational resources on this measure. As with all quality measures, the technical specification provides information on how to implement the measure, including clinical recommendation statements and rationale, and will be posted in the December timeframe for review.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46666), we are finalizing the above measure for addition to the *Podiatry Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

B.37. Preventive Medicine

MEASURES FINALIZED FOR ADDITION TO THE PREVENTIVE MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association	We proposed to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure complements other measures within their set. Adding this measure to this specialty set will elevate the importance of secondary prevention in cardiovascular disease.
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Preventive Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	488	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46671 through 46672), we are finalizing the above measures for addition to the *Preventive Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SPECIALTY SET

N Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46673), we are finalizing the above measures for removal from the *Preventive Medicine Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Pulmonology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46677 through 46678), we are finalizing the above measures for addition to the *Pulmonology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PULMONOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46678), we are finalizing the above measures for removal from the *Pulmonology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Rheumatology

MEASURES FINALIZED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Rheumatology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES FINALIZED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Rheumatology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

Comment: One commenter supported the inclusion of the Screening for Social Drivers of Health measure in the Rheumatology Specialty Set.

Response: We thank the commenter for supporting the addition of this new measure to the Rheumatology Specialty Set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46682 through 46683), we are finalizing the above measures for addition to the *Rheumatology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

Comment: One commenter opposed the removal of measures Q110 and Q111 from the Rheumatology Specialty Set and replacing them with the Adult Immunization Status measure. The proposed replacement measure includes immunizations for issues they believe are not relevant to the field of rheumatology, such as Td, Tdap, and zoster. Our focus on including immunization measures has been around those necessary for rheumatology patients to receive, given their immunocompromised state. Measures Q110 and Q111 for influenza and pneumococcal have served rheumatology care teams and their patients very well.

Response: The clinical concepts found within measures Q110 and Q111 are also included within the new Adult Immunization Status measure. We understand that some of these immunizations may not be a priority for, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Currently, the Rheumatology Specialty Set contains 17 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46683), we are finalizing the above measures for removal from the *Rheumatology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS 145v1 1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS 144v1 1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS 156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.40. Skilled Nursing Facility

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee on Quality Assurance	We proposed to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco will reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.40. Skilled Nursing Facility

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Skilled Nursing Facility specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.40. Skilled Nursing Facility

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	493	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We proposed to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46686 through 46688), we are finalizing the above measures for addition to the *Skilled Nursing Facility Specialty Set* as proposed, except measure Q226 will not be added to this specialty set for the CY 2023 performance period/2025 MIPS payment year and future years. Upon further review of the finalized measure, we determined that measure Q226, as currently specified, is not applicable for the skilled nursing facility because the revised denominator coding does not reflect codes billed in this setting. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE SKILLED NURSING FACILITY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46688), we are finalizing the above measures for removal from the *Skilled Nursing Facility Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.41. Speech Language Pathology

MEASURES NOT FINALIZED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Speech Language Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.41. Speech Language Pathology

MEASURES NOT FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter supported the inclusion of the Screening for Social Drivers of Health measure in the Speech Language Pathology Specialty Set to improve care and because it provides another measure to meet minimum reporting requirements associated with the quality performance category. **Response:** We thank the commenter for supporting the addition of this measure to the Speech Language Pathology Specialty Set. However, as we implement the Screening for Social Drivers of Health measure within the MIPS quality measure inventory and measure sets starting with the CY 2023 performance period, we believe it is critical for individual MIPS eligible clinicians, groups, and virtual groups to have the option of choice in selecting and reporting such measure. We recognize that the Speech Language Pathology Specialty Set would contain six MIPS quality measures if the Screening for Social Drivers of Health measure were implemented within this set. For specialty sets that contain more than six MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups have the flexibility to select a minimum of six MIPS quality measures to report to meet the MIPS reporting requirement for the quality performance category. For specialty sets that contain six or less MIPS quality measures, individual MIPS eligible clinicians, groups, and virtual groups must report on all MIPS quality measures within the specialty set. In the case of the Speech Language Pathology Specialty Set, this measure would inadvertently become mandatory to report. While we believe that the Screening for Social Drivers of Health measure is an important topic for speech language pathologists, to assess within their patient population, the inclusion of such measure within this set would eliminate the option of choice to select and report such measure. As we intend to provide clinician choice in selecting and reporting the Screening for Social Drivers of Health measure, we will not include such measure within the Speech Language Pathology Specialty Set. Consequently, we are not finalizing the above measure for addition to the *Speech Language Pathology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* §	0028 / 0028e	226	CMS 138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons	We proposed to include this measure in the Thoracic Surgery specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that thoracic surgeons are engaged in surgical procedures where appropriate management through supportive care can help decrease avoidable 30-day reoperation due to surgical complications. This measure will help incentivize appropriate management and avoidance of unnecessary and costly procedures.

B.42. Thoracic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Thoracic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.42. Thoracic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter supported the addition of these two measures to the Thoracic Specialty Set if clinicians can continue to choose measures relevant to their practice. However, the commenter noted their thoracic surgery specialty registry would not be able to calculate the Screening for Social Drivers of Health measure and mentioned the need to allow clinician choice in reporting meaningful measures.

Response: We thank the commenter for supporting the addition of these measures to the Thoracic Surgery Specialty Set and encourage clinicians within this specialty to choose measures that are most meaningful to them. Regarding the inability to calculate the Screening for Social Drivers of Health measure, because the Thoracic Surgery Specialty Set has over 6 measures available, this measure would be voluntary reporting for those who choose to report the measure. Clinicians have the flexibility to choose measures to report and this measure's performance represents the first step in the collection of this data. Additionally, since this measure is only assessing the screening of patients, we do not believe there would be unintended consequences for the clinicians or the patients they serve.

After consideration of public comments, we are finalizing the above measures for addition to the *Thoracic Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A streptococcus (strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.43. Urgent Care

MEASURES FINALIZED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Urgent Care specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set; therefore, we are finalizing the above measure for addition to the *Urgent Care Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / 0389e	102	CMS129 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645 v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
* ! (Outcome)	N/A / N/A	476	CMS771 v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
* ! (Appropriate Use)	N/A/ N/A	481	CMS646 v3	eCQM Specifications	Process	Effective Clinical Care	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology Institute

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A/ N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that depression screening and intervention is an essential care process for patients diagnosed with cancer, including patients with urological cancers. Depression can be a disabling co-morbidity in cancer patients and it's vital to incorporate this assessment and intervention in their comprehensive care.
* ! (Patient Safety)	0022/ N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class	National Committee for Quality Assurance	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that medications used for supportive care for patients with cancer diagnoses (including urological cancers), such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-effects and toxicity. Cancer care management between specialists (for example, urologists and oncologists) heightens the need for closer collaboration of medication management for this patient population.

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that inclusion of this patient-centered CAHPS survey measure in this specialty set will incentivize evaluation of patient-centered domains relevant to urological cancer care (for example, timely care, provider communication, access to specialists, health promotion and education, shared decision making, functional status, care coordination).
* § ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that end-of-life care measures can provide meaningful feedback and create incentives to improve patient-centered, appropriate care to cancer patients, including patients with urological cancers. End-of-life care decisions may extend beyond oncologists to other specialty providers on the care team, including urologists for bladder or prostate cancers.

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Outcome)	0216/ N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agreed with interested parties' feedback that end-of-life care measures can provide meaningful feedback and create incentives to improve patient-centered, appropriate care to cancer patients, including patients with urological cancers. End-of-life care decisions may extend beyond oncologists to other specialty providers on the care team, including urologists for bladder or prostate cancers.

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Urology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	488	CMS951 v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46704 through 46708), we are finalizing the above measures for addition to the *Urology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.44. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0062 / N/A	119	CMS134v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
We received no public comments on the measures proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46708), we are finalizing the above measures for removal from the *Urology Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.								

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.45. Vascular Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE VASCULAR SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	487	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We proposed to include this measure in the Vascular Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believed this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (87 FR 46712), we are finalizing the above measure for addition to the *Vascular Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Where applicable, see Table Group A in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to new measures that were proposed for addition to MIPS.									

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons	This measure was proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
We received no public comments on the measure proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (87 FR 46713), we are finalizing the above measure for removal from the *Vascular Surgery Specialty Set* as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note: Where applicable, see Table Group C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.								

TABLE Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

In this final rule, we are removing 11 previously finalized MIPS quality measures, of the 15 measures proposed for removal, for the CY 2023 performance period/2025 MIPS payment year and future years. These measures are discussed in detail below. Our process measure removal criteria were discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) to implement an approach to incrementally remove process measures.

Under measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

Under Table Group CC, we finalized to partially remove 2 additional measures from traditional MIPS and to retain these 2 measures for MVP use and retain 1 of these measures for purposes of Shared Savings Program ACOs reporting through the APP.

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion that we use for the removal of measures includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent.

For a measure that is finalized for removal due to criteria relating to the benchmark and performance data, further information regarding MIPS benchmarking data can be located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.

NOTE: Since publication of the measures in Table Group C in the CY 2023 PFS proposed rule (87 FR 46714 through 46722), we have determined the following measures will be retained in the CY 2023 performance period/2025 MIPS payment year: Q260, Q261, Q275, and Q439. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures in Table Group C in Tables C.4, C.5, C.7, and C.11, respectively.

As noted in the introduction to Table Group B, measures that were not finalized for removal under Table Group C have been added back to the Previously Finalized tables, where applicable, and removed from the Removal tables, under the appropriate specialty set in Table Group B.

C.1. Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections

Category	Description
NQF # / eCQM NQF #:	2726 / N/A
Quality #:	076
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), we believed it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter opposed removal of measure Q076 because the measure is still useful for monitoring patient safety and the impact of patient outcomes. Another commenter opposed removal of the measure to ensure improvements in infection control do not backslide and stated that CMS should monitor negative changes in outcomes for patients if this measure is removed.

Another commenter opposed removal of this measure because the measure is aimed at reducing infections and remains an important barometer of quality and patient safety. The commenter stated that the measure is endorsed by NQF and is consistently reported by anesthesiologists, surgeons, hospitalists, and other non-anesthesiologists. The commenter also did not believe that this measure has reached the end of the topped-out lifecycle as specialties other than anesthesiology also report this measure. The commenter stated that CMS should review the totality of data across specialties and review data that shows high performance of this measure is closely associated with reduced infections during a patient's length of stay.

Response: We agree that reducing infections is an important barometer of patient safety and recognize that the measure is endorsed by NQF. Topped out status is determined by the data reported to MIPS within the 2022 Historic Benchmark file from individual clinicians, groups, and virtual groups; therefore, we would be unable to utilize data from other reporting programs as there may be differences in implementation and/or the level of analysis needed to determine topped out status of a quality measure. The data shows that both the MIPS CQMs and Medicare Part B Claims Specifications collection types have reached the end of their topped-out life cycles which does not allow meaningful benchmarks to be established. Measures that are topped out demonstrate performance that is so high and unvarying that meaningful distinctions and improvement in performance can no longer be determined. Therefore, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Measures classified as topped out for three consecutive years may be removed the fourth year subject to rulemaking and public comment. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2022 Benchmark File.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46714), we are finalizing the removal of measure Q076 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.2. Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality #:	119
CMS eCQM ID:	CMS134v11
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the Kidney Health Evaluation measure being proposed in Table A.4. The Kidney Health Evaluation measure focuses on patients with diabetes and encourages annual evaluation of estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR) to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidity of diabetes and CKD. The Kidney Health Evaluation measure, if finalized, will support the clinical conditions of kidney disease and diabetes, both identified as gaps within MIPS and considered priority areas for future measure development.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we propose to apply the following substantive changes to the measure specifications: 1) the initial patient population and the denominator exclusion for the eCQM Specifications collection type will be revised to change the age anchor from the start of the measurement period to the end of the measurement period so that it aligns with the HEDIS measure requirements and creates consistency for implementation across programs; 2) the logic and logic definitions related to hospice care for the eCQM Specifications collection type will also be updated to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely; and 3) the denominator note for the MIPS CQMs Specifications collection type will be revised to assess the age for exclusions on the date of the encounter to reduce clinician burden and ensure alignment with guidelines when utilizing this collection type. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C. The substantive changes outlined above will be applied to the measure specifications.
Comment: Several commenters supported the removal of measure Q119 if the proposed new measure Kidney Health Evaluation was finalized. One commenter stated the new Kidney Health Evaluation measure is better aligned with current American Diabetes Association (ADA) Standards of Practice recommendations and should provide more actionable feedback to providers to help them deliver better care to their patients with diabetes. **Response:** We thank the commenters for supporting the removal of this measure. The Kidney Health Evaluation measure was finalized in MIPS under Table A.4. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46715), we are finalizing the removal of measure Q119 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

C.3. Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	258
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.
We received no public comments on this measure removal. For the reasons stated above and in the proposed rule (87 FR 46715), we are finalizing the removal of measure Q258 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

C.4. Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	260
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter opposed the removal of measure Q260 because limited patient population and limited adoption have not allowed for the creation of performance benchmarks. The commenter expressed concern about eliminating specialty-specific measures since MIPS reporting and scoring policies have historically disincentivized clinicians from reporting more granular measures. The commenter stated that starting in 2023, CMS proposed to further disincentivize specialty-specific measures by assigning measures that lack a benchmark zero rather than 3 points. While the commenter appreciated that CMS adopted a 5-point floor for "new" measures during their first 2 years in the program, the commenter stated that this policy does nothing to address the numerous measures that have been in the program for many years but continue to lack a benchmark and are at risk for removal. The commenter stated that with minimal incentive to report on measures that lack a benchmark, this measure did not have the opportunity to gain traction.

The commenter strongly urged CMS to maintain measures that lack a benchmark to ensure a diverse inventory of measures that reflect specialty care. The commenter stated that CMS should maintain these measures until it has had time to implement, test, and expand MVPs. MVPs, as well as the subgroup participation policy associated with this pathway, present an important opportunity for clinicians to focus on more specialty-specific measures, and CMS must maintain an adequate inventory of quality measures for use in MVPs.

Response: We thank the commenter for their comments and agree with maintaining an adequate inventory of quality measures for use in MVPs, however we also balance the need to maintain our standards of meaningful measures and will continue to evaluate the potential use of this measure within an MVP in future years.

Based on the comments received, we conducted a literature search and found that newer guidelines, Society for Vascular Surgery (SVS) clinical practice guidelines for management of extracranial cerebrovascular disease (https://pubmed.ncbi.nlm.nih.gov/34153350/), recommend carotid artery endarterectomy (CEA) over carotid artery stenting (CAS) for symptomatic low risk surgical patients, as well as CEA over maximal medical therapy for asymptomatic patients with carotid bifurcation stenosis >70 percent. This updated guideline presented strong evidence that CEA is superior for long-term prevention of stroke/death for low-risk surgical patients and supports retaining this measure within MIPS. After careful consideration, we will maintain this measure for specialty specific MIPS eligible clinicians as it aligns with current guidelines but may consider removal in the future.

After further consideration, we are not finalizing the removal of measure Q260 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.5 Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	261
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.
Measure Steward:	Audiology Quality Consortium
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: Several commenters were supportive of removing measure Q261 from MIPS.

Response: We thank the commenters for supporting the removal of this measure.

Comment: One commenter did not support the removal of measure Q261, stating this measure is a critical element of care for patients with hearing loss and has the potential to prevent potentially avoidable negative health outcomes, such as falls, which could lead to hospital admissions or fractures. The commenter stated that low reporting rates are partly due to the limited number of audiologists required to report to MIPS based on the low-volume threshold. The commenter stated that low reporting is not an indication of a measure's lack of importance or utility in improving patient care but is rather a construct of the limited number of clinicians reporting this measure under current eligibility requirements.

Another commenter expressed similar concerns, stating that many otolaryngology practices include audiology professionals, and these clinicians would no longer have any specialty-specific measures. The commenter encouraged CMS to consider the limited timeframe in which audiologists were considered eligible clinicians (2019) and the limited participation due to the provision of the EUC for 2020 and 2021 due to the public health emergency. The commenter stated that it is premature to remove the only audiology-specific measure given the limited eligibility and proposed change to the audiology referral requirements.

Another commenter opposed removal of the measure due to the aging population and increased risk of falls in the elderly, stating that audiologists are an important part of the fall-prevention teams and are uniquely positioned to alleviate patient and economic burdens of dizziness.

Response: We thank the commenters for their comments and acknowledge that this measure addresses a critical element in ensuring patients receive appropriate referrals for otologic evaluations. Based on the comments received, we recognize that this measure represents a very small sub-specialty of otologists within the Audiology and Otolaryngology Specialty Sets. Our goal is to ensure that we have as many measures as possible for specialty-specific clinicians while also ensuring that the measures within MIPS are leading to meaningful data driving positive outcomes. We found the commenter's argument that participation in MIPS for audiologists was limited in 2020 and 2021 compelling and would be further limited in the future by the removal of this measure; therefore, we will maintain this measure and continue to monitor performance for measure Q261 but may consider removal in the future.

After further consideration, we are not finalizing the removal of measure Q261 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.6. Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), we believed it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: Several commenters did not support the removal of measure Q265 because this measure is relevant for urologists and data from their registry suggests there is still room for improvement among clinicians. Another commenter stated that this high priority measure is used in multiple specialty sets and should be retained for continued use in traditional MIPS and for future MVPs. Another commenter stated this measure allows clinicians to improve lines of communications between specialties which in turn increase efficiency, reduces overall costs, and promotes wellness and prevention in healthcare. Another commenter stated this measure promotes a coordinated patient centered team approach to healthcare, is helpful with patient follow-up and retention, and is a pillar in the dermatology space in terms of ensuring that clinicians have a stake in the health outcomes for the patient.

Response: We thank the commenters for their comments and agree this is a relevant measure for several specialties including urology and dermatology; however, we strive to ensure that all measures align with MIPS goals and priorities, including the removal of measures that are at the end of the topped-out lifecycle. We utilize MIPS data to determine the measure's year over year performance.

This measure, which is at its sixth year of being topped out, only assesses the quality action for new patients undergoing biopsy but does not track performance for existing patients who undergo subsequent biopsies. This concern was expressed in a discussion with the measure steward in 2022 with a recommendation to consider revising the numerator of the measure to include all biopsies performed, as we believe it is important to have care communication with the primary care clinician with all performed biopsies. With no revisions proposed for PY2023 and this measure being topped-out for 6 consecutive years, we believe it has a limited opportunity to improve clinical outcomes.

We acknowledge the importance of improving coordination and communication between clinicians and patients to drive quality of care. However, as noted, measure Q265 is a high-performing measure that no longer allows for improvement in clinical outcomes. Based on the feedback from the commenters, confirmation that this measure is a pillar in the dermatology space seems to ensure that this measure is a standard of care for most dermatology clinicians. This finding is supported by the MIPS Benchmark File and the performance of this measure as topped out within MIPS.

By removing measures at the end of the topped-out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2022 Benchmark File.

Comment: One commenter expressed concern about removing this measure and in general topped-out measures before analysis regarding disparities in care related to race, ethnicity, and or/language, can be completed.

Response: We encourage the commenter to reach out to measure developers/stewards to develop new biopsy follow-up measures that consider race, ethnicity, and/or language for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46717), we are finalizing the removal of measure Q265 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.7. Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	275
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter did not support removal of measure Q275 because it has been a quality measure for approximately 10 years and is the only measure specific to patients with IBD remaining in 12 national reporting programs. The commenter stated that CMS had not informed the measure steward about any benchmarking issues prior to recommending the removal of the measure for 2023. The commenter stated that as a result, the measure steward has not had an opportunity to address any concerns. The commenter stated that before initiating biologic or small molecule therapy such as anti-TNF drugs for a patient with IBD, it is essential to screen the patient for HBV, as reactivation of HBV after such therapy can occur with significant risks for patient decompensation. The commenter stated that severe reactivation of the hepatitis B virus can occur during immunosuppression. The commenter stated that assessment of hepatitis B virus in immunosuppressed patients, including those who are initiating IBD biologic therapies, is critical to the safety of the patient.

The commenter stated that measure Q275 was recommended for inclusion in the 2022 Core Quality Measures Collaborative (CMQC) Gastroenterology Measures Set for 2023 implementation which involved CMS leadership and participation. The commenter stated that the identification and selection process for the Gastroenterology Specialty Set included multiple interested parties, including CMS, who all voted in favor of retaining this measure in the set. Removing this measure conflicts with previously agreed upon processes.

Response: To elaborate on our initial rationale for removal, the measure does not have a "benchmarking issue," but rather is reported by a very limited number of clinicians which does not allow for the creation of a benchmark. Historical benchmarks are driven by the data submitted for a measure 2 years prior. For example, 2022 historical benchmarks are based on data reported for PY2020. To be benchmarked, data completeness and case volumes must be reached, therefore, when a measure has low adoption, a benchmark cannot be created.

We acknowledge the importance of this measure for the gastroenterology specialty and upon further review will continue to monitor the measure's performance to determine if adoption of the measure is viable for the production of fruitful performance rates.

After further consideration, we are not finalizing the removal of measure Q275 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.8. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	323
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle (82 FR 53640). Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.87 percent for the MIPS CQMs Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. Given this measure's continued topped out status, we believed it has a limited opportunity to improve clinical outcomes and should be a standard of care. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter supported removing this measure from MIPS.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46718), we are finalizing the removal of measure Q323 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.9. Functional Status Assessment for Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	375
CMS eCQM ID:	CMS66v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	eCQM Specifications
Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q470: Functional Status After Primary Total Knee Replacement. The process measure Q375 is only assessing whether pre- and post-assessments were completed; however, outcome measure Q470 requires a certain post-surgical PRO-PM score to meet performance.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we proposed to apply the following substantive changes to the measure specifications: (1) the measure description will be revised to capture the measure intent and logic surrounding the age requirement to provide clarity and alignment across the header and logic; (2) the denominator exclusion will be updated so that the timing of the lower body fracture in relation to the THA will align with intent of exclusion; and (3) the logic and logic definitions related to hospice care will be updated to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C. The substantive changes outlined above will be applied to the measure specifications.

Comment: Several commenters did not support removal of measure Q375 as duplicative to measure Q470. The commenters stated that instead of removing this eCQM measure for being duplicative, the commenters wanted CMS to provide more flexibility for clinicians to choose how to report and to offer vendors options to choose what measures they provide to their customers. The commenters stated that some her vendors are not third-party intermediaries and even those who are may be unable to offer all registry measures. The commenters did not support removal of eCQMs when the only reason is that they are duplicative of MIPS CQMs. One commenter stated there is value in offering a variety of measures in different reporting types to give clinicians flexibility in meeting their reporting requirements. Another commenter suggested either updating measure Q375 to become an outcome measure or updating measure Q470 to allow reporting via eCQMs.

Response: It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care. We encourage the commenters to reach out to the measure steward for measure Q470 to discuss revisions and possibly add the eCQM collection type in future years. In the instance measure Q470 can be included within the eCQM collection type, it would add another outcome measure which requires a certain post-surgical PRO-PM score to meet performance.

We agree that having a variety of measures and collection types in the program for reporting provides additional flexibility for clinicians to choose how to report their applicable measures; however, rather than offering duplicate measures, we believe that offering measures with more robust evaluation methods would drive better quality of care provided. Measure Q470 requires the use of a functional status assessment score/tool to evaluate measurable change in functional status postoperatively whilst measure Q375 simply assesses whether pre- and post-assessments were completed. Duplicative measures have no purpose in quality measurement.

Comment: One commenter opposed the removal of measure Q375 as duplicative and stated that significant time had been expended to test this measure and other functional status measures proposed for removal. The commenter's QCDR team is actively working on its patient-reported outcomes measures (PROMs) tool and has engaged sites that want to capture and report this assessment data. The commenter stated it is important to consider the resources required to test and implement measures with the QCDR system. The commenter requested that CMS consider longer intervals between the proposed removal of measures and the finalization of such changes. The commenter also cited that measure Q375 also impacts the Comprehensive Care for Joint Replacement (CJR) model and the proposed future requirement for reporting pre- and post-operative PROMs. The commenter requested guidance on how these programs would be impacted.

Response: Removal of this measure from MIPS will not have a direct impact on the CJR model as it falls under a separate CMS program with different policy and reporting requirements from MIPS. We appreciate the comment regarding the interval between the proposal and removal of measures. Measures proposed for removal are not removed from MIPS during the same calendar year they are proposed for removal. For example, a measure proposed for removal in the CY 2023 proposed rule, published in summer 2022, would not result in the measure being removed until January 2023, for that performance period, as public notice and comment is needed.

Measure Q375 has been a measure within MIPS since inception of the program in 2017 and we believe this should have allowed time for QCDRs to test any measures within the QCDR system. Also, because MVPs are currently optional rather than required, this gives registries another year to prepare for MVP reporting.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46719), we are finalizing the removal of measure Q375 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.10. Photodocumentation of Cecal Intubation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	425
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.
Measure Steward:	American Society for Gastrointestinal Endoscopy
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because we believed this process measure represents performance outcomes that are clinically a standard of care and does not drive quality outcomes for patients.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter did not support the removal of measure Q425, stating that the goal of the measure is to establish a complete screening or surveillance examination based on photodocumentation of at least two landmarks of cecal intubation. The commenter stated that this measure assesses eligible clinicians performing screening and surveillance colonoscopy to determine if examinations are truly complete so that appropriate follow-up intervals can be recommended and whether patients are being recalled too soon or later than recommended by the U.S. Multi-Society Task Force on Colorectal Cancer.

The commenter stated that the measure specifications were updated beginning with the 2019 performance year to align with the now recognized best practice of photo documenting two cecal landmarks, rather than one, to establish a complete colonoscopy. The commenter stated that the impact of the public health emergency on clinicians' ability to report for the 2020 and 2021 performance years resulted in a 48 percent drop in QCDR reporting of this measure. The commenter stated that CMS should allow measure Q425 with its updated measure specifications to have at least two full performance years in MIPS to assess the performance of the measure and its continuation in MIPS. The commenter stated that the measure provides insight into potential over- or under-utilization of screening and surveillance colonoscopy and the commenter stated that CMS should also continue inclusion of this measure in public reporting until performance variability relative to race, ethnicity, and the senior population is reduced, and performance is consistently closer to 100 percent.

Response: We agree that completing a colonoscopy is extremely important. However, measure Q425 only ensures that photos are taken of at least two landmarks of cecal intubation to establish a complete examination but does not require any follow-up action that ties the rate of complete examinations to whether the clinician is recalling patients for surveillance colonoscopies sooner or later than recommended or making recommendations for appropriate follow up intervals where needed. This is a high performing measure that has been topped out for the last 3 years. It is considered a clinical standard of care that should already be happening for each colonoscopy and documented in procedural notes. Additionally, we are using our National Quality Strategy to guide our measure decisions and are striving to use only high-value quality measure that impact key quality domains and prioritize outcome-based measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46719), we are finalizing the removal of measure Q425 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.11. Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has a very low adoption rate which does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we proposed that the measure denominator, denominator criteria, and numerator options will be updated to align with USPSTF guidance that screening colonoscopies should start at age 45. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C. The substantive changes outlined above will be applied to the measure specifications.

Comment: One commenter did not support the removal of measure Q439, stating the goal of the measure is to eliminate inappropriate screening. The commenter stated that 2892his measure assesses eligible clinicians routinely performing screening colonoscopy, including those doing lower volumes, to determine if unnecessary screening of the elderly is being performed.

The commenter stated that recognizing there was opportunity for misinterpretation of the measure specifications, the measure owners and CMS agreed to modify the measure specifications redefining the target population to clarify the measure's intent and ultimately to strengthen analysis and benchmarking of the measure. The commenter stated that I modified measure specifications were introduced beginning with the 2021 performance year, the year for which CMS automatically applied its EUC exception to individually eligible clinicians. The commenter noted a 50 percent drop in reporting of the measure through QCDRs for the 2021 performance year compared to the 2020 performance year. The commenter indicated that CMS should allow measure Q439 with its updated measure specifications to have at least two full performance years in MIPS to assess the adoption rate of the measure.

The commenter stated that measure Q439 was recommended for inclusion in the 2022 CQMC Gastroenterology Measures Set for 2023 implementation which involved CMS leadership and participation. The commenter stated that the identification and selection process for the Gastroenterology Specialty Set included multiple interested parties, including CMS, who all voted in favor of retaining this measure in the set. Removing this measure conflicts with previously agreed upon processes.

Response: We acknowledge the importance of eliminating inappropriate screening. Based on the comments, we reassessed the timing of the modified measure being introduced and circumstances surrounding the 50 percent drop in reporting of the measure. We also recognize that this measure addresses a patient population that is unique from other colonoscopy measures within MIPS. Additionally, a performance period benchmark was able to be produced for the 2021 performance period despite the availability of EUC, indicating this measure is meaningful to the clinicians that report it.

After consideration of public comments, we are not finalizing the removal of measure Q439 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.12. Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0213 / N/A
Quality #:	455
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. Additionally, interested parties' feedback has consistently indicated that retrieval of data from the ICU is difficult, which makes this measure hard to submit. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: One commenter did not support removal of measure Q455 from MIPS. ICU admission in the last 30 days of life continues to be a concern and a priority area in the cancer population. The commenter stated that studies suggest that over time, cancer care is becoming more aggressive near the end of life. The commenter stated that ICU admissions in the last 30 days of life are deemed as "aggressive care" and often used as an indicator of lower quality of care. The commenter stated that external interested parties have recently identified this measure as a priority measure. The commenter stated that in 2020, this measure was included in the CQMC Medical Oncology Core Set. Additionally, the commenter stated that in 2020, this measure was included in NCCN Quality and Outcomes Committee endorsements of impactful and feasible quality and outcomes measures in cancer care. The commenter stated that as CMS and other interested parties evolve toward a more robust data framework to support digital measures with the integration of multiple data sources, the commenter anticipated reporting on this measure will improve over time.

Response: As noted, interested parties have reported difficulties in retrieving data from the ICU, making this measure hard to submit. This concern was also discussed during the CQMC Medical Oncology meeting in January 2020, regarding challenges collecting data across systems. We agree that end of life care is an important clinical topic; however, low adoption and subsequent limited submission of the measure have made it impossible to create a benchmark to provide meaningful impact. While we endeavor to enhance data capture through use of digital quality measures, not all measures will be appropriate for these revisions, and our priority is to ensure that for PY2023 we have a robust, meaningful inventory of quality measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46720), we are finalizing the removal of measure Q455 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.13. Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We proposed the removal of this measure (finalized in 82 FR 53968) as a quality measure from MIPS because this measure is duplicative to measure Q459: Back Pain After Lumbar Discectomy/Laminectomy. We proposed in Table D.65 substantive changes to measure Q459: Back Pain After Lumbar Discectomy/Laminectomy that will encompass the eligible patient population and clinical quality action represented within measure Q460.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: Several commenters opposed removal of measure Q460 as duplicative to measure Q459. The commenters stated that lumping fusions in with discectomies/decompressions would not reflect the indications and expectations for surgery. The commenters stated that although both groups may see improvements in back pain and/or leg pain, the discectomy patients are more likely to have leg pain as an indication for surgery, and the fusion patients are more likely to have back pain as an indication for surgery. Therefore, the commenters stated that combining the measures will only further muddy the waters on the assessment of outcomes.

Response: We thank the commenters for their comments; however, substantive changes were proposed to measure Q459 to encompass the eligible patient population and clinical quality action in measure Q460. Although fusions and discectomy/laminectomy have been combined in measure Q459 as lumbar surgery, the measure is divided into separate submission criteria. Therefore, each procedure would be assessed for numerator compliance separately. In addition, the numerator for each submission criterion addresses if the patient is not experiencing pain which would reflect the desirable outcome. The patient experiencing pain below the threshold points, or the patient experiencing reduced pain, both of which would indicate that the quality action has been met. Given these substantive changes, we believe measure Q459 will adequately and separately account for lumbar fusion and lumbar discectomy/laminectomy. Because back pain and leg pain are not assessed within the same measure, the scenario given would not be a concern given the separation of the two anatomic areas.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46721), we are finalizing the removal of measure Q460 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.14. Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We proposed the removal of this measure (finalized in 83 FR 60098 through 60099) as a quality measure from MIPS because this measure is duplicative to measure Q471: Functional Status after Discectomy/Laminectomy. We proposed in Table D.69 substantive changes to measure Q471: Functional Status After Lumbar Discectomy/Laminectomy that will encompass the eligible patient population and clinical quality action represented within measure Q469.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: Several commenters opposed removal of this measure as duplicative to measure Q471. Another commenter opposed removal of this measure, stating that the measure continues to provide critical information about patients to their functional status and the pain they are experiencing.

Response: We thank the commenters for their comments; however, substantive changes were proposed to measure Q471 to encompass the eligible patient population and clinical quality action in measure Q469. Although fusions and discectomy/laminectomy have been combined in measure Q471 as lumbar surgery, the measure is divided into separate submission criteria. Therefore, each procedure type would be

assessed for numerator compliance separately. In addition, the numerator for each submission criterion addresses if the patient experienced an improvement in functional status which would reflect the desirable outcome of the patient's functional status, either below a threshold or meeting an improvement target, in accordance with the measure criteria, at specific timelines postoperatively both of which would indicate that the quality action has been met. Given these substantive changes, we believe measure Q471 will adequately and separately account for lumbar fusion and lumbar discectomy/laminectomy.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46721), we are finalizing the removal of measure Q469 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

C.15. Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We proposed the removal of this measure (finalized in 83 FR 60106) as a quality measure from MIPS because this measure is duplicative to measure Q461: Leg Pain After Lumbar Discectomy/Laminectomy. We proposed in Table D.66 substantive changes to measure Q461: Leg Pain After Lumbar Discectomy/ Laminectomy that will encompass the eligible patient population and quality action represented within measure Q473.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it will be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention will be addressed under Table Group C.

Comment: Several commenters strongly opposed removal of measure Q473 as duplicative to measure Q461. The commenters stated that lumping fusions in with discectomies/decompressions would not reflect the indications and expectations for surgery. The commenters stated that although both groups may see improvements in back pain and/or leg pain, the discectomy patients are more likely to have leg pain as an indication for surgery, and the fusion patients are more likely to have back pain as an indication for surgery. Therefore, the commenters stated that combining the measure will only further muddy the waters on the assessment of outcomes. Another commenter opposed removal of this measure, stating that the measure continues to provide critical information about patients to their functional status and the pain they are experiencing.

Response: We thank the commenters for their comments; however, substantive changes were proposed to measure Q461 to encompass the eligible patient population and clinical quality action in measure Q473. Although fusions and discectomy/laminectomy have been combined in measure Q461 as lumbar surgery, the measure is divided into separate submission criteria. Therefore, each procedure type would be assessed for numerator compliance separately. In addition, the numerator for each submission criterion addresses if the patient is not experiencing pain, which would reflect the desirable outcome of the patient experiencing pain below the threshold points or the patient experiencing reduced pain both of which would indicate that quality action has been met. Given these substantive changes, we believe measure Q461 will adequately and separately account for lumbar fusion and lumbar discectomy/laminectomy. Because back pain and leg pain are not assessed within the same measure, the scenario given would not be a concern given the separation of the two anatomic areas.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46722), we are finalizing the removal of measure Q473 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

TABLE Group CC: Finalized Partial Removal of 2 Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Finalized Retention of These 2 Measures for Use in Relevant MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Beginning with the CY 2023 performance period/2025 MIPS payment year and future years, we proposed to maintain measures Q110**:** Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults for MVP development and implementation and maintain measure Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this final rule. We believed the clinical concepts represented by these MIPS quality measures will support some specialties in a more targeted approach rather than the broader clinical concept of multiple vaccinations represented within the proposed Adult Immunization Measure proposed under Table A.9 of this appendix. The tables within this section offer the rationale of the removal of measures Q110 and Q111 from traditional MIPS reporting.

Therefore, we proposed in the CY 2023 PFS proposed rule to remove these 2 previously finalized quality measures from traditional MIPS due to the proposal of adding the Adult Immunization Status measure under Table A.9 of this appendix (FR 87 46722 through 46723). We simultaneously proposed to retain measures Q110 and Q111 for use in MVPs and retain measure Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this final rule. See Table Group E for finalized changes to the CMS Web Interface collection type of this measure.

Measures Q110 and 111 are currently finalized as quality measures within the finalized Optimal Care for Kidney Health MVP (see Appendix 3: MVP Inventory Table A.2). Measure Q111 was retained in the updated Advancing Rheumatology MVP under the MVP maintenance process (see Appendix 3: MVP Inventory Table B.3).

We solicited comments on this proposal.

CC.1. Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / N/A
Quality #:	110
CMS eCQM ID:	CMS147v12
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we proposed a more robust measure under Table A.9: Adult Immunization Status that will help improve complete vaccination rates for patients. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. However, the clinical quality action assessed within measure Q110 may be appropriate and applicable for some MVP topics where the proposed Adult Immunization Status measure may not be as it contains more clinical quality actions for assessment that may not apply to the clinician types submitting that MVP. Therefore, we proposed the removal of this measure from traditional MIPS, but proposed retention of this measure for use in relevant MVPs and use by Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this final rule. See Table Group E for finalized changes to the CMS Web Interface collection type for this measure.
In the Circumstance the Measure is Retained	If measure A.9: Adult Immunization Status is not finalized for the CY 2023 performance period/2025 MIPS payment year and future years, we will retain measure Q110 in traditional MIPS in all relevant specialty sets under Table Group B. See Table Group DD for any substantive changes proposed for this measure.

We note that commenters who opposed removal of measure Q110: Preventive Care and Screening: Influenza Immunization also opposed removal of measure Q111: Pneumococcal Vaccination Status for Older Adults in Table CC.2 for the same reasons summarized below.

Comment: Several commenters opposed removal of measure Q110 because this measure is important to a wide range of specialties who report these measures every year. One commenter stated the proposed replacement measure includes immunizations for issues that are not relevant to the field of rheumatology, such as Td, Tdap, and zoster. One commenter requested that measure Q110 be retained for cardiologists. While the proposed adoption of the Adult Immunization Status measure would likely be duplicative in the primary care setting, one commenter urged CMS to retain measure Q110 due to its importance in the oncology setting. The commenter stated that patients with cancer and in active cancer treatment are often immunocompromised, making the influenza vaccination important in this population and requested that measure Q110 be retained in traditional MIPS until that pathway sunsets.

Response: This measure's clinical concept is included the new Adult Immunization Status measure. We understand that some of these immunizations may not be relevant to, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being.

Comment: One commenter opposed removal of measure Q110 and stated that having similar measures reportable via registry is not sufficient for its customers who do not want to pay for a registry to report to MIPS. The commenter wanted to know if it will it be necessary to re-certify these measures for MVP only reporting or whether its certification status for the eCQM measures would be maintained.

Response: This measure will be maintained within the program for MVPs as an eCQM measure. We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures, however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include different collection types within our quality measure inventory to allow flexibility in reporting. The current process for certification of eCQM measures would remain unchanged under MVPs. ONC has the latest CEHRT requirements for measures (https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method). We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter did not support removing measure Q110 as it is an established measure that is not topped out. The commenter stated that while there is value in the new Adult Immunization Status measure, the new measure should be rolled out in parallel with measure Q110 so that it can establish a benchmark.

Response: As mentioned, the new Adult Immunization Status is more robust and will help improve complete vaccination rates for patients. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. We acknowledge that measure Q110 is not considered topped-out, however, it is being removed from traditional MIPS as it would be duplicative to Adult Immunization Status measure. While it is not guaranteed, it may be possible to create a performance benchmark for newly implemented measures.

Comment: Several commenters stated that partial removal of measure Q110 and retention for MVPs is unnecessary and confusing. The commenters stated that the clinical quality action assessed with these measures may be appropriate and applicable for all providers in MIPS, not just those reporting an MVP. The commenters stated that the Adult Immunization Status measure that would replace these two measures may not be appropriate as it contains more clinical actions for assessment that may not be relevant to all clinician types, MVP or not. Another commenter stated that retention of this measure in MVPs would cause a fundamental lack of alignment between the programs and could harm

data analysis opportunities regarding immunization rates. Another commenter stated that if this measure is sufficiently important to be included in MVPs, the measure should also be sufficiently important to maintain for traditional MIPS reporting.

Response: Although this measure is being removed from traditional MIPS, it will be retained for use in relevant MVPs and for use by the Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this final rule. See Table Group E for finalized changes to the CMS Web Interface collection type for this measure. As the intent of MVPs is to tightly focus on a clinical topic or specialty, there are nuances in the determination of quality measure inclusion. This does not indicate importance of a measure, but the intent of utilization. Measure Q110 is being removed from traditional MIPS as it would be duplicative to Adult Immunization Status measure outside of the aforementioned contexts.

Comment: One commenter stated that combining immunizations into the broader Adult Immunization Status measure creates additional burden and complexity for physicians. Another commenter opposed the proposed removal of measure Q110 as its removal will force their practice to find another measure to meet regulatory requirements, taking valuable time away from patients.

Another commenter opposed removal of measure Q110 and was concerned that the Adult Immunization Status measure will be burdensome for data collection purposes. Additionally, the commenter stated that scoring with multiple submission criteria may present problems for calculation of the measure, which is a challenge that providers previously observed when CMS split a measure into multiple criteria. The commenter believed there is value for most specialties in collecting and reporting the influenza and pneumococcal measures, and some specialties the Adult Immunization Status measure creates burden for additional data collection for information that may be irrelevant to their specialty.

Response: This measure's clinical concept is included the new Adult Immunization Status measure. We understand that some of these immunizations may not be relevant to, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. Despite this measure representing four different submission criteria, the measure is calculated using a weighted average. This means that all performance data from the four different submission criteria will be used to provide an overall performance rate for the measure. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being.

Comment: One commenter opposed the removal of measure Q110 because many Commercial and Medicare Advantage Value Based Payment models include these measures. The commenter stated that by eliminating these measures, CMS will be increasing provider burden, as additional measures (that do not align with non-CMS VBP models) will need to be selected and reported on.

Response: While we endeavor to align across CMS programs when feasible and possible, we strive to ensure that all measures align with MIPS goals and priorities, including the removal of measures that are duplicative in nature. Removal from traditional MIPS will not impact use in other programs.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46723), we are finalizing the partial removal of measure Q110 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

CC.2. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	111
CMS eCQM ID:	CMS127v11
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we proposed a more robust measure under Table A.9: Adult Immunization Status that will help improve complete vaccination rates for patients. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q111 only focuses on the administration of the pneumococcal vaccination rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Therefore, we proposed the removal of this measure from traditional MIPS, but proposed retention of this measure for use in relevant MVPs, because the clinical quality action assessed within measure Q111 may be appropriate and applicable for some MVP topics where the proposed Adult Immunization Status measure may not be as it contains more clinical quality actions for assessment that may not apply to the clinician types submitting that MVP.
In the Circumstance the Measure is Retained	If measure A.9: Adult Immunization Status is not finalized for the CY 2023 performance period/2025 MIPS payment year and future years, we will retain measure Q111 in traditional MIPS in all applicable specialty sets under Table Group B. See Table Group DD for any substantive changes proposed for this measure.
We note that the commenters who opposed removal measure Q111: Pneumococcal Vaccination Status for Older also opposed removal of measure Q110: Preventive Care and Screening: Influenza Immunization Adults for the same reasons. See comments and responses under Table CC.1.	

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46723), we are finalizing the partial removal of measure Q111 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Finalized for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2023. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2023 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2024. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believed are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2023 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2023 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible will the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow. For eCQM Release Notes, see the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2023.

Note: The CMS Web Interface collection type is no longer available in MIPS, except for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period; therefore, this collection type is no longer listed in any tables under Table Group D. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the CMS Web Interface collection type for APP reporting, see sections III.G.4.b.(9) and III.G.4.c.(1) of this final rule. For information on changes to measures under the CMS Web Interface collection type finalized for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this final rule.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications| eCQM Specifications| MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-75 years of age by the end of the measurement period, with diabetes with a visit during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator criteria: For all collection types: Added:** coding for nutrition and dietitian. **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated numerator instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the guidance/numerator instructions for all collection types to remove "Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included" because it does not align with the intent of the measure, which is to ensure hemoglobin A1c control in all patients with any diagnosis of diabetes. These updates will allow the measure to better reflect its clinical intent, in accordance with the given diabetes diagnoses codes within the denominator criteria of the measure. We proposed to update multiple components of the measure for the eCQM Specifications collection type so that the patient age is determined as of the end of the measurement period and aligns with Healthcare Effectiveness Data and Information Set (HEDIS) measure requirements and creates consistency in implementation. We proposed to add encounter codes for MIPS eligible nutrition and dietitian clinicians, for all collection types, based upon interested parties' feedback, as they may provide nutrition counseling or therapy to patients to help manage diabetes and to ensure hemoglobin A1c control. The American Diabetes Association (ADA) emphasizes the need for medical nutrition therapy (MNT) as fundamental for diabetes management and the overall care plan.[1] "Strong evidence supports the effectiveness of MNT interventions provided by RDNs [registered dietitian nutritionist/registered dietitian] for improving A1C, with absolute decreases up to 2.0 percent (in type 2 diabetes) and up to 1.9 percent (in type 1 diabetes) at 3–6 months. Ongoing MNT support is helpful in maintaining glycemic improvements." [2] We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored, as this will allow for different workflows and

	systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
Comment: One commenter supported the inclusion of secondary diabetes in the denominator in this measure, the inclusion of nutritionist and dietician coding, as well as the alignments made with the HEDIS measure. **Response:** We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46725 through 46726), we are finalizing the changes to measure Q001 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Evert, A. B., Dennison, M., Gardner, C. D., Garvey, W. T., Lau, K., MacLeod, J., Mitri, J., Pereira, R. F., Rawlings, K., Robinson, S., Saslow, L., Uelmen, S., Urbanski, P. B., & Yancy, W. S., Jr (2019). Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report. *Diabetes care*, 42(5), 731–754. https://doi.org/10.2337/dci19-0014.

[2] Franz, M. J., MacLeod, J., Evert, A., Brown, C., Gradwell, E., Handu, D., Reppert, A., & Robinson, M. (2017). Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *Journal of the Academy of Nutrition and Dietetics*, 117(10), 1659–1679. https://doi.org/10.1016/j.jand.2017.03.022.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <=40% who were prescribed or already taking ACE inhibitor or ARB or ARNI therapy during the measurement period. **For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge. **Updated guidance: For the eCQM Specifications collection type: Revised:** This eCQM is to be reported as patient-based. To satisfy this measure, it must be reported for all heart failure patients at least once during the measurement period if seen in the outpatient setting. The requirement of two or more visits is used to establish that the eligible professional or eligible clinician has an existing relationship with the patient. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than or equal to 40% threshold noted in the denominator logic. A range that is greater than 40% would not meet the measure requirement. **Updated rate aggregation: For the eCQM Specifications collection type: Removed:** rate aggregation. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of heart failure. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria**: **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated denominator note: For the MIPS CQMs Specifications collection type**: **Revised:** LVEF threshold to <= 40%. **Updated denominator exclusion: For the eCQM Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD) prior to the end of the outpatient encounter with Moderate or Severe LVSD. **For the MIPS CQMs Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD). **Updated definition: For the eCQM Specifications collection type: Removed:** Prescribed-Inpatient setting: prescription given to the patient for ACE inhibitor or ARB or ARNI therapy at discharge OR ACE inhibitor or ARB or ARNI therapy to be continued after discharge as documented in the discharge medication list. **Revised:** LVEF threshold to <= 40%. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who were prescribed or already taking ACE inhibitor or ARB or ARNI therapy during the measurement period. **Updated denominator exception: For all collection types: Removed:** Documentation of system reason(s) for not prescribing ACE inhibitor or ARB or ARNI therapy (for example, other system reasons).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and numerator language for the eCQM Specifications collection type by changing the "12-month" verbiage to "measurement period" to harmonize language with other MIPS quality measures for consistency and clarity in implementation. We proposed to revise the description, numerator, and guidance, and to remove a definition and rate aggregation from the eCQM Specifications collection type in order to remove the inpatient population to resolve logic issues such as implementing two populations with different intended reporting frequencies. Additionally, we proposed to revise the initial patient population to add clarity around the required number of qualifying encounters and to align with the measure logic. The measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We proposed to update LVEF value for all collection types from <40 percent to <=40 percent to ensure all patients considered to have heart failure with reduced ejection fraction are included in the denominator, by including patients with a LVEF value of 40 percent, and add a denominator exclusion for patients with left ventricular assist device or a history of heart transplant, as these patients were not included in clinical treatment trials for low LVEF heart failure. We also proposed the removal of the

Category	Description
	denominator exception for system reasons for all collection types as the medication is widely available.[1] These revisions will help to ensure a complete and appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to revise the numerator for the eCQM Specifications collection type to accurately reflect the clinical actions allowed in the current technical specification to ensure alignment between the measure logic, description, and numerator fields. Please note, if the revisions to the eCQM Specifications collection type are finalized, the MIPS version of the measure will not align with the NQF endorsed version of the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46727 through 46728), we are finalizing the changes to measure Q005 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
NQF # / eCQM NQF #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator criteria: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove coding for Dressler's Syndrome from the denominator, as it is not a conclusive diagnosis to indicate coronary artery disease. Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with continued antiplatelet therapy, which will not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with antiplatelets (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision will ensure the patients captured within the measure denominator are appropriate.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46728), we are finalizing the changes to measure Q006 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**The measure title is revised from 'Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)' to:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%). **The measure description is revised to read: For all collection types**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF <=40% who were prescribed beta-blocker therapy. **Updated instructions: For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated guidance**: **For the eCQM Specifications collection type: Revised:** LVEF threshold to <= 40%. . **Updated rate aggregation: For the eCQM Specifications collection type: Revised:** LVEF threshold to <= 40%. **The measure initial patient population is revised to read**: **For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of coronary artery disease. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria**: **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated definition: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator note: For the MIPS CQMs Specifications collection type**: **Revised:** LVEF threshold to <= 40%. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure patients who satisfy both denominator eligibility criteria are only counted once. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update LVEF value from <40 percent to <=40 percent to better align with current clinical guidelines[1], and to ensure all patients considered to have heart failure with reduced ejection fraction are included in the denominator eligible patient population, by including patients with a LVEF value of 40 percent. This revision is reflected in the measure title, description, denominator, and definitions for all collection types; in the instructions, denominator criteria, and denominator note for the MIPS CQMs Specifications collection type; and in the guidance for the eCQM Specifications collection type. This will help to ensure a complete and appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to revise the initial patient population for the eCQM Specifications collection type to add clarity around the required number of qualifying encounters and to align with the measure logic. The measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We proposed to update measure logic and logic definitions for the eCQM Specifications collection type to avoid counting a patient more than once if the patient satisfies both denominator criteria. This is in alignment with the guidance and the intent of the measure to only count patients who fit both denominator criteria in Population Criteria 1. We proposed to remove coding for Dressler's Syndrome from the denominator for the MIPS CQMs Specifications collection type as it is not a as it is not a conclusive diagnosis to indicate coronary artery disease, which will align with revisions previously made to the eCQM Specifications collection type in the 2022 PFS final rule (86 FR 65895). Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with beta blocker therapy, which will not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with beta blocker therapy (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision will ensure the patients captured within the measure denominator are appropriate.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46729), we are finalizing the changes to measure Q007 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L.,

Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications| MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type**: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <= 40% who were prescribed or already taking beta-blocker therapy during the measurement period. **For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge. **Updated guidance: For the eCQM Specifications collection type: Revised:** This eCQM is to be reported as patient-based. To satisfy this measure, it must be reported for all heart failure patients at least once during the measurement period. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than or equal to 40% threshold noted in the denominator logic. A range that is greater than 40% would not meet the measure requirement. Beta-blocker therapy: -For patients with prior LVEF <= 40%, beta-blocker therapy should include bisoprolol, carvedilol, or sustained release metoprolol succinate. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. **Updated rate aggregation: For the eCQM Specifications collection type: Removed:** rate aggregation. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of heart failure. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator exclusion: For the eCQM Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD) prior to the end of the outpatient encounter with Moderate or Severe LVSD. **For the MIPS CQMs Specifications collection type**: Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD). **Updated definition: For the eCQM Specifications collection type: Removed:** Prescribed-Outpatient setting: prescription given to the patient for beta-blocker therapy at one or more visits in the measurement period OR patient already taking beta-blocker therapy as documented in current medication list. Prescribed-Inpatient setting: prescription given to the patient for beta-blocker therapy at discharge OR beta-blocker therapy to be continued after discharge as documented in the discharge medication list. **Revised:** LVEF threshold to <= 40%. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who were prescribed or already taking beta-blocker therapy during the measurement period. **Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** Beta-blocker Therapy definition LVEF threshold to <= 40%. **Updated denominator exception: For all collection types: Removed:** denominator exception for system reasons. **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and numerator language for the eCQM Specifications collection type by changing the "12-month" verbiage to "measurement period" to harmonize the language with other MIPS quality measures for consistency and clarity in implementation of this measure. Additionally, we proposed to revise multiple components of the eCQM Specifications collection type to include only the outpatient population, in an effort to resolve measure logic issues such as implementing two populations with different intended reporting frequencies. We proposed to revise the initial patient population of the eCQM Specifications collection type to add clarity around the required number of qualifying encounters and to align with the measure logic. Measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We proposed to update multiple components of the measure, across all collection types, to reflect an LVEF value of <=40 percent, to better align with current clinical guidelines, and to ensure all patients considered to have heart failure with reduced ejection fraction are included in the measure denominator, by including patients with a LVEF value of 40 percent, and add a

Category	Description
	denominator exclusion for patients with left ventricular assist device or a history of heart transplant as these patients were not included in clinical treatment trials for low LVEF heart failure.[1] These revisions ensure a clinically appropriate patient population is assessed for the quality action of prescribing beta-blocker pharmacotherapy resulting in meaningful data. We also proposed the removal of the denominator exception for system reasons for all collection types as the medication is widely available. We proposed to revise the numerator for the eCQM Specifications collection type to accurately reflect the clinical actions allowed in the current technical specification to ensure alignment between the measure logic, description, and numerator fields. Please note, if the revisions to the eCQM Specifications collection type are finalized, the MIPS version of the measure will not align with the NQF endorsed version of the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46730 through 46731), we are finalizing the changes to measure Q008 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;*129*(16):e462]. *Circulation*, *126*(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.6 Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	009
CMS eCQM ID:	CMS128v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18 years of age and older as of April 30 of the measurement period who were dispensed antidepressant medications during the Intake Period, and were diagnosed with major depression 60 days prior to, or 60 days after the dispensing event and had a visit 60 days prior to, or 60 days after the dispensing event. **The measure definition is revised to read:** Intake Period: The 12-month window starting on May 1 of the year prior to the measurement period and ending on April 30 of the measurement period. Index Prescription Start Date (IPSD): The date of the earliest prescription dispensing event for an antidepressant medication during the Intake Period. The "continuous treatment" described in this measure allows for gaps in medication treatment up to a total 31 days during the 115-day period (numerator 1) or 52 days during the 232-day period (numerator 2). Gaps can include either gaps used to change medication, or treatment gaps to refill the same medication. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Numerator 1: Patients who have received antidepressant medication for at least 84 days (12 weeks) of continuous treatment beginning on the IPSD through 114 days after the IPSD (115 total days). Numerator 2: Patients who have received antidepressant medications for at least 180 days (6 months) of continuous treatment beginning on the IPSD through 231 days after the IPSD (232 total days).
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure definition to define and clarify the intake period. Additionally, to align with the updated definition, we proposed to revise the initial patient population and patient age to ensure that patients meet the measure's age requirement. Additionally, we proposed to update the logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored, as this will allow for different workflows and systems to align with exclusion criteria more closely ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We proposed additional revisions to the language and logic to improve transparency of timing related to Index Prescription Start Date that will clarify that the continuous treatment period to include the IPSD, ensuring consistent implementation and improving readability.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46731), we are finalizing the changes to measure Q009 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.7 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / 0086e
Quality#:	012
CMS eCQM ID:	CMS143v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.
Substantive Change:	**Updated value set/coding: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46732), we are finalizing the changes to measure Q012 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.8 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	019
CMS eCQM ID:	CMS142v11
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the value set/coding for the eCQM Specifications collection type to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46732), we are finalizing the changes to measure Q019 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.9 Screening for Osteoporosis for Women Aged 65-85 Years of Age

Category	Description
NQF # / eCQM NQF #:	0046 / N/A
Quality#:	039
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.
Substantive Change:	**Updated denominator criteria: For all collection types: Removed:** AND NOT Diagnosis of osteoporosis on date of encounter. **Updated denominator exclusion: For all collection types: Added:** diagnosis of osteoporosis on date of encounter. **Updated definitions: For all collection types: Added:** definition including coding for diagnosis of osteoporosis that would suffice.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to move the diagnosis of osteoporosis from the denominator criteria to a denominator exclusion. While this will not change the intent or intended patient population of the measure, it will clarify how to capture the denominator eligible patient population and ensure only patients who are appropriate for quality action assessment are included.
We received no public comments on the substantive changes proposed for this measure we are finalizing the changes to measure Q039 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.10 Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	050
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for occupational therapy.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add coding for occupational therapy to this measure as this measure is applicable to their scope of care. Non-surgical interventions can be utilized to improve quality of life for patients with urinary incontinence[1], which has been demonstrated in a preliminary study showing clinically significant improvement for patients receiving occupational therapy interventions.[2]
Comment: Two commenters appreciated the update to the denominator for measure Q050. **Response:** We thank the commenters for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46733), we are finalizing the changes to measure Q050 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Engberg, Sandra & Li, Hongjin. (2017). Urinary Incontinence in Frail Older Adults. Urologic Nursing. 37. 119. https://www.researchgate.net/publication/327898228_Urinary_Incontinence_in_Frail_Older_Adults.

[2] Cunningham, R., & Valasek, S. (2019). Occupational Therapy Interventions for Urinary Dysfunction in Primary Care: A Case Series. *The American Journal of Occupational Therapy*, 73(5), 7305185040p1-7305185040p8. https://doi.org/10.5014/ajot.2019.038356.

D.11 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** URI episodes when the patient had an active prescription of antibiotics (Table 1) in the 30 days prior to the episode date or is still active the same day of the encounter.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We proposed to revise the denominator exclusion for the MIPS CQMs Specifications collection type to add clarity regarding those patients that should not be included within the denominator population due to active or previous antibiotic prescriptions, as this patient population will impact the performance calculated for the measure as the intent is to assess whether an antibiotic is prescribed.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46733), we are finalizing the changes to measure Q065 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.12 Appropriate Testing for Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.
Substantive Change:	**The measure denominator instructions are revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. The intent is to determine whether antibiotics are being ordered appropriately. Antibiotics should only be ordered if a strep test has been performed to confirm a bacterial infection. Antibiotics should not be ordered for viral infections. Antibiotics should be ordered on the episode date through three days after the episode date. An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order during the measurement period. If a patient has more than one eligible episode in a 31-day period, include only the first eligible episode. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** The test must be performed to confirm a bacterial infection prior to the antibiotic order. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** timing of antibiotic to align with measure intent and current narrative for the denominator exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator and numerator instructions for the MIPS CQMs Specifications collection type to clarify the intent of the measure which is to ensure appropriate antibiotic dispensing following confirmation of a bacterial infection. We proposed to update the logic and logic definitions for the eCQM Specifications collection type related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We proposed to revise the denominator exclusion for the MIPS CQMs Specifications collection type to add clarity regarding those patients that should not be included within the denominator eligible patient population due to active or previously prescribed antibiotic. This patient population will impact the performance calculated for this measure as the intent is to assess that a group A streptococcus test is completed prior to prescribing an antibiotic. Patients actively on an antibiotic will most likely not benefit from this test due to the recommended treatment for the group A streptococcus infection is common, inexpensive antibiotics (https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46734), we are finalizing the changes to measure Q066 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.13 Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 0104e
Quality#:	107
CMS eCQM ID:	CMS161v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.
Substantive Change:	**The measure description is revised to read:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit. **Updated guidance: Revised:** This eCQM is an episode-based measure and should be reported for each instance of a new or recurrent episode of major depressive disorder (MDD) during the measurement period. This measure should be reported for each eligible encounter during which a new or recurrent episode of MDD is identified in adults that turn 18 or older during the measurement period. **The measure initial patient population is revised to read:** Patient visits for patients that turn 18 or older during the measurement period during which a new diagnosis of MDD, single or recurrent episode, was identified.
Measure Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the language for the measure description, guidance, and initial patient population to accurately capture the adult population by including patients that turn 18 years of age or older during the measurement period.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46734), we are finalizing the changes to measure Q107 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.14 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Women 52-74 years of age by the end of the measurement period with a visit during the measurement period **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure, for the eCQM Specifications collection types, so that the patient age will be determined as of the end of the measurement period and aligns with HEDIS measure requirements and creates consistency in implementation. We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46735), we are finalizing the changes to measure Q112 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.15 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer. **The measure description is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer. **Updated stratification: For the eCQM Specifications collection type: Added:** Report a total rate, and each of the following age strata: Stratum 1: Patients age 46-49 by the end of the measurement period Stratum 2: Patients age 50-75 by the end of the measurement period **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 46-75 years of age by the end of the measurement period with a visit during the measurement period. **The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients 45-75 years of age with a visit during the measurement period **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patients 45 to 75 years of age on date of encounter. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and multiple measure components for all collection types to align with the 2021 U.S. Preventive Services Task Force (USPSTF) guidelines that recommend Colorectal Cancer Screenings begin at age 45 rather than beginning at age 50. We proposed to add stratification for the eCQM Specifications collection type to monitor performance of the newly recommended 45-49 year age group, and to continue monitoring the previously established population of patients aged 50-75 years. We proposed to update multiple components of the measure, for the eCQM Specifications collection type, so that the patient age is determined as of the end of the measurement period and aligns with the HEDIS measure requirements and creates consistency in implementation. We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
Comment: One commenter supported the revision to measure Q113 to align with recent changes to the United States Preventive Services Task Force guideline that lower the age of colorectal cancer screening from 50 to 45. **Response:** We thank the commenter for supporting the substantive changes to this measure.	

Category	Description
After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46736), we are finalizing the changes to measure Q113 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.16 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated numerator instructions: Revised:** Table 1 - Antibiotic Medications by removing Erythromycin stearate, Erythromycin ethylsuccinate, and Erythromycin lactobionate from Macrolides AND Nitrofurantoin macrocrystals from Urinary anti-infectives.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator instructions in order to standardize the medication names.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46737), we are finalizing the changes to measure Q116 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.17 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-75 years of age by the end of the measurement period, with diabetes with a visit during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it is extremely topped out and at the end of the topped-out lifecycle as finalized in 82 FR 53640. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. We proposed to update multiple components of the measure, for the eCQM Specifications collection type, so that the patient age is determined as of the end of the measurement period and aligns with the HEDIS measure requirements and creates consistency in implementation. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.

Comment: One commenter opposed the proposed substantive changes to measure Q117 because the commenter stated that the changes are replacing a successful quality program check that is widely being performed well.

Response: The proposed substantive changes will help improve the accuracy of reporting on this measure.

Comment: One commenter opposed the removal of the claims collection type for this measure. While the commenter recognized that the measure is topped out under the claims collection type, the clinician reported there are already a limited number of appropriate measures available to this specialty. Another commenter opposed removal of the claims collection type to allow meaningful measurement of ophthalmologists and ophthalmic subspecialists in small and rural practices.

Response: We thank the commenter for their comment opposing the removal of the Medicare Part B Claims measure specifications collection type. This collection type has not only reached the end of the topped-out life cycle but showed an average performance rate of 100 percent in the 2022 Historical benchmarks file, which does not allow for meaningful benchmarks to be established.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46738), we are finalizing the changes to measure Q117 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.18 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0066 / N/A
Quality#:	118
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**The measure title is revised from 'Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)' to:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%). **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy. **Updated instructions: Revised:** LVEF threshold to <= 40%. **Updated denominator: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria: Revised:** LVEF threshold to <= 40%. **Updated denominator definition: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure to reflect LVEF to <=40 percent to align with current clinical guidelines.[1] We also proposed to remove coding for Dressler's Syndrome from the denominator as it is not a definitive diagnosis for CAD. Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with ACE or ARB therapy, which will not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with ACE or ARB therapy (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision will ensure the patients captured within the measure denominator are appropriate.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46739), we are finalizing the changes to measure Q118 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.19 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the performance period AND who had a follow-up plan documented if BMI was outside of normal parameters **Updated guidance: For the eCQM Specifications collection type: Revised:** BMI Measurement Guidance: * Height and Weight – An eligible professional or their staff is required to measure both height and weight. Both height and weight must be measured during the measurement period. Self-reported values cannot be used. * The BMI may be documented in the medical record of the provider or in outside medical records obtained by the provider. * If the documented BMI is outside of normal parameters, then a follow-up plan is documented during the encounter or during the measurement period. *If more than one BMI is reported during the measurement period, and any of the documented BMI assessments are outside of normal parameters, documentation of an appropriate follow-up plan will be used to determine if performance has been met. * Review the exclusions and exceptions criteria to determine those patients that BMI measurement may not be appropriate or necessary. Follow-Up Plan Guidance: * The documented follow-up plan must be based on the documented BMI, outside of normal parameters, example: "Patient referred to nutrition counseling for BMI above or below normal parameters." **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1. Patients who are pregnant at any time during the measurement period. 2. Patients receiving palliative or hospice care at any time during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Removed:** sort function. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients with a documented BMI during the encounter or during the measurement period, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the measurement period. **Updated numerator instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Height and Weight – An eligible clinician or their staff is required to measure both height and weight. Both height and weight must be measured within 12 months of current encounter. Self-reported values cannot be used. **Updated value set/coding: For the eCQM Specifications collection type: Added:** Plenity, Saxenda, Contrave, Naltrexone-bupropion, Benzphetamine, Phendimetrazine, and Wegovy to the "Medications for Above Normal BMI" value set (OID: 2.16.840.1.113883.3.526.3.1561).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and numerator for the eCQM Specifications collection type to correct the misalignment between the updated logic performed in 2021 and the measure description. Therefore, we proposed to change the timing associated with BMI calculation and intervention to reduce implementation burden on clinicians. We also proposed this change for the measure guidance for the eCQM Specifications collection type. We proposed to revise the measure denominator exclusion language for the eCQM Specifications collection type to incorporate timing elements that we believed will improve clarity for implementation and reduce ambiguity. We proposed to update the numerator instructions for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types to remove the language allowing for measurements to be obtained from separate encounters to ensure both height and weight are associated for utilization in obtaining a BMI. This will ensure the most accurate BMI is being assessed aligning with the intent of the measure, which is to screen all adults for BMI to initiate further evaluation and follow-up plan if necessary. We proposed to update the value set/coding for the eCQM Specifications collection type by adding other weight loss management medications to the "Medications for Above Normal BMI" value set (OID: 2.16.840.1.113883.3.526.3.1561) for numerator compliance.
Comment: One commenter appreciated the update to the value set "Medications for Above Normal BMI" for measure Q128 to include newly approved medications.	

Category	Description
Response: We thank the commenter for supporting the substantive changes to this measure. **Comment:** Several commenters were alarmed to see the proposed new exclusion of those receiving palliative care from measure Q128. Palliative care seems to be being equated here with hospice, which is incorrect. The commenters stated that excluding those on hospice, who are at the end of life, is appropriate while those receiving palliative care could live for years longer. According to the commenters, palliative care is appropriate at any point in a serious illness and can be provided along with any curative, disease-modifying treatment. The commenters requested that this exclusion be removed as it perpetuates the harmful misconception that palliative care and hospice are the same thing when they are not. **Response:** We agree that palliative care is appropriate at any point in a serious illness and can be provided with any curative, disease-modifying treatment. It is our expectation that clinicians know the difference between palliative and hospice care and would not equate them. Palliative care is generally provided by an interdisciplinary medical team that focuses on the patient as a whole and would be inclusive of the types of services addressed by this measure as needed. We note that patients receiving palliative care or hospice care were previously excluded from this measure and the update to the denominator exclusion was to define the timing. We continue to believe that patients receiving palliative care are not appropriate for this measure as a result of the extent of physical, psychosocial and spiritual care required for patients with life-threatening illnesses and their families (https://doi.org/10.1186/s12913-019-3961-0). We believe Due to the complexities of care required for this population, clinicians that support patients receiving palliative care may inadvertently not perform well from the aspect of producing quality metrics. However, we encourage clinicians to provide care as they determine best supports all patients during their healthcare journey even if the patient population is not included within the targeted denominator of a given measure specification. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46740), we are finalizing the changes to measure Q128 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.20 Documentation of Current Medications in the Medical Record

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	130
CMS eCQM ID:	CMS68v12
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **Updated guidance: For the eCQM Specifications collection type: Revised:** This list must include all known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements, cannabis/cannabidiol products AND must contain the medications' name, dosage, frequency and route of administration. **Updated numerator definition: For the MIPS CQMs Specifications collection types: Revised:** Current Medications – Medications the patient is presently taking including all prescriptions, over-the- counters, herbals, vitamins, minerals, dietary (nutritional) supplements, and cannabis/cannabidiol products with each medication's name, dosage, frequency and administered route. **Updated numerator note: For the MIPS CQMs Specifications collection types: Revised:** This list must include ALL known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements, cannabis/cannabidiol products AND must contain the medications' name, dosage, frequency and route of administration.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped-out lifecycle as finalized in 82 FR 53640. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. However, the benchmarking data continues to show a gap for the eCQM Specifications and MIPS CQMs Specifications collection types, as such, we proposed to retain the measure for eCQM Specifications and MIPS CQMs Specifications collection types. We proposed to update the guidance for the eCQM Specifications collection type, as well as the numerator note and numerator definition for the MIPS CQMs Specifications collection type to add recommendations to assess patient's usage of cannabis/cannabidiol/etc., as use of these drugs can affect the metabolization of other medications but is often not included in the medical record. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46741), we are finalizing the changes to measure Q130 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.21 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days (48 hours) after the eligible date of the qualifying encounter. **The measure description is revised to read: For the MIPS CQMs Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated guidance: For the eCQM Specifications collection type: Revised:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two days (48 hours) after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. **Updated definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for manic episodes to the denominator exclusions definition for bipolar depression. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days (48 hours) after the date of the qualifying encounter **The measure numerator is revised to read: For the MIPS CQMs Specifications collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Revised:** A depression screen is completed on the date of the encounter or up to 14 calendar days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two calendar days after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. An example to illustrate the follow-up plan documentation timing: if the encounter is on a Monday from 3-4 pm (day 0) and the patient screens positive, the clinician has through anytime on Wednesday (day 2) to complete follow-up plan documentation. **Added:** The follow-up plan MUST still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician or provider's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for manic episodes to the Bipolar Diagnosis value set (2.16.840.1.113883.3.600.450).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure for the eCQM Specifications and the MIPS CQMs Specifications Collection types to add a grace period after the end of the encounter to document the follow-up plan, which will allow more flexibility in the clinical workflow giving clinician's time for documentation. This will ensure that those clinicians who meet the intent of the measure, which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. We proposed to update the measure definition for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to improve alignment with measure intent which is to screen for new cases of depression in patients who have never had a diagnosis of depression or bipolar disorder, as well as to clarify the timing requirements of diagnoses for the measure exclusions. We proposed to add coding for manic episodes to the Bipolar Diagnosis value set for the eCQM Specifications collection type to align with measure intent.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46742), we are finalizing the changes to measure Q134 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.22 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated denominator instructions: For the MIPS CQMs Specifications collection type: Added:** The two chemotherapy administrations must occur on different days within the timeframe of on or within 30 days before the denominator eligible encounter and on or within 30 days after the denominator eligible encounter. Two chemotherapy administrations performed on the same day will not meet the patient procedure requirement. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to only apply lookback period for radiation treatment management code. **Revised:** logic related to chemotherapy treatments to further constrain the two unique chemotherapy treatments and data collection requirements to not extend beyond the measurement period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator instructions for the MIPS CQMs Specifications collection type and logic related to chemotherapy treatments for the eCQM Specifications collection type to clarify that two chemotherapy administrations performed on the same day will not meet the patient procedure requirement. Additionally, we proposed to update the logic and logic definitions for the eCQM Specifications collection type to only apply lookback period for radiation treatment management code to meet the numerator intent of ensuring the intensity of pain experienced by patients is quantified during face-to-face or telehealth encounters, as required. This revision will also assist implementers in these instances, ensuring alignment with measure intent of quantifying a patient's pain severity so that those patients experiencing moderate to severe pain can be identified as the National Comprehensive Cancer Network (NCCN, 2021) suggests there is an undertreatment of pain in a subset of this patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46743), we are finalizing the changes to measure Q143 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.23 Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	145
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).
Substantive Change:	**The measure title is revised from 'Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy' to: For all collection types:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy **The measure description is revised to read: For all collection types:** Final reports for procedures using fluoroscopy that document radiation exposure indices. **Updated denominator criteria: For all collection types: Removed:** coding related to procedures that do not use fluoroscopy. **The measure numerator is revised to read: For all collection types:** Final reports for procedures using fluoroscopy that include radiation exposure indices. **The measure numerator definition is revised to read: For all collection types:** Radiation exposure indices – For the purposes of this measure, "radiation exposure indices" should include at least one of the following: 1. Reference air kerma (Ka,r) in Gy or mGy 2. Kerma-area product (PKA) or Dose area product (DAP) in uGy*m², mGy*cm² (or similar) 3. Peak skin dose (PSD) in Gy or mGy When reporting indices the report must clearly state what radiation quantity is being submitted, that is only reporting dose in mGy is insufficient. PSD in mGy is very different from Ka,r in mGy. As an example, PSD = 10 mGy or Ka,r = 10 mGy would meet numerator performance, but "10 mGy" alone would not. Note: When reporting reference air kerma or kerma-area product for biplane systems, the value should be reported as the sum of both planes (or the value for each plane should be reported individually). **The measure numerator instructions are revised to read: For all collection types:** **Documentation:** Dose information in the final report may be located in a variety of sources and should be available to the referring physician on receipt of report. **The measure numerator note is revised to read: For all collection types:** In interventional radiology procedures with runs, dose indices are displayed on the console and in the radiation dose structured report (RDSR). **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Radiation exposure indices documented in final report for procedure using fluoroscopy. **Performance Not Met:** Radiation exposure indices not documented in final report for procedure using fluoroscopy, reason not given.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise multiple components to better align with forthcoming AAPM Medical Physics Practice Guideline for Fluoroscopy Dose Management by Fisher, et al.[1] which indicates that exposure time and number of images is the least useful index for predicting potential tissue effects related to radiation exposure. Therefore, multiple components of the measure, across all collection types, will be updated to reflect the removal of exposure time and number of images as being numerator compliant. The measure steward indicated, and we believed it is reasonable, to expect practices providing fluoroscopy services to document one of the three accepted exposure indices in the radiology report, based upon the aforementioned guidelines. Additionally, we proposed to revise the numerator definition to include the common units of measurement to emphasize our requirement that the report should include both the dose index AND the measurement. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46744), we are finalizing the changes to measure Q145 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Fisher, R. F., Applegate, K. E., Berkowitz, L. K., Christianson, O., Dave, J. K., DeWeese, L., Harris, N., Jafari, M. E., Jones, A. K., Kobistek, R. J., Loughran, B., Marous, L., Miller, D. L., Schueler, B., Schwarz, B. C., Springer, A., & Wunderle, K. A. (2022). AAPM Medical Physics Practice Guideline 12.a: Fluoroscopy Dose Management. *Journal of Applied Clinical Medical Physics*, *23*(3), e13526. https://doi.org/10.1002/acm2.13526.

D.24 Tuberculosis Screening Prior to First Course Biologic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**The measure title is revised from 'Tuberculosis Screening Prior to First Course Biologic Therapy' to:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy. **The measure description is revised to read:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period. **Updated instructions: Revised:** This measure is to be submitted a minimum of once per performance period for patients who are being considered or prescribed a first course of a biologic and/or immune response modifier therapy seen during the performance period. **The measure denominator is revised to read:** All patients aged 18 years and older who are receiving a first course of therapy using a biologic and/or immune response modifier (such as kinase inhibitors) that includes a warning for potential reactivation of a latent infection. **Updated denominator criteria is revised to read:** Patient receiving first-time biologic and/or immune response modifier therapy. **Updated denominator instructions: Revised:** Patients are considered to be receiving a first course of therapy using a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection only if they have been prescribed such a biologic and/or immune response modifier during the performance period and also have not been prescribed any such biologic and/or immune response modifier in the 15 months preceding the encounter at which the biologic and/or immune response modifier was newly started. A biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection includes: **Added:** - Adalimumab-adbm (Cyltezo) - Adalimumab-atto (Amjevita) - Brodalumab (Siliq) - Risankizumab-rzaa (Skyrizi) - Tildrakizumab (Ilumya) **Revised:** The list of therapies is subject to change as new therapies are approved by the FDA. To be included in the denominator, patient must have an encounter and a prescription for a biologic and/or immune response modifier in the performance period (1/1/2023-12/31/2023) WITHOUT a prior prescription for a biologic and/or immune response modifier within the 15 months prior to the biologic and/or immune response modifier prescribed during the performance period. **The measure numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic and/or immune response modifier prescription. **Updated numerator options: Revised:** **Performance Met:** TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure to be more inclusive of non-rheumatology specialties so the measure may be used to evaluate additional clinician types, such as dermatology. We proposed to revise the measure to include biologics rather than just immune response modifier therapies in order to support the variety of clinicians that may be able to report the measure. Additionally, we proposed to revise the list of pharmacological agents that will meet the denominator criteria of the measure to more completely capture patients appropriate for the assessment of the quality action and intent of the measure, which is to ensure that all patients receiving a first course of biologic and/or immune response modifier that may cause latent TB reactivation are tested for TB appropriately.[1]

Comment: One commenter supported the addition of biologics, such as Skyrizi and Ilumya, to measure Q176. The commenter indicated there are several therapies that require tuberculosis testing that do not have anti-rheumatic capabilities; the addition of these therapies will support dermatology specialty providers who treat skin primarily. The commenter stated that eligible biologics medications should not be exclusive to disease-modifying antirheumatic drugs (DMARD) therapies.

Another commenter supported the revisions and updates to the title, description, performance period, and denominator of measure Q176. The commenter requested clarification regarding the language of the list of therapies being "subject to change". The commenter's concern was that EHRs may not be aware of, or able to review, recent FDA approvals relevant to this measure in real-time. The lack of clarity as to what therapies qualify under this measure could lead to decreased reporting due to the risk of unintentionally not complying with the quality action. The commenter requested that CMS provide further guidance

Category	Description
regarding notification of the addition of applicable therapies to the measure, as well as clarification as to whether additions of new therapies could lead to measure suppression. **Response:** In regard to the list of therapies being "subject to change," we note that any substantive changes to the measure would occur through rulemaking, allowing time for public review and comment. The intent is to allow some flexibility in implementation as the available treatments is continuously changing, as this measure is available for the MIPS CQMs specifications collection type multiple data sources may be utilized to determine denominator eligibility and numerator compliance. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46745), we are finalizing the changes to measure Q176 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Hasan, T., Au, E., Chen, S., Tong, A., & Wong, G. (2018). Screening and Prevention for Latent Tuberculosis in Immunosuppressed Patients at Risk for Tuberculosis: A Systematic Review of Clinical Practice Guidelines. *BMJ Open*, 8(9), e022445. https://doi.org/10.1136/bmjopen-2018-022445.

D.25 Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen. **The measure denominator is revised to read: For all collection types:** All patients aged 60 years and older. **Updated denominator criteria: For all collection types: Revised:** Patients aged ≥ 60 years on date of encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise multiple components of this measure for all collection types to include patients aged 60 years of age and older, which expands the intended patient population and allows clinicians to screen a broader patient population for elder maltreatment. The American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion in 2021 stating that ACOG "supports screening of patients older than 60 years to help identify victims of abuse and provide them with appropriate medical and psychosocial care and referrals (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/elder-abuse-and-womens-health)."
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46746), we are finalizing the changes to measure Q181 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.26 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**The measure description is revised to read:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies. **The measure numerator is revised to read:** Visits where patient has a documented current functional outcome assessment using a standardized tool AND a documented care plan based on the identified functional outcome deficiencies within two days of the assessment **Updated numerator definition: Revised:** Patient unable to participate in administration of the functional outcome assessment(s) within the 'Not Eligible (Denominator Exception)' definition. **Updated numerator instructions: Added:** The follow-up plan must still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record. **Updated numerator options: Revised:** **Performance Met:** Functional outcome assessment documented as positive using a standardized tool AND a care plan based on identified deficiencies is documented within two days of the functional outcome assessment. **Performance Met:** Functional outcome assessment using a standardized tool is documented within the previous 30 days and a care plan, based on identified deficiencies is documented within two days of the functional outcome assessment. **Performance Not Met:** Documentation of a positive functional outcome assessment using a standardized tool; care plan not documented within two days of assessment, reason not given.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure to allow flexibility in the clinical workflow by allowing two days following the functional outcome assessment for the clinician to document a care plan based on the identified deficiencies for their patients. This update was recommended by the American Physical Therapy Association (APTA). This will ensure that those clinicians who meet the intent of the measure, which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. Additionally, we proposed to update the definition for 'Not Eligible (Denominator Exception)' to generalize the process of administering the assessment to the patient. Rather than only allowing an exception for patients who are unable to complete the assessment, the measure will allow the denominator exception to be utilized in clinical situations where the patient is not able to participate in the administration of the assessment. We also proposed to add language to the numerator instructions to clarify the additional two-day documentation period and determine if the clinician meets the intent of the measure.

Comment: One commenter supported the proposal to update the measure to allow flexibility in the clinical workflow by allowing two days following the functional outcome assessment for the clinician to document a care plan based on the identified deficiencies for their patients. The commenter also supported the proposal to update the definition for "Not Eligible (Denominator Exception)."

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: One commenter appreciated the clarification proposed for measure Q182. The commenter stated the 2-day grace period would prevent clinicians who meet the intent of the measure from being penalized due to external circumstances delaying documentation. For the final measure, the commenter encouraged CMS to consider language related to "performance deficits" in the measure description, instead of using the word "deficiencies", as this terminology is more consistent with a supportive patient centered focus.

Response: We thank the commenter for their support and will take the suggested language updates into considerations for possible future implementation. This suggestion would be considered a substantive change and would need to be proposed through rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46747), we are finalizing the changes to measure Q182 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.27 Stroke and Stroke Rehabilitation: Thrombolytic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	187
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic was initiated within 4.5 hours of time last known well. **Updated instructions: Revised:** This measure is to be submitted for each episode of acute ischemic stroke for patients who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic was initiated within 4.5 hours of time last known well. **The measure denominator is revised to read:** All patients aged 18 years and older with a diagnosis of acute ischemic stroke whose time of arrival is within 3.5 hours (≤210 minutes) of time last known well. **Updated denominator criteria: Revised:** Time last known well to hospital arrival less than or equal to 3.5 hours (≤ 210 minutes). **The measure numerator is revised to read:** Patients for whom IV thrombolytic therapy was initiated at the hospital within 4.5 hours (≤ 270 minutes) of time last known well. **Updated numerator note: Added:** Updated clinical practice guidelines recommend this extended timeframe for thrombolytics, however, earlier intervention is preferred and leads to better outcomes. Patients who are eligible for thrombolytics should receive treatment as quickly as possible after arrival at the hospital. **The measure numerator options are revised to read:** **Performance Met:** IV thrombolytic therapy initiated within 4.5 hours (≤ 270 minutes) of time last known well. **Denominator Exception:** IV thrombolytic therapy not initiated within 4.5 hours (≤ 270 minutes) of time last known well for reasons documented by clinician (for example, patient enrolled in clinical trial for stroke, patient admitted for elective carotid intervention, patient received tenecteplase (TNK)). **Performance Not Met:** IV thrombolytic therapy not initiated within 4.5 hours (≤ 270 minutes) of time last known well, reason not given.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure to align with the 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association.[1] We proposed to update the measure to reflect the updated guidelines for appropriate treatment with IV thrombolytic for the clinical situation when the patient presents with acute ischemic stroke. These updates will be consistently applied to multiple components throughout the measure and a numerator note will be added to address timeliness of intervention.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46748), we are finalizing the changes to measure Q187 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Kleindorfer, D. O., Towfighi, A., Chaturvedi, S., Cockroft, K. M., Gutierrez, J., Lombardi-Hill, D., Kamel, H., Kernan, W. N., Kittner, S. J., Leira, E. C., Lennon, O., Meschia, J. F., Nguyen, T. N., Pollak, P. M., Santangeli, P., Sharrief, A. Z., Smith, S. C., Jr, Turan, T. N., & Williams, L. S. (2021). 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack: A Guideline from the American Heart Association/American Stroke Association. *Stroke*, *52*(7), e364–e467. https://doi.org/10.1161/STR.0000000000000375.

D.28 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Added:** coding for traction retinal detachment to Table 1 "Retinal Detachment with Retinal Defect" coding. **Updated value set/coding: For the eCQM Specifications collection type: Added**: coding for heteronymous bilateral field defects to valueset "Visual Field Defects" (2.16.840.1.113883.3.526.3.1446) and tractional retina detachment to valueset "Retinal Detachment with Retinal Defect" (2.16.840.1.113883.3.526.3.1478).
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the denominator exclusion of this measure to include coding for traction retinal detachment. Additionally, we proposed to update the value set for the eCQM Specifications collection type to encompass this update as well as heteronymous bilateral field defects. This will allow for better alignment with the intent of the denominator exclusions which remove eye conditions that may hinder the best corrected visual acuity of 20/40 or better within the 90 days following cataract surgery allowing a homogenous patient population to support equitable and clinically realistic outcomes. The expansion of the coding ensures the appropriate patient population is included within the denominator eligible patient population. We believed these significant ocular conditions, which can negatively impact the visual outcome of surgery, can also potentially impact a clinician's performance on this measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46749), we are finalizing the changes to measure Q191 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.29 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Revised:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the FOTO LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definitions to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. The commenter, however, remained concerned they are charged to use the electronic version of the patient-reported outcome measure (PROM) tool used for this measure.

Response: We acknowledge the concern regarding a fee for using the copyrighted electronic version of the survey; however, FOTO's Public Access Survey provides a computer adaptive test (CAT) administration of the survey with scoring results provided on the last screen of the assessment without a fee.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46749), we are finalizing the changes to measure Q217 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.30 Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the FOTO LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46750), we are finalizing the changes to measure Q218 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.31 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described in the introduction under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46751), we are finalizing the changes to measure Q219 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.32 Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Low Back FS PROM score:** The Low Back FS PROM score may be achieved using one of three forms: the FOTO Low Back FS PROM computer adaptive test, the FOTO Low Back FS PROM short form, or an alternative PROM score that is cross-walked to the Low Back FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets acceptable scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Low Back** FS **PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Low Back FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46752), we are finalizing the changes to measure Q220 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.33 Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Shoulder FS PROM:** The Shoulder FS PROM score may be achieved using one of three forms: the FOTO Shoulder FS PROM computer adaptive test, the FOTO Shoulder FS PROM short form, or an alternative PROM score that is cross-walked to the FOTO Shoulder FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Shoulder** FS **PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Shoulder PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting.

Another commenter supported the proposed change to allow a crosswalk for this measure, stating that it will enable a greater focus on client-centered care and allow more accurate reporting of care outcomes through use of assessments that more closely match individual patient needs and more accurately reflect patient progress.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46753), we are finalizing the changes to measure Q221 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.34 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Elbow/Wrist/Hand FS PROM score:** The Elbow/Wrist/Hand FS PROM score may be achieved using one of three forms: the FOTO Elbow/Wrist/Hand FS PROM computer adaptive test, the FOTO Elbow/Wrist/Hand FS PROM short form, or an alternative PROM score that is cross-walked to the FOTO Elbow/Wrist/Hand FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Elbow/Wrist/Hand FS PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition**: Revised: Functional Status (FS) Score – This is the Elbow/Wrist/Hand FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure definitions to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We proposed to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We proposed to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

Comment: One commenter strongly supported the proposal to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting.

Another commenter supported the proposed change to allow a crosswalk for this measure, stating that it will give greater flexibility to allow occupational therapy practitioners to utilize their clinical judgement to select the assessment that is best suited to patient needs. The commenter stated that it will also enable a greater focus on client-centered care and allow more accurate reporting of care outcomes through use of assessments that more closely match individual patient needs and more accurately reflect patient progress.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: One commenter stated that when reporting measure Q222: the use of the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure is required. The commenter stated that those of us who work in this setting understand that the disability experienced by a person with a thumb injury or osteoarthritis is very different from that of someone with a traumatic elbow injury. The commenter stated that it would seem that a scale such as this FOTO Elbow/Wrist/Hand FS patient-reported outcome measure, that is neither body region nor condition-specific, might fail to pick up change in disability/symptoms when such change does, in fact, exist. For example, the commenter stated that the DASH, like the FOTO, is a more global assessment of upper limb disability, and, is less responsive than a more regional scale, the Patient Reported Wrist Evaluation, in persons with wrist fractures (https://pubmed.ncbi.nlm.nih.gov/35415515/).

The commenter stated that their review of this tool would suggest that it has no published psychometrics yet it, along with other like measures, are being used to measure the quality of occupational therapy services. The commenter stated that psychometrics should be tested in in various populations. The commenter stated that there needs to be some method to allow occupational therapists to have more autonomy in selecting the scales that will be used to measure their worth when treating persons with upper limb dysfunction (in addition to various other populations).

Response: We note that the FOTO Elbow/Wrist/Hand FS is specific to upper arm, elbow, forearm, wrist, and hand, allowing evaluation of the specific problem for which the patient is receiving treatment. The measure steward indicated that the methods of administration were developed using modern psychometric methods (for example, item response theory) or utilize psychometric equating methods to crosswalk alternative PROM scores to the FOTO Elbow/Writs/Hand FS PROM. We encourage the commenter to reach out to the measure steward of current measures to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46754), we are finalizing the changes to measure Q222 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.35 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients who were screened for tobacco use AND 2) All patients who were identified as a tobacco user during the measurement period and who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period AND 3) All patients who were screened for tobacco use and, if identified as a tobacco user received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period, or identified as a tobacco non-user This measure contains three submission criteria which aim to identify patients who were screened for tobacco use (submission criteria 1), patients who were identified as tobacco users during the measurement period and who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period (submission criteria 2), and a comprehensive look at the overall performance on tobacco screening and cessation intervention (submission criteria 3). **Updated denominator: For the eCQM Specifications collection type: Revised:** Population 2: Equals Initial Population who were screened for tobacco use during the measurement period and identified as a tobacco user. **Updated denominator criteria: For all collection types: Added:** coding for nutrition and dietitian. **Updated denominator exclusion: For all collection types: Added:** denominator exclusion for all submission criteria for patients receiving hospice any time during the measurement period. **The measure definition is revised to read: For all collection types:** Tobacco Use – use of any tobacco product

Category	Description
	The 2021 USPSTF recommendation references the US Food and Drug Administration definition of tobacco which includes "any product made or derived from tobacco intended for human consumption (except products that meet the definition of drugs), including, but not limited to, cigarettes, cigars (including cigarillos and little cigars), dissolvables, hookah tobacco, nicotine gels, pipe tobacco, roll-your-own tobacco, smokeless tobacco products (including dip, snuff, snus, and chewing tobacco), vapes, electronic cigarettes (e-cigarettes), hookah pens, and other electronic nicotine delivery systems." The 2021 USPSTF recommendation describes smoking as generally referring to "the inhaling and exhaling of smoke produced by combustible tobacco products such as cigarettes, cigars, and pipes." The 2021 USPSTF recommendation describes vaping as "the inhaling and exhaling of aerosols produced by e-cigarettes." In addition, it states, "vaping products (that is, e-cigarettes) usually contain nicotine, which is the addictive ingredient in tobacco. Substances other than tobacco can also be used to smoke or vape. While the 2015 USPSTF recommendation statement used the term 'electronic nicotine delivery systems' or 'ENDS,' the USPSTF recognizes that the field has shifted to using the term 'e-cigarettes' (or 'e-cigs') and uses the term e-cigarettes in the current recommendation statement. E-Cigarettes can come in many shapes and sizes, but generally they heat a liquid that contains nicotine (the addictive drug in tobacco) to produce an aerosol (or 'vapor') that is inhaled ('vaped') by users." Tobacco Cessation Intervention – Includes brief counseling (3 minutes or less), and/or pharmacotherapy – **For the eCQM Specifications collection type:** Note: Concepts aligned with brief counseling (for example, minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the value set for the numerator. Other concepts such as written self-help materials (for example, brochures, pamphlets) and complementary/alternative therapies are not included in the value set and do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Note: Concepts aligned with brief counseling (for example, minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the numerator. Other concepts such as written self-help materials (for example, brochures, pamphlets) and complementary/alternative therapies do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **Updated numerator: For the eCQM Specifications collection type: Revised:** Population 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. Population 3: Patients who were screened for tobacco use at least once during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated numerator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. For Submission Criteria 3: Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 2 and Submission Criteria 3: language to reflect the tobacco cessation intervention needing to be completed during the measure period or in the six months prior. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 3: language to reflect the tobacco cessation intervention needing to be completed during the measure period or in the six months prior. **Updated denominator exception: For all collection types: Removed:** denominator exceptions for all submission criteria. **Updated value set/coding: For the eCQM Specifications collection type: Added:** Encounter Inpatient value set.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure for all collection types to better define and align the lookback period for tobacco cessation intervention and to allow a lookback of 6-months prior to the current measurement period. We proposed to update the denominator statement for Population 2 for all collection types to clarify the timing of the screening for tobacco cessation intervention and to align with the logic timing in the eCQM Specifications collection type. We proposed to update the denominator criteria to include encounter codes for MIPS eligible registered dieticians and nutritionists to allow them to screen for tobacco use as part of a comprehensive patient assessment. Additionally, we proposed to add denominator exclusions for all collection types for patients receiving hospice care during the measurement period and remove all denominator exceptions. This will lessen clinician burden as those patients for whom it is not appropriate to complete the quality action will be removed for the denominator eligible patient population. We also proposed to update the measure definition to align with 2021 USPSTF recommendations. We proposed to update the value set/coding for the eCQM Specifications collection type to include inpatient encounter codes as this patient population is appropriate for the denominator and should be assessed for the clinical quality action. Smoking increases the risk for many adverse health effects and though many patients that use tobacco abstain during hospitalization, they

Category	Description
	relapse upon discharge and as health crises can be a powerful motivator, this represents an important setting for completing tobacco cessation intervention.[1]
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46755 through 46757), we are finalizing the changes to measure Q226 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Cummins, S. E., Gamst, A. C., Brandstein, K., Seymann, G. B., Klonoff-Cohen, H., Kirby, C. A., Tong, E. K., Chaplin, E., Tedeschi, G. J., & Zhu, S. H. (2016). Helping Hospitalized Smokers: A Factorial RCT of Nicotine Patches and Counseling. *American journal of preventive medicine*, *51*(4), 578–586. https://doi.org/10.1016/j.amepre.2016.06.021.

D.36 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Do not include BP readings taken during an acute inpatient stay or an ED visit. **Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-85 years of age by the end of the measurement period who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66-80 by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior 3. Exclude patients 81 and older by the end of the measurement period with an indication of frailty for any part of the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated instructions and numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the measure guidance for the eCQM Specifications collection type to streamline and clarify language regarding blood pressure readings and which readings are appropriate to utilize for the purposes of assessing the quality action for this measure. Additionally, this revision will better align with the logic and intent of the measure which is to control high blood pressure in an effort to reduce adverse health effects such as cardiovascular disease and mortality. We proposed to update multiple components of the measure, for the eCQM Specifications and MIPS CQMs Specifications collection types, so that the patient age is determined as of the end of the measurement period and will align with Healthcare Effectiveness Data and Information Set (HEDIS) measure requirements and creates consistency in implementation. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to update the numerator note for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types to provide additional guidance around multiple blood pressure readings taken on the same day. We proposed to add language to all collection types to ensure that only distinct numeric results are being utilized for the purpose of this measure as ranges and thresholds do not meet the measure's intent.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46758), we are finalizing the changes to measure Q236 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.37 Use of High-Risk Medications in Older Adults

Category	Description
NQF # / eCQM NQF #:	0022 / N/A
Quality#:	238
CMS eCQM ID:	CMS156v11
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Calculate average daily dose for each prescription event. To calculate average daily dose, multiply the quantity of pills prescribed by the dose of each pill and divide by the days supply. For example, a prescription for the 30-days supply of digoxin containing 15 pills, 0.25 mg each pill, has an average daily dose of 0.125 mg. To calculate average daily dose for elixirs and concentrates, multiply the volume prescribed by daily dose and divide by the days supply. Do not round when calculating average daily dose. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 65 years and older at the end of the measurement period who had a visit during the measurement period. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Added: For Submission Criteria 1: coding for hospital/hospital observation discharge, outpatient observation, inpatient, and emergency department. For Submission Criteria 2: coding for emergency department. **Updated definition: For the MIPS CQMs Specifications collection type: Added:** For Submission Criteria 1: • At least two high-risk medications from the same drug class in Table 3 on different dates of service, each exceeding average daily dose criteria. And Calculate average daily dose for each prescription event. To calculate average daily dose, multiply the quantity of pills prescribed by the dose of each pill and divide by the days supply. For example, a prescription for the 30-days supply of digoxin containing 15 pills, 0.25 mg each pill, has an average daily dose of 0.125 mg. To calculate average daily dose for elixirs and concentrates, multiply the volume prescribed by daily dose and divide by the days supply. Do not round when calculating average daily dose. **Added:** For the **definition** of 'Cumulative Medication Duration': Table 3: High-Risk Medications With Average Daily Dose Criteria. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** A prescription for medications classified as high risk exceeding average daily dose criteria listed in Table 3. **Updated definition: For the eCQM Specifications collection type: Revised:** Index Prescription Start Date (IPSD) – The start date of the earliest prescription ordered for a high-risk medication during the measurement period. A high-risk medication is identified by any one of the following: a. A prescription for medications classified as high risk at any dose and for any duration. b. A prescription for medications classified as high risk at any dose with greater than a 90 day supply. c. A prescription for medications classified as high risk exceeding average daily dose criteria. An order is identified by either a prescription order or a prescription refill. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Rate 1: Patients with at least two orders of high-risk medications from the same drug class on different days. a. At least two orders of high-risk medications from the same drug class. b. At least two orders of high-risk medications from the same drug class with summed days supply greater than 90 days. c. At least two orders of high-risk medications from the same drug class each exceeding average daily dose criteria. Rate 2: Patients with at least two orders of high-risk medications from the same drug class (that is, antipsychotics and benzodiazepines) on different days. Total rate (the sum of the two previous numerators, deduplicated). **Updated value set/coding: For the eCQM Specifications collection type: Revised:** to group drugs by class rather than medication. **Added:** belladonna alkaloids, chlordiazepoxide-clidinium, glimepiride. **Removed:** naloxone/pentazocine, pentazocine, ticlopidine hydrochloride.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the initial patient population for the eCQM Specifications collection type to change the age anchor to the end of the measurement period so that it will align with HEDIS measure requirements and create consistency for implementation across programs. We proposed to update the definition, guidance, and numerator language for the eCQM Specifications collection type to incorporate average daily dose criteria for determining the numerator submission criteria 1 option for submission. Additionally, we proposed to revise the numerator language and correct the logic to account for at least two orders from same drug class rather than two orders of the same medication to support patient safety when prescribing high risk medications.

Category	Description
	We proposed to update the definitions and numerator instructions for the MIPS CQM Specifications collection type to incorporate average daily dose criteria for determining the numerator submission criteria 1 option for submission and clarify calculations. We proposed to update the definition for the eCQM Specifications collection type to add definition for 'order' to align with updates to the logic and to look for multiple orders OR an order with a refill for determining numerator submission criteria 2 option for submission. We proposed to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46759 through 46760), we are finalizing the changes to measure Q238 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.38 Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	239
CMS eCQM ID:	CMS155v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.
Substantive Change:	**Updated stratification: Revised:** Stratum 1 – Patients age 3-11 years at the end of the measurement period Stratum 2 – Patients age 12-17 years at the end of the measurement period **The measure initial patient population is revised to read:** Patients 3-17 years of age by the end of the measurement period, with at least one outpatient visit with a primary care physician (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the stratification and initial patient population for the eCQM Specifications collection type to change the age anchor from the start of the measurement period to the end of the measurement period so that it aligns with HEDIS measure requirements and creates consistency for implementation across programs. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46760), we are finalizing the changes to measure Q239 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.39 Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	240
CMS eCQM ID:	CMS117v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**Updated guidance: Removed:** Numerator criteria includes evidence of receipt of the recommended vaccine or the following: -- DtaP: Adverse reaction to the DtaP or Td vaccine; or encephalopathy due to DtaP or Td vaccination -- Polio (IPV) vaccine: Adverse reaction to the IPV vaccine, streptomycin, polymyxin B, or neomycin -- MMR Vaccination: Immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; history of measles, mumps, or rubella; or a seropositive result for the antigens -- Hib: Adverse reaction to the Hib vaccine -- Hepatitis B: Seropositive result for the antigen, adverse reaction to the hepatitis B vaccine, adverse reaction to common baker's yeast, or a history of hepatitis B illness -- Chicken pox (varicella zoster): Seropositive result for the antigen; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; or a history of varicella zoster -- Pneumococcal: Adverse reaction to the pneumococcal vaccine -- Hepatitis A: Seropositive result for the antigen, adverse reaction to the hepatitis A vaccine, or a history of hepatitis A illness -- Rotavirus: Adverse reaction to the rotavirus vaccine, severe combined immunodeficiency, or a history of intussusception -- Influenza: Adverse reaction to the influenza vaccine; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; or adverse reaction to neomycin **Updated denominator exclusion: Added:** Exclude children with any of the following on or before the child's second birthday: • Severe combined immunodeficiency • Immunodeficiency • HIV • Lymphoreticular cancer, multiple myeloma or leukemia • Intussusception **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Diphtheria, tetanus, and pertussis (DtaP) vaccination Children with any of the following on or before the child's second birthday meet criteria: • At least four DtaP vaccinations, with different dates of service. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the diphtheria, tetanus or pertussis vaccine. • Encephalitis due to the diphtheria, tetanus or pertussis vaccine. Poliovirus vaccination (IPV) At least three IPV vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. Measles, mumps, and rubella vaccination (MMR) Children with either of the following meet criteria: • At least one MMR vaccination on or between the child's first and second birthdays. • All of the following anytime on or before the child's second birthday (on the same or different date of service): o History of measles o History of mumps o History of rubella Haemophilus influenzae type b vaccination (HiB) Children with either of the following meet criteria on or before the child's second birthday: • At least three HiB vaccinations, with different dates of service. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the HiB vaccine. Hepatitis B Children with any of the following on or before the child's second birthday meet criteria: • At least three hepatitis B vaccinations, with different dates of service.

Category	Description
	O One of the three vaccinations can be a newborn hepatitis B vaccination during the eight-day period that begins on the date of birth and ends seven days after the date of birth. For example, if the member's date of birth is December 1, the newborn hepatitis B vaccination must be on or between December 1 and December 8. • Anaphylaxis due to the hepatitis B vaccine. • History of hepatitis B illness. Varicella vaccination (VZV) Children with either of the following meet criteria: • At least one VZV vaccination, with a date of service on or between the child's first and second birthdays. • History of varicella zoster (for example, chicken pox) illness on or before the child's second birthday. Pneumococcal Conjugate At least four pneumococcal conjugate vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. Hepatitis A Children with either of the following meet criteria: • At least one hepatitis A vaccination, with a date of service on or between the child's first and second birthdays. • History of hepatitis A illness on or before the child's second birthday. Rotavirus Children with any of the following meet criteria: • At least two doses of the two-dose rotavirus vaccine on different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • At least three doses of the three-dose rotavirus vaccine on different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • At least one dose of the two-dose rotavirus vaccine and at least two doses of the three-dose rotavirus vaccine, all on different dates of service, on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the rotavirus vaccine on or before the child's second birthday. Influenza At least two influenza vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 6 months (180 days) after birth. • One of the two vaccinations can be an LAIV vaccination administered on the child's second birthday. Do not count an LAIV vaccination administered before the child's second birthday.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure guidance to remove the numerator criteria related to adverse reactions to vaccines, as these do not align with intent of the measure which is to ensure children receive the CDC-recommended appropriate vaccines by age 2 to prevent disease, which is more cost effective than treatment, and to protect the health of their community. We also proposed to update the denominator exclusions by moving the numerator inclusion criteria for children who are immunocompromised to the denominator exclusion, as this patient population is not appropriate for assessment of the quality action. Additionally, we proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment data and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Furthermore, we proposed to update the numerator to remove seropositive test results as the CDC does not specifically recommend conducting antibody testing to determine immunity to disease in lieu of vaccination.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46761 through 46762), we are finalizing the changes to measure Q240 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.40 Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	277
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea. **The measure numerator is revised to read:** Patients who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea. **Updated numerator definition: Added:** Respiratory Event Index (REI) – is a measure of respiratory events per unit of time for a home sleep apnea test. **Updated numerator note: Revised:** The quality data codes below should be used for assessment of a MIPS eligible clinician's actions within 2 months of the initial evaluation for obstructive sleep apnea. **The measure numerator options are revised to read:** **Performance Met:** Apnea hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea **Denominator Exception:** Documentation of reason(s) for not measuring an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) within 2 months of initial evaluation for suspected obstructive sleep apnea (for example, medical, neurological, or psychiatric disease that prohibits successful completion of a sleep study, patients for whom a sleep study would present a bigger risk than benefit or would pose an undue burden, dementia, patients who decline AHI/RDI/REI measurement, patients who had a financial reason for not completing testing, test was ordered but not completed, patients decline because their insurance (payer) does not cover the expense)) **Performance Not Met:** Apnea hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) not documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea, reason not given
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description and numerator options language to harmonize the description with the revised numerator language. We proposed to revise the numerator to add a respiratory event index (REI) assessment and a 2-month timeframe within which a sleep study must be performed to determine the severity of suspected obstructive sleep apnea as the REI is appropriate for determining sleep apnea severity and the extended time frame will allow the clinicians flexibility in clinical workflow. We proposed to update the numerator definition to include a definition of REI to provide clarity and consistency. We also proposed to update the numerator note to provide further guidance on meeting numerator compliance. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46763), we are finalizing the changes to measure Q277 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.41 Rehabilitative Therapy Referral for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.
Substantive Change:	**Updated denominator criteria: Removed:** coding for Physical and Occupational Therapy and Speech Language Pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove coding for Physical and Occupational Therapy and Speech Language Pathology from the denominator eligible encounters. While these clinicians may treat patients with Parkinson's disease, the required quality actions cannot be feasibly implemented for these clinician types as it requires a referral.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46763), we are finalizing the changes to measure Q293 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.42 Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	305
CMS eCQM ID:	CMS137v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation. **Updated guidance: Removed:** The new episode of alcohol and other drug dependence should be the first episode of the measurement period that is not preceded in the 60 days prior by another episode of alcohol or other drug dependence. **The measure stratification is revised to read:** Report a total score, and each of the following strata: Stratum 1: Patients age 13-17 at the start of the measurement period Stratum 2: Patients age 18-64 at the start of the measurement period Stratum 3: Patients age 65 and older at the start of the measurement period **The measure initial patient population is revised to read:** Patients age 13 years of age and older as of the start of the measurement period who were diagnosed with a new SUD episode during a visit between January 1 and November 14 of the measurement period. **The denominator exclusions are revised to read: Removed**: Exclude patients with a negative diagnosis history, defined as an encounter or medication treatment for a diagnosis of alcohol, opioid or other drug abuse or dependence in the 60 days prior to the first episode of alcohol or drug dependence. **The measure definition is revised to read:** The new SUD episode is the first encounter during the Intake Period with a diagnosis of SUD with no encounter or medication treatment for a diagnosis of SUD in the 60 days prior. The initiation of treatment is the first SUD treatment within 14 days of a new SUD episode. Treatment includes inpatient SUD admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations, and medications for the treatment of SUD. The Intake Period: January 1-November 14 of the measurement year. The Intake Period is used to capture new SUD episodes. The November 14 cut-off date ensures that all services can occur before the measurement period ends. **Updated logic and logic definitions: Removed:** emergency department visits and medically managed withdrawals from the negative lookback rules. **Revised:** to account for instances when there are multiple qualifying initiation events. **Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Numerator 1: Initiation of treatment includes either an intervention or medication for the treatment of SUD within 14 days of the new SUD episode Numerator 2: Engagement in ongoing SUD treatment within 34 days of initiation includes: 1. A long-acting SUD medication on the day after the initiation through 34 days after the initiation of treatment 2. One of the following options on the day after the initiation of treatment through 34 days after the initiation of treatment: a) two engagement visits, b) two engagement medication treatment events, c) one engagement visit and one engagement medication treatment event
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description, initial patient population, numerator, denominator exclusions, and definition to remove any reference to 'substance abuse' with the measure as the terms "abuse and dependence" have been replaced by 'substance use disorder (SUD)' in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5). This will align terminology within the measure to current clinical terminology. We proposed to update the measure guidance and definition to clarify what defines an episode of SUD and update the stratification from 2 age groups to 3 age groups. We proposed to update the measure logic and logic definitions to remove emergency department visits and medically managed withdrawals from the negative lookback rules to align with the measure intent since the emergency department may not represent the best setting for the initiation of SUD treatment and the measure will not be applicable for patients already receiving SUD therapy. We also proposed an additional revision to the measure logic and logic definitions to specify how data should be handled

Category	Description
	when there are multiple qualifying initiation events to ensure data collection accuracy. Additionally, we proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

Comment: One commenter stated that CMS proposed to update the measure logic and logic definitions for measure Q305 to remove emergency department visits and medically managed withdrawals from the negative lookback rules to align with the measure intent in part since CMS believed that the emergency department may not represent the best setting for the initiation of SUD treatment. The commenter stated there is a plethora of evidence around the benefits of initiating medication assisted treatment (MAT) for the treatment of opioid use disorder (OUD) and other substance use disorders (including alcohol abuse disorder) in the emergency department. Previous comments were provided in rulemaking around the effectiveness of MAT on Modifications Related to Medicare Coverage for OUD Treatment Services Furnished by OTPs (opioid treatment programs). The commenter questioned the rationale behind why CMS would include such a statement in the proposed rule.

Response: While we agree that the emergency department may represent a setting for providing immediate intervention for a patient in SUD crisis; the intent of the measure is to assess initiation and continued SUD treatment. We believe that SUD treatment initiated in the ED is unlikely to meet the standards of this measure because of the inherent difficulties in following up with ED patients. Since the ED does not provide ongoing treatment, it would be a challenge to report the second rate which includes "two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation."

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46764 through 46765), we are finalizing the changes to measure Q305 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.43 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years
Substantive Change:	**Updated guidance: Removed:** Patient self-report for procedures as well as diagnostic studies should be recorded in 'Procedure, Performed' template or 'Diagnostic Study, Performed' template in QRDA-1. **The measure initial patient population is revised to read:** Women 24-64 years of age by the end of the measurement period with a visit during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure guidance to remove statements related to QRDA-1 as we publish separate QRDA implementation guides. We also proposed to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it will align with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

Comment: Two commenters requested that CMS confirm that changing the initial patient population would still include women who are 21 to 23 years of age, and that screening initiation is still recommended for women who are 21 years of age and above. One commenter indicated that cervical cancer screening initiation at 21 years of age is supported by USPSTF, ACOG, ASCP and other professional organizations, as it prevents disease progression. The commenter stated that raising the screening age could increase the already high rate of underscreening among individuals aged 25-29 years and exacerbate existing health inequities in cervical cancer screening, incidence, morbidity, and mortality, according to ACOG.

Response: To clarify, the revised initial patient population would still include women who are 21 to 23 years of age as the age anchor for when the age is determined was moved from the start of the measurement period to the end of the measurement period. This ensures that the patient is at least 23 years of age at the time of their visit and allows assessment of cervical cancer screening within the measurement period and within a 2-year look back period, that is the two previous performance periods. Since performance is based upon having an assessment within the last 3 years, the measure will allow performance to be captured for the patient when they were 21 years of age.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46765), we are finalizing the changes to measure Q309 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.44 Chlamydia Screening for Women

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	310
CMS eCQM ID:	CMS153v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**The measure stratification is revised to read:** Stratum 1: Patients age 16-20 by the end of the measurement period Stratum 2: Patients age 21-24 by the end of the measurement period. **The measure initial patient population is revised to read:** Women 16 to 24 years of age by the end of the measurement period who are sexually active and who had a visit in the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure stratification and initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it will align with HEDIS measure requirements and creates consistency for implementation across programs. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46765), we are finalizing the changes to measure Q310 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.45 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure there are values captured for both diastolic and systolic blood pressure when evaluating criteria. And to avoid blood pressure values falling into multiple categories. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type we proposed to revise the logic for the second hypertensive blood pressure reading (systolic blood pressure (SBP) 130-139 or diastolic blood pressure (DBP) 80-89) to avoid blood pressure values falling into multiple categories and to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46766), we are finalizing the changes to measure Q317 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.46 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v11
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**The measure initial patient population is revised to read:** Patients aged 65 years and older at the start of the measurement period with a visit during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated value set/coding: Added:** coding for physical and occupational therapy.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it will align with HEDIS measure requirements and creates consistency for implementation across programs. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Additionally, we proposed to add occupational and physical therapy evaluation visits as applicable encounters as these clinicians interact with older adults that may be more susceptible to falls. Occupational therapists are "uniquely qualified to address the multifactorial nature of falls, given their knowledge of factors that influence occupational performance."[1] There is a strong body of evidence that supports the role of physical therapists in reducing fall risk and fall prevention as outlined within the American Physical Therapy Association (APTA) handout: https://www.apta.org/patient-care/public-health-population-care/balance-and-falls/research-on-falls#.
Comment: One commenter appreciated the update to add coding for occupational therapy evaluation visits as applicable encounters for measure Q318. **Response:** We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46766), we are finalizing the changes to measure Q318 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Peterson, E. W., & Clemson, L. (2008). Understanding the role of occupational therapy in fall prevention for community-dwelling older adults. OT Practice, 13(3), CE1–CE8. https://www.researchgate.net/publication/286974169_Understanding_the_role_of_occupational_therapy_in_fall_prevention_for_community-dwelling_older_adults.

D.47 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
NQF # / eCQM NQF #:	0658 / N/A
Quality#:	320
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. **The measure denominator is revised to read: For all collection types:** All patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy. **Updated denominator criteria: For all collection types: Revised:** Patients aged 45 to 75 on date of encounter.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description, denominator, and denominator criteria for all collection types to expand the denominator eligible patient population to reflect USPSTF guidance that screening colonoscopies begin at age 45.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46767), we are finalizing the changes to measure Q320 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.48 CAHPS for MIPS Clinician/Group Survey

Category	Description
NQF # / eCQM NQF #:	0005 / N/A
Quality#:	321
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	CMS-approved Survey Vendor
Current Measure Description:	The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)
Substantive Change:	**Updated case-mix adjustor: Removed:** Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey item specific to the case-mix adjustor for "Asian language survey completion". **Added:** language other than English spoken at home.
Measure Steward:	Agency for Healthcare Research & Quality
High Priority Measure:	Yes
Measure Type:	Patient Engagement/Experience
Rationale:	We proposed to update the case-mix adjustor as only a small percentage of patients who report speaking a language other than English at home actually complete the survey in that language. By capturing the language that is actually spoken within the patient's home, we believed this will more accurately capture their language preference. For more information please refer to section IV.A.6.c.(1)(b)(ii)(A) of this final rule.

Comment: One commenter was supportive of the substantive changes to measure Q321 as it captures more culturally appropriate data. Another commenter expressed support for the change as this would help ensure consistent adjustment between CAHPS surveys in other settings, as well as more accurately represent meaningful comparisons of performance between MIPS groups.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: One commenter did not necessarily disagree with CMS' premise that collecting information on the language spoken by the participant at home is potentially more accurate than the language used by the respondent to complete the survey, but rather requested that CMS share more detail on how this revision would improve the reliability and validity of the scores. The commenter supported this modification as long as CMS shares sufficient data demonstrating that the revised scoring better reflects the quality of care provided. Another commenter supported this refinement to the CAHPS for MIPS Survey measure if it truly demonstrates that the revised scoring better reflects the care provided.

Response: We believe that collecting information on the language spoken by the participant at home as a case-mix adjustor is likely to increase participation and allow for a more meaningful comparison of performance between MIPS groups and aligns with CMS' effort to provide culturally and linguistically appropriate services (CLAS), which are intended to advance health equity, improve quality, and help eliminate health care disparities. Analysis of CY 2019 performance period for CAHPS for MIPS Survey measure data found that adding case-mix adjustors for Spanish language spoken at home, Asian language(s) spoken at home, and other language spoken at home has minimal impacts on scoring for most groups, and slightly positively impacts the scores of groups with substantial patient populations who speak a language other than English at home.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46767), we are finalizing the change to measure Q321 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.49 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator exception: Revised:** Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (for example, present or planned atrial appendage occlusion or ligation).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception by revising the language to account for the removal of patients that do not get prescribed an FDA-approved anticoagulant based on medical reason(s) from the performance rate as prescribing medication may not be appropriate in the instance a patient has or may undergo an atrial appendage occlusion or ligation. This procedure will eliminate the patient's need to take oral anticoagulation (OAC) therapy as left atrial appendage occlusion (LAAO) has shown similar efficacy to OAC on stroke rate (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7189129/#).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46768), we are finalizing the changes to measure Q326 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.50 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	366
CMS eCQM ID:	CMS136v12
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated definition: Revised:** Index Prescription Start Date (IPSD): The earliest prescription dispensing date for an ADHD medication where the date is in the Intake Period and an ADHD medication was not dispensed during the 120 days prior. Continuation and Maintenance Phase: The 300 days following the IPSD. **The measure initial patient population is revised to read:** Initial Population 1: Children 6-12 years of age as of the Intake Period who were prescribed an ADHD medication during the Intake Period and who had a visit during the measurement period. Children are removed if they were actively on ADHD medication in the 120 days prior to the IPSD, or had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Initiation Phase. Initial Population 2: Children 6-12 years of age as of the Intake Period who were prescribed an ADHD medication during the Intake Period and remained on the medication for at least 210 days during the 301-day period, beginning on the IPSD through 300 days after the IPSD, and who had a visit during the measurement period. Children are removed if they were actively on ADHD medication in the 120 days prior to the IPSD, or had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Continuation and Maintenance Phase. **The measure denominator exclusion is revised to read:** Exclude patients diagnosed with narcolepsy at any point in their history or during the measurement period. Exclude patients who are in hospice care for any part of the measurement period. **The measure numerator is revised to read:** Numerator 1: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase. Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits during the 31-300 days after the IPSD. **Updated logic and logic definitions: Revised:** For Numerator 2: logic to allow for only one of the two qualifying follow up visits to be an online assessment visit. **Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to extend the intake period to 12-months to allow for the assessment to follow-up for patients newly prescribed ADHD medications to occur at any time during the year. We proposed to align the definitions with the 12-month intake period as well as adding clarity to the definitions. We proposed to revise the denominator exclusions, repositioning criteria listed within the denominator exclusion to the initial patient population to streamline measure logic. Additionally, we proposed to revise the initial patient population to align with definitions and to revise the anchor for age calculation to be based off of the intake period, as this is when patients can start taking ADHD medication. We proposed to revise the logic and logic definitions for numerator two to ensure that only one of the two qualifying follow up visits be an online assessment for numerator compliance. We believed this revision will align with current clinical care which may not occur as an in-office visit. We proposed to update logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46769), we are finalizing the changes to measure Q366 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.51 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1: Patients who died any time prior to the end of the measure assessment period. 2: Patients who received hospice or palliative care services between the start of the denominator period and the end of the measurement assessment period. 3: Patients who were permanent nursing home residents between the start of the denominator period and the end of the measurement assessment period. 4: Patients with a diagnosis of bipolar disorder any time prior to the end of the measure assessment period. 5: Patients with a diagnosis of personality disorder emotionally labile any time prior to the end of the measure assessment period. 6: Patients with a diagnosis of schizophrenia or psychotic disorder any time prior to the end of the measure assessment period. 7: Patients with a diagnosis of pervasive developmental disorder any time prior to the end of the measure assessment period. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Added:** coding for preventive medicine encounters. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Adolescent patients 12 to 17 years of age and adult patients 18 years of age and older who achieved remission at 12 months as demonstrated by the most recent 12 month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding to "Contact or Office Visit" value set for preventive encounters.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the denominator exclusion statements for the eCQM Specifications collection type by adding relevant interval periods to clarify timing associated with each denominator exclusion in the logic. We also proposed to revise the numerator statement to provide clarity around the measure's intent to evaluate the most recent PHQ-9 or PHQ-9M assessment and to align with measure logic, which better expressed our intent. The intent of the measure is to facilitate improved response and remission scores through appropriate and effective treatment for patients diagnosed with depression. Additionally, we proposed to update the value set/coding for the denominator criteria for all collection types to include preventive medicine encounters to engage patients and assess remission of depression.

Comment: Several commenters were alarmed to see the proposed new exclusion of those receiving palliative care from measure Q370. The commenters stated that palliative care seems to be being equated here with hospice, which is incorrect. The commenters stated that excluding those on hospice, who are at the end of life, is appropriate while those receiving palliative care could live for years longer. According to the commenters, palliative care is appropriate at any point in a serious illness and can be provided along with any curative, disease-modifying treatment. The commenters requested that this exclusion be removed as it perpetuates the harmful misconception that palliative care and hospice are the same thing when they are not.

Response: We agree that palliative care is appropriate at any point in a serious illness and can be provided with any curative, disease-modifying treatment. It is our expectation that clinicians know the difference between palliative and hospice care and would not equate them. Palliative care is generally provided by an interdisciplinary medical team that focuses on the patient as a whole and would be inclusive of the types of services addressed by this measure as needed. We note that patients receiving palliative care or hospice care were previously excluded from this measure and the update to the denominator exclusion was to define the timing. We continue to believe that patients receiving palliative care are not appropriate for this measure as a result of the extent of physical, psychosocial and spiritual care required for patients with life-threatening illnesses and their families. Due to the complexities within this population, clinicians that support patients receiving palliative care may inadvertently not perform well from the aspect of producing quality metrics (https://doi.org/10.1186/s12913-019-3961-0). However, we encourage clinicians to provide care as they determine best supports all patients during their healthcare journey even if the patient population is not included within the targeted denominator of a given measure specification.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46770), we are finalizing the change to measure Q370 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.52 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v11
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Only the first referral made between January 1 – October 31 of the measurement period will be considered for this measure to allow adequate time for the referring clinician to collect the consult report by the end of the measurement period. **Revised:** The consultant report that will successfully close the referral loop should be related to the first referral for a patient during the measurement period. If there are multiple consultant reports received by the referring clinician which pertain to a particular referral, use the first consultant report to satisfy the measure. Eligible clinicians reporting on this measure should note that all data for the reporting year is to be submitted by the deadline established by CMS. Therefore, eligible clinicians who refer patients towards the end of the reporting period (that is, October), should request that clinicians to whom they referred their patients share their consult reports as soon as possible in order for those patients to be counted in the measure numerator during the measurement period. When clinicians to whom patients are referred communicate the consult report as soon as possible with the referring clinician, it ensures that the communication loop is closed in a timely manner and that the data are included in the submission to CMS. **The measure instructions are revised to read: For the MIPS CQMs Specifications collection type:** This measure is to be submitted a minimum of once per performance period for the first referral for all patients during the measurement period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure for the patients for whom a referral was made during the measurement period based on the services provided and the measure-specific denominator coding. The clinician who refers the patient to another clinician is the clinician who should be held accountable for the performance of this measure. All MIPS eligible clinicians reporting on this measure should note that all data for the reporting year is to be submitted by the deadline established by CMS, however, only first referrals made between January 1 – October 31 (the measurement period) will count towards the denominator to allow adequate time for the referring clinician to collect the consult report by the end of the performance period. When clinicians to whom patients are referred communicate the consult report as soon as possible with the referring clinicians, it ensures that the communication loop is closed in a timely manner and that the data is included in the submission to CMS. **Updated initial patient population: For the eCQM Specifications collection type: Revised:** Number of patients, regardless of age, who had an encounter during the measurement period and the first referral occurred by one clinician to another clinician on or before October 31. **The measure denominator is revised to read: For the MIPS CQMs Specifications collection type:** Number of patients, regardless of age, who had an encounter during the performance period and were referred by one clinician to another clinician on or before October 31. **The measure numerator is revised to read: For all collection types:** Number of patients with a referral on or before October 31, for which the referring clinician received a report from the clinician to whom the patient was referred.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure, across all collection types, to allow for a 2-month period to close the referral loop in alignment with interested parties' feedback and published literature. This revision will allow adequate time for the referring clinician to collect the consult report prior to the end of the performance period. Additionally, we proposed to shorten the timeframe to determine denominator eligibility to account for the extension in timeframe for numerator compliance. We proposed to add language to multiple components of the measure for all collection types to clarify that only the first referral should be utilized for denominator eligibility.
Comment: One commenter supported the proposed changes to measure Q374. Another commenter strongly supported the modification to reflect the time referrals require and to align the measure with other measures regarding follow-up care. The commenter stated that 2967his change would solve the main issue with this measure's use and allow for practices to assess their care coordination more accurately within each performance year. The commenter stated that 2967his proposed change would greatly increase the appeal of this measure and could lead to improved care coordination for many patients **Response:** We thank the commenters for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46771), we are finalizing the changes to measure Q374 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.53 Functional Status Assessment for Total Hip Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	376
CMS eCQM ID:	CMS56v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery. **Updated denominator exclusion: Revised:** 1. Exclude patients with two or more fractures indicating trauma in the 24 hours before or at the start of the total hip arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description to clarify the logic associated with the age requirement, as described above in the revised measure description. We proposed to revise the denominator exclusion so the timing of the lower body fracture in relation to the THA is clearly reflected. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46772), we are finalizing the changes to measure Q376 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.54 Functional Status Assessments for Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v12
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored to allow for different workflows and systems and more closely align with exclusion criteria, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46772), we are finalizing the changes to measure Q377 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.55 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist. **The measure initial patient population is revised to read:** Children, 6 months – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the measure description and initial patient population to add context and clarify that the measure is to be reported by dentists. We proposed to revise the age criteria in the initial patient population logic to clarify the measure's intent to include patients that are 20 years of age at the start of the measurement period, to ensure the appropriate patient population is being assessed for tooth decay or cavities. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

Comment: One commenter expressed concern on limiting the denominator of measure Q378 to only include "Clinical Oral Evaluation," stating that the measure, as currently defined, measures the number of children who have dental decay. The commenter stated that it requires the identification and diagnosis of caries related lesions. The commenter stated that it is not clear from the description of the CPT codes currently included in the value set, if accurate identification and documentation of dental decay is feasible. The commenter stated that limiting the specification for the measure denominator to children with reported CDT (dental) codes for clinical oral evaluation that broadly include diagnosis and treatment planning for all oral conditions, may increase the feasibility of an accurate identification of caries related lesions. However, the commenter assumed it is unlikely that a primary care physician or a pediatrician will document care using CDT codes and that limiting the denominator to children with a CDT oral evaluation code may significantly impact on the denominator size. The commenter requested that CMS please consider these limitations as the agency reviews the measure further.

Response: We note that the codes within the measure were updated based on the changes proposed and finalized above for the initial patient population to ensure the measure is reported by dentists. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46773), we are finalizing the changes to measure Q378 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.56 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v12
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist. **Updated guidance: Added:** Telehealth encounters are not eligible for this measure because the measure does not contain telehealth-eligible codes and requires a clinical action that cannot be conducted via telehealth. **The measure stratification is revised to read:** Population 1: Patients age 6 months – 5 years at the start of the Measurement Period Population 2: Patients age 6-12 years at the start of the Measurement Period Population 3: Patients age 13-20 years at the start of the Measurement Period **The measure initial patient population is revised to read:** Children, 6 months – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated value set/coding: Removed:** value sets for Preventive Care, Telephone Visits, Online Assessments, and Office Visits.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and initial patient population to capture patients who are 20 years old at the start of the measurement period, which will align with the measure narrative and intent of being reported by a dentist. We proposed to clarify that telehealth encounters are not eligible. We proposed to make further revisions to the guidance and initial patient population based on USPSTF recommendations and reimbursement practices that primary care providers are unlikely to perform the clinical action of providing a fluoride varnish, therefore the measure intent, as described in the revised measure description, is for dentists to report this measure. We proposed to update the stratification to provide clarity on the age anchor timing and align with measure intent and incorporate the recommended format into the stratification logic. We also proposed to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Additionally, we proposed to remove value set/coding for preventive medicine encounters, telephone visits and online assessments.

Comment: One commenter expressed concern on limiting the denominator of measure Q379 to only include "Clinical Oral Evaluation," stating that this measure by description is designed for reporting by primary care physicians as well as dentists. The commenter stated that given limited dental coverage within medical plans, non-dentist providers, such as primary care physicians or pediatricians, are more likely to document the visit with a CPT code, rather than a CDT (Current Dental Terminology) code associated with an oral evaluation. The commenter stated that limiting the value set to "Clinical Oral Evaluation" may significantly impact the denominator size.

The commenter also stated that measure Q379 does not meet the consideration criterion of "whether the measure reflects current clinical guidelines." The commenter stated that measure Q379 only tracks a single fluoride varnish applied during the measurement period. The commenter stated that evidence-based clinical recommendations suggest that efficacy of topical fluoride is dose-dependent and fluoride varnish should be applied at least every three to six months in children.

Response: While we acknowledge that limiting the denominator to clinical oral evaluations only may limit the denominator eligible patient population, difficulties with accurately capturing primary care physician data for some age groups were identified and it was determined to focus on dental clinicians only to maintain data integrity. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46773), we are finalizing the changes to measure Q379 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.57 Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.
Substantive Change:	**Updated denominator exclusion: Removed:** 1. Meningococcal, Tdap and/or HPV vaccine contraindicated OR patient allergic to the meningococcal, Tdap, and/or HPV vaccine. 2. Encephalopathy due to Tdap vaccine. **Updated numerator options: Added:** denominator exception option for each submission criteria to reflect patients who had anaphylaxis due to the vaccine(s) being assessed. **Added:** For Submission Criteria 2: denominator exception option for patients who had encephalitis due to the tetanus, diphtheria or pertussis vaccine. **Updated numerator: Revised:** For Submission Criteria 3: Adolescents who completed the HPV vaccine series on or between the patient's 9th and 13th birthdays.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the denominator exclusions for anaphylaxis and encephalopathy as patients associated with these clinical conditions should still be assessed for administration of the meningococcal, Tdap and/or HPV vaccines. We proposed to revise the numerator options to add additional parameters for denominator exceptions for those patient populations that are not appropriate for the clinical quality action of vaccine administration. We also proposed to update the numerator for Submission Criteria 3 to require completion of the HPV vaccine series on or between the 9th and 13th birthday to align with the measure's intent as described in the current measure description which is to ultimately improve adolescent immunization rates and prevent disease which is more cost effective than treatment of the disease.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46774), we are finalizing the changes to measure Q394 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.58 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications collection type.
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type for this measure due to an insufficient volume of data as indicated in the 2022 Quality Benchmarks. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46774), we are finalizing the changes to measure Q416 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.59 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator note: For** the **MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46775), we are finalizing the changes to measure Q418 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.60 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
NQF # / eCQM NQF #:	2152 / N/A
Quality#:	431
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**Updated denominator exclusion: Added: For all submission criteria:** 1. Patients with dementia any time during the patient's history through the end of the measurement period. 2. Patients who use hospice services any time during the measurement period. **Updated denominator criteria: Added:** coding for audiology. **Updated numerator definition: Revised: For Submission Criteria 1:** AUDIT Screening Instrument (score > 8) **Updated numerator options: Removed: For all submission criteria:** all denominator exceptions.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to add denominator exclusions and remove denominator exceptions to reduce burden by removing patients from the denominator eligible patient population as the clinical quality action may not be appropriate. This revision will allow clinicians to identify the measure's intended patient population prior to numerator compliance being determined, which will reduce the denominator patient population applicable for reporting. Additionally, we proposed to revise the AUDIT screening instrument score as this will align with the World Health Organization (WHO) guidelines. We also proposed to update the denominator criteria to include coding for audiology as this measure is applicable to their scope of care. Studies have shown a positive correlation between hearing loss and alcohol consumption, more markedly with heavy alcohol consumption, making this concept important for audiologists to assess (https://academicworks.cuny.edu/cgi/viewcontent.cgi?article=5338&context=gc_etds).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46775), we are finalizing the changes to measure Q431 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.61 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated guidance: For the eCQM Specifications collection type: Revised:** Initial Population 1: All patients who have an active diagnosis of clinical ASCVD anytime during the measurement period or ever had an ASCVD procedure. **Added:** Millimoles per liter (mmol/L) should be converted to milligrams per deciliter (mg/dL) for reporting this measure. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Population 1: All patients who have an active diagnosis of clinical ASCVD or ever had an ASCVD procedure. **Updated denominator exclusion: For all collection types: Removed: For all submission criteria:** Patients who have a diagnosis of pregnancy at any time during the measurement period. **Updated definition: For the MIPS CQMs Specifications collection type: Added:** Ezetimibe / Rosuvastatin – Roszet – Fixed Dose Combination' to Table 1 – Statin Medication Therapy List. **Revised:** Lipoprotein Density Cholesterol (LDL-C) result – A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. **Updated denominator exception: For the eCQM Specifications collection type: Added:** Patients with documentation of a medical reason for not being prescribed statin therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure, for the eCQM Specifications collection type, to revise the timing associated with a clinical ASCVD diagnosis to align with the measure intent of only including patients with an active diagnosis. We also proposed to remove the pregnancy exclusion for all collection types to align with U.S Food and Drug Administration (FDA) recommendations that pregnancy be removed as a contraindication in prescribing statins (https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol). We proposed to revise the eCQM Specifications collection type in order to standardize the method that represents the lab value for low-density lipoprotein cholesterol (LDL-C). We proposed to revise the measure to request that Millimoles per liter (mmol/L) should be converted to milligrams per deciliter (mg/dL). We also proposed to update the definitions for the MIPS CQMs Specification collection type by adding another medication to the statin medication therapy list for completeness and to clarify which test results should be used for both direct and calculated test results for fasting or non-fasting LDL-C test if they happen to be available on the same day. We proposed to update the denominator exceptions for the eCQM Specification collection type by adding a medical reason for not being prescribed statin therapy to align with American College of Cardiology/American Heart Association (ACC/AHA) guidelines (https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2019/03/07/16/00/2019-acc-aha-guideline-on-primary-prevention-gl-prevention).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46776), we are finalizing the changes to measure Q438 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.62 Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	440
CMS eCQM ID:	N/A

Category	Description
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**Updated denominator note: Removed:** denominator note. **Updated denominator exception: Added:** Pathology report for tissue specimens produced from wide local excisions or re-excisions.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the denominator note and add a denominator exception to simplify identifying the denominator eligible patient population and better address cases of excisions and re-excisions that may be included via the pathology CPT codes 88304 & 88305.
Comment: Several commenters were supportive of the addition of a denominator exception as proposed for measure Q440. These exceptions align the measure with its intended purpose more accurately. **Response:** We thank the commenters for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46777), we are finalizing the changes to measure Q440 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.63 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	441
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated
Substantive Change:	**The measure numerator note is revised to read:** For Component 1: • Submit G9789 for blood pressures recorded during Inpatient Stays, Emergency Room Visits, or Urgent Care Visits. In order to meet performance, the most recent blood pressure should be recorded within the performance period. • Home BP results which can be obtained digitally, in writing or verbally, and are able to be stored in the EMR in a discrete field can be included. Accepting these BP results is at the discretion of the provider. **Updated denominator exception: Revised:** For Component 1: Blood pressure recorded during inpatient stays, Emergency Room Visits, or Urgent Care Visits
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to revise the numerator note to capture additional blood pressure results as a response to the impact COVID-19 has had on the availability of in-office blood pressure results. Additionally, we proposed to revise the denominator exception with the removal of self-reported blood pressure results. This revision allows clinicians to utilize patient reported blood pressures, documented in the electronic medical record, for the determination of numerator compliance.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46777), we are finalizing the changes to measure Q441 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.64 Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.
Substantive Change:	**The measure title is revised from 'Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)' to:** Percentage of Patients who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) **The measure description is revised to read:** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life. **The measure numerator is revised to read:** Patients who received systemic cancer-directed therapy in the last 14 days of life. **Updated numerator note: Added:** Definition of systemic cancer-directed therapy includes: • All traditional cytotoxic chemotherapy (such as alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, and antitumor antibiotics); • Immunotherapy; • Biologics (such as Herceptin, Rituxan); and • Targeted agents Do not include supportive care therapies (for example, growth factors, bisphosphonates, RANK ligand inhibitors, nausea medications or fluids if these are not given in association with "systemic cancer-directed therapy"). Hormonal therapies and steroids are not included in this systemic cancer directed therapy definition. **The measure numerator options are revised to read:** **Performance Met:** Patient received systemic cancer-directed therapy in the last 14 days of life. **Performance Not Met:** Patient did not receive systemic cancer-directed therapy in the last 14 days of life.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure to reflect the measure intent to only include systemic cancer-directed therapy for the purposes of this measure. We proposed to clarify the terminology and revise the numerator note to include a definition for systemic cancer-directed therapy to allow for precise implementation of the measure. This ensures that the denominator eligible patient population aligns with the treatments that have been shown to not only negatively impact the patient's experience at the end of life, but also have not been shown to improve outcomes (https://ascopubs.org/doi/full/10.1200/JCO.2016.70.1474). ASCO advocates that "curtailing unnecessary treatments at the end of life will help drive down end-of-life resource utilization costs" and that "early integration of palliative care/hospice services for patients with late stage cancer in order to avoid aggressive measures at the end-of-life."

Comment: One commenter supported these changes which, importantly, improve the measure's ability to incentivize appropriate care at the end of life. The commenter agreed that early integration of palliative care/hospice services for patients with late-stage cancer can avoid aggressive measures that are not consistent with patients' goals and preferences at the end-of-life.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46778), we are finalizing the changes to measure Q453 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

D.65 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Back Pain After Lumbar Discectomy/Laminectomy' to:** Back Pain After Lumbar Surgery **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion and numeric pain scale. **Updated denominator: Revised:** DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The 12-month period in which eligible patients have a procedure. This allows for enough time for a follow-up assessment to occur during the performance period. The "denominator identification period" includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Revised:** NUMERATOR (Submission Criteria 1): All eligible patients whose back pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS or Numeric Pain scale at three months (6 to 20 weeks) postoperatively. **Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose back pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Updated numerator definition: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance and allow for telephone screenings. **Added:** For Submission Criteria 1: Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (for example, phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that is in which a postoperative VAS or Numeric pain scale score is obtained. Preoperative Assessment VAS or Numeric Pain – A preoperative VAS or Numeric pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS or Numeric score was obtained, use the VAS or Numeric score that is the most recent and prior to the procedure. Postoperative Assessment VAS or Numeric Pain – A postoperative VAS or Numeric pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months

Category	Description
	postoperatively will not be used for measure calculation. If more than one postoperative VAS or Numeric score was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Visual Analog Scale (VAS) – A "visual analog scale" is a continuous line indicating the continuum between two states of being. A copy of the tool can be obtained below or at the following link Visual Analog Scale Tool. Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (for example, phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. Back Pain Target #2 – A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement in back pain is greater than or equal to 5.0 points. **Updated numerator note: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance, replace 'change' with 'improvement', and updated to allow for telephone screenings. **Added:** For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 or G2139 is submitted. • VAS Pain or Numeric Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool • Postop VAS or Numeric Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS or Numeric value is greater than 3.0 and no valid preop to measure improvement • Postoperative VAS or Numeric value is greater than 3.0 and preoperative VAS or Numeric Pain Scale (to measure improvement) is administered beyond the 3-month timeframe prior to and including the date of procedure (for example, 6 months before procedure) **Updated numerator options: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance. **Added:** For Submission Criteria 2: **Performance Met:** Back pain as measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater. **Performance Not Met:** Back pain was not measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Performance Not Met:** Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was greater than 3.0 AND Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated less than an Improvement of 5.0 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise this measure to expand the eligible procedures to include lumbar fusion, to capture a more complete patient population for lumbar surgery. This will be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision will be reflected within multiple components within the specification. Additionally, we proposed to add the Numeric Pain scale as an option for numerator compliance. Inclusion of this tool will allow flexibility by allowing virtual visits for completion of the assessment. We proposed to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We also proposed to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we proposed to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions aligned with the measure intent and combining of two lumbar procedures as stated in the revised measure description. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46779 through 46780), we are finalizing the changes to measure Q459 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.66 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Leg Pain After Lumbar Discectomy/ Laminectomy' to:** Leg Pain After Lumbar Surgery **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion and numeric pain scale. **Updated denominator: Revised**: DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The 12- month period in which eligible patients have a procedure. This allows for enough time for a follow-up assessment to occur during the performance period. The "denominator identification period" includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Revised:** NUMERATOR (Submission Criteria 1): All eligible patients whose leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS or Numeric Pain scale at three months (6 to 20 weeks) postoperatively. **Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) or Numeric Pain scale at one year (9 to 15 months) postoperatively. **Updated numerator definition: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance and allow for telephone screenings. **Added:** For Submission Criteria 1: Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (for example, phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that is in which a postoperative VAS or Numeric pain scale score is obtained. Preoperative Assessment VAS or Numeric Pain – A preoperative VAS or Numeric pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS or Numeric score was obtained, use the VAS or Numeric score that is the most recent and prior to the procedure. Postoperative Assessment or Numeric VAS Pain – A postoperative VAS or Numeric pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months

Category	Description
	postoperatively will not be used for measure calculation. If more than one postoperative VAS or Numeric score was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Visual Analog Scale (VAS) – A "visual analog scale" is a continuous line indicating the continuum between two states of being. A copy of the tool can be obtained below and at the following link Visual Analog Scale Tool. Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (for example, phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. Leg Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their leg pain as less than or equal to 3.0. Leg Pain Target #2 – A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively one year (9 to 15 months) after the procedure AND the improvement in leg pain is greater than or equal to 5.0 points. **Updated numerator note: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance, replace 'change' with 'improvement', and updated to allow for telephone screening. **Added:** For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1052 or G2147 is submitted. • VAS Pain or Numeric Scale is not administered postoperatively at one year (9 to 15 months) • Leg pain is measured using a different patient reported functional pain tool • Postoperative VAS or Numeric Pain scale is administered less than 9 months or greater than 15 months (1 year window) • Postoperative VAS or Numeric value is greater than 3.0 and no valid preoperative VAS Pain scale to measure improvement • Postoperative VAS or Numeric value is greater than 3.0 and preoperative VAS or Numeric Pain scale (to measure improvement) is administered beyond the 3-month timeframe prior to and including the date of procedure (for example, 6 months before procedure) **Updated numerator options: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance. **Added:** For Submission Criteria 2: **Performance Met:** Leg pain as measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater. **Performance Not Met:** Leg pain was not measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Performance Not Met:** Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise this measure to expand the eligible procedures to include lumbar fusion, in order to capture a more complete patient population for lumbar surgery. This will be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision will be reflected within multiple components within the specification. Additionally, we proposed to add the Numeric Pain scale as an option for numerator compliance. Inclusion of this tool will allow flexibility by allowing virtual visits for completion of the assessment. We proposed to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We also proposed to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we proposed to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions aligned with the measure intent and combining of two lumbar procedures. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46781 through 46782), we are finalizing the changes to measure Q461 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.67 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated denominator exception: Revised:** Patient refused the bone density evaluation at the time ordered or did not have it performed within 3 months after the start of ADT.
Measure Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception to align with the measure logic and intent of receiving an initial bone density evaluation prior to the start or within 3 months of ADT.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46783), we are finalizing the changes to measure Q462 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.68 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**The measure denominator definition is revised to read:** Risk factors for POV – • Surgery ≥ 30 minutes • Age ≥ 3 years • Strabismus surgery • History of POV or Post-Operative Nausea and Vomiting (PONV)/motion sickness in patient • Family History of POV/PONV • Post-pubertal female • Adenotonsillectomy • Otoplasty • Anticholinesterases • Long-acting opioids
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure denominator definition to reflect the 2020 clinical guidance for the management of postoperative nausea and vomiting.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46783), we are finalizing the changes to measure Q463 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.69 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Functional Status After Lumbar Discectomy/Laminectomy' to:** Functional Status After Lumbar Surgery **The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion. **Updated denominator: Revised:** DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The twelve month period in which eligible patients have a denominator eligible procedure. This allows for enough time for a follow-up assessment to occur during the twelve month performance period. The denominator identification period includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI Version 2.1a) patient reported outcome tool at one year (9 to 15 months) postoperatively. **Updated numerator definition: Added:** For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that a postoperative Oswestry Disability Index (ODI version 2.1a) functional status score can be obtained. Preoperative Assessment Oswestry Disability Index (ODI version 2.1a)- A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) – A postoperative ODI functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to nine months and after fifteen months postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Oswestry Disability Index (ODI version 2.1a) Patient Reported Outcome Tool – An ODI patient reported outcome tool (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools. A copy of the tool can be obtained below or at the following link: https://eprovide.mapi-trust.org/instruments/oswestry-disability-index. Functional Status Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22.

Category	Description
	Functional Status Target #2 – A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement is demonstrated as a decrease in ODI score by greater than or equal to 30 points. **Updated numerator note: Added:** For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 or G2143 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI is greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (for example, 6 months before procedure.) **Updated numerator options: Added:** For Submission Criteria 2: **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of less than 30 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise this measure to expand the eligible procedures to include lumbar fusion, in order to capture a more complete patient population for lumbar surgery. This will be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision will be reflected within multiple components within the specification. We proposed to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We also proposed to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we proposed to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions aligned with the measure intent and combining of two lumbar procedures. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46784 through 46785), we are finalizing the changes to measure Q471 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.70 Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A / 3475e
Quality#:	472
CMS eCQM ID:	CMS249v5
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Substantive Change:	**Updated guidance: Revised:** Patients are excluded from the measure if they have one or more risk factors for osteoporosis, including a result indicating that the patient should be considered for bone density testing on one of the following risk assessment instruments: • 10-year probability of major osteoporotic fracture of 8.4 percent or higher as determined by the FRAX • ORAI score of >=9 • OSIRIS score of <1 • OST score of <2" **The measure initial patient population is revised to read:** Female patients ages 50 to 63 years at the start of the measurement period with an encounter during the measurement period. **The measure denominator exclusion is revised to read:** 1. Exclude patients with one of the following risk factors. 2. Risk factors are grouped by when they occur in relation to the measurement period. 3. The following risk factors must be active during the measurement period: BMI <= 20 kg/m2 (must be the first BMI of the measurement period) Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) 4. The following risk factors may occur at any time in the patient's history prior to the start of the measurement period: Osteoporosis Osteopenia 5. The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: Gastric bypass Aromatase inhibitors Documentation of history of hip fracture in parent 6. The following risk factors may occur at any time in the patient's history or during the measurement period: Glucocorticoids [cumulative medication duration >= 90 days] Osteoporotic fracture Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic malnutrition Chronic liver disease Rheumatoid arthritis Hyperthyroidism Type I Diabetes End stage renal disease Osteogenesis imperfecta Ankylosing spondylitis Psoriatic arthritis Ehlers-Danlos syndrome Cushing's syndrome Hyperparathyroidism Marfan syndrome Lupus Chemotherapy Multiple myeloma Premature menopause Double or bilateral oophorectomy Eating disorder Amenorrhea Organ transplant" **The measure definition is revised to read:** The measure allows for clinicians to use 4 tools to assess osteoporosis or osteoporotic fracture risk. 1. The Fracture Risk Assessment Tool (FRAX[R]) is used to calculate 10-year absolute fracture risk. The FRAX evaluates a patient's 10-year probability of hip fracture and major osteoporotic fracture (clinical spine, forearm, hip, or shoulder fracture). It is applicable to people aged 40-90 years. 2. The Osteoporosis Risk Assessment Instrument (ORAI) is used to calculate osteoporosis risk. It is applicable to women >=45 years. 3. The Osteoporosis Index of Risk (OSIRIS) is used to calculate osteoporosis risk. It is applicable to patients of any age. 4. The Osteoporosis Self-Assessment Tool (OST) is used to calculate osteoporosis risk. It is applicable to patients of any age."

Category	Description
	Updated logic and logic definitions: Revised: the glucocorticoid active medication duration to calculate number of calendar days covered. **Updated numerator exclusion: Added:** Exclude patients with a result on one of the following tools, which indicates the patient should be considered for bone density testing, anytime in the patient's history prior to the time of the first DXA scan during the measurement period: FRAX[R] ten-year probability of all major osteoporosis related fracture >= 8.4 percent ORAI score of >=9 OSIRIS score of <1 OST score of <2
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure guidance to remove 'combination risk factors' and add 3 additional risk assessment tools to align with USPSTF recommendations (https://www.uspreventiveservicestaskforce.org/Home/GetFileByID/3427). Additionally, we proposed to reflect the addition of the 3 risk assessment tools within the measure definition and numerator exclusions through revision of the measure. We proposed to revise the initial patient population to change the time anchor from the start of the measurement period to the end of the measurement period so that it aligns with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we proposed to revise the denominator exclusion to align exclusion timing of osteoporosis with the timing of osteopenia, so the same exclusion criteria will be applied to both within the narrative and logic. We proposed to update the measure logic and logic definitions to evaluate the number of calendar days active on glucocorticoids to align the cumulative medication duration logic with the intent of the measure to identify patients appropriate for denominator exclusion.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46786 through 46787), we are finalizing the changes to measure Q472 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.71 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v4
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**Updated denominator exclusion: Revised:** Patients with a diagnosis of morbid obesity, or with a BMI Exam >=40 before the follow up urinary symptom score. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the denominator exclusions to include a body mass index value equal to 40, which will align with the Centers for Disease Control and Prevention's (CDC) guideline for morbid obesity. We also proposed to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46787), we are finalizing the changes to measure Q476 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.72 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. Added: Neck FS PROM score – The Neck FS PROM score may be achieved using one of three forms: the FOTO Neck FS PROM computer adaptive test the FOTO Neck FS PROM short form, or an alternative PROM score that is cross-walked to the Neck FS PROM. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the Neck FS PROM score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Neck FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the denominator criteria to add coding for skilled nursing facilities for physiatrists who care for patients in nursing home settings. We believed this coding will provide additional opportunity for those clinicians to report this measure. We also proposed to revise the definition to include Skilled Nursing Facility coding within the initial evaluation definition. Additionally, we proposed to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update will promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.
We received no public comments on the substantive changes proposed for this measure, For the reasons stated above and in the proposed rule (87 FR 46788), we are finalizing the changes to measure Q478 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.73 Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	481
CMS eCQM ID:	CMS646v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Substantive Change:	**Updated logic and logic definitions: Revised:** for the Initial Patient Population to capture patients whose first Bladder Cancer staging occurred during the measurement period.
Measure Steward:	Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the logic and logic definitions for the initial patient population to accurately capture the intended population, as stated in the current measure description. Only the first staging performed with the appropriate pathology should count for denominator eligibility for the purposes of this measure, and the first staging must occur in the measurement period. This change will better align with measure intent of capturing patients who received intravesical BCG within 6 months of bladder cancer staging, and more accurately anchor the administration of treatment.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46788), we are finalizing the changes to measure Q481 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

D.74 Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Substantive Change:	**Updated denominator: Revised:** patient age to 45 years or greater. **Updated denominator criteria: Revised:** patient age to 45 years or greater. **Numerator Options: Revised:** Patients between 45 and 85 years of age who received a screening colonoscopy during the performance period.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the measure denominator, denominator criteria, and numerator options to align with USPSTF guidance that screening colonoscopies should start at age 45. This change will reflect the latest USPSTF guidance for this measure.
After consideration of public comments, as outlined in Table C.11, the substantive changes above to measure Q439 are finalized as proposed for the CY 2023 performance period.2025 MIPS payment year and future years.	

TABLE Group DD: Previously Finalized Quality Measures with Substantive Changes Finalized for Partial Removal as Component Measures in Traditional MIPS and Finalized for Retention for Use in Relevant MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

As noted under Table Group CC, beginning with the CY 2023 performance period/2025 MIPS payment year and future years, we finalized to maintain measures Q110**:** Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults for MIPS Value Pathways (MVP) development, and maintain measure Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this final rule. These measures have proposed substantive changes under Table Group DD and Table Group E.

Note: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table DD as follows: NQF # / eCQM NQF #.

The DD Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2023. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2023 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2024. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believed are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2023 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2023 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the DD table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: The CMS Web Interface collection type is no longer available in MIPS, except for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period. This collection type is therefore no longer listed in any tables under Table Group DD. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the CMS Web Interface collection type for APP reporting, see sections III.G.4.b.(9) and III.G.4.c.(1) of this final rule. For information on changes to measures under the CMS Web Interface collection type finalized for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this final rule.

We solicited comments on these substantive changes.

DD.1 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / N/A
Quality#:	110
CMS eCQM ID:	CMS147v12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**The measure guidance is revised to read: For the eCQM Specifications collection type**: To enable reporting of this measure at the close of the measurement period, this measure will only assess the influenza season that starts on October 1 of the year prior to the measurement period and ends on March 31 of the measurement period. The subsequent influenza season (ending March of the following year) will be measured and reported in the following year. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.6. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure denominator is revised to read: For the eCQM Specifications collection type:** Equals Initial Population and seen for a visit between October 1 of the year prior to the measurement period and March 31 of the measurement period. **Updated denominator exclusion: For all collection types: Added:** denominator exclusion for patients receiving hospice any time during the measurement period. **Updated definition: For the eCQM Specifications collection type: Revised:** Previous Receipt - receipt of the current season's influenza immunization from another provider OR from same provider prior to the visit to which the measure is applied (typically, prior vaccination would include influenza vaccine given since July 1st). **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization between July 1 of the year prior to the measurement period to June 30 of the measurement period. **Updated numerator instructions: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types: Removed:** Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (for example, for patient preference) or a system reason (for example, the institution only carries LAIV). **Updated denominator exception: For the eCQM Specifications collection types: Removed:** all denominator exceptions (medical, patient, and system reasons).
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure guidance for the eCQM Specifications collection type to remove the paragraph regarding the influenza encounter value set and replace it with individual value sets grouped into a logic definition to be more transparent about applicable encounters. We also proposed to revise the denominator for the eCQM Specifications collection type to align the identification of patients with visits that coincide with the flu season as referenced by the Food and Drug Administration (FDA) approved time for licensed flu vaccination administration (https://www.cdc.gov/flu/about/season/flu-season.htm). We proposed to add hospice as a denominator exclusion for all collection types to align with other MIPS immunization measures. Additionally, we proposed to revise the definition and numerator for the eCQM Specifications collection type to align performance of the measure with the immunization timeframe of the FDA approved time for licensed flu vaccination. Furthermore, for the eCQM Specifications collection type we proposed to remove the denominator exceptions for medical/patient/system reasons since the ACIP guidelines specify only life-threatening allergic reactions to vaccination (that is, anaphylaxis) as a contraindication to vaccination. Therefore, these updates reflect the ACIP recommendations and support vaccination of patients with an allergy after careful evaluation of the patient by the clinician. We proposed to revise the numerator instructions for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types and the guidance for the eCQM Specifications collection type to remove the language for the LAIV formulation to align with current guidelines and will allow for the use of this formulation.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46790), we are finalizing the changes to measure Q110 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note that under Table CC.1, we are finalizing the partial removal of measure Q110 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

DD.2 Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	111
CMS eCQM ID:	CMS127v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 66 years of age and older at the start of the measurement period with a visit during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** denominator note. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for ESRD services, dialysis, patient counseling and/or risk factor reduction intervention services, preventive medicine, and home visit services. **Updated definitions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** definitions and coding for the added denominator exclusions: active chemotherapy, bone marrow transplant, and history of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks. **Updated denominator exclusions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** 1. Active chemotherapy during the measurement period. 2. Bone marrow transplant during the measurement period. 3. History of immunocompromising conditions prior to or during the measurement period. 4. Patent had anaphylaxis due to the pneumococcal vaccine any time during or before the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who received a pneumococcal vaccination on or after their 60th birthday and before the end of the measurement period. **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine on or after their 60th birthday and before the end of the measurement period. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** to allow for receipt of any pneumococcal vaccine. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** Documentation of medical reason(s) for not administering pneumococcal vaccine (for example, adverse reaction to vaccine).
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description as this will reflect that the measure is no longer assessing for any receipt of the pneumococcal vaccination. Additionally, we proposed to remove the denominator note from the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types as it no longer aligned fully with the revised timeframe for the administration of the pneumococcal vaccine. We proposed to revise the initial patient population for the eCQM Specifications collection type to change the age determination from the start of the measurement period to the end of the measurement period so that it aligns with the HEDIS measure requirements and creates consistency for implementation. We proposed to update the logic and logic definitions for the eCQM Specifications collection type related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion intent and criteria more closely. We also proposed to revise the numerator for the eCQM Specifications collection type to remove language pertaining to patients who had an adverse reaction to vaccines from the numerator, so the quality action more accurately reflects patients who received a pneumococcal vaccination. We proposed to update the denominator criteria for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to add coding to capture a more complete patient population as this patient population will be appropriate for the pneumococcal vaccination. We proposed to update the denominator exclusions for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to add denominator exclusions as this patient population will not be appropriate for the pneumococcal vaccination. We proposed to add definitions for these added denominator exclusions to outline the coding that will be sufficient to identify this patient population for consistency.

Category	Description
	Additionally, we proposed to revise the numerator and numerator note to allow for receipt of any pneumococcal vaccine in accordance with the current ACIP guidelines (https://www.cdc.gov/vaccines/acip/recommendations.html). We proposed to remove the numerator option allowing for documentation of medical reason(s) for not administering the vaccine and add a denominator exclusion for anaphylaxis from pneumococcal vaccine as this will better align with ACIP guidelines (https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (87 FR 46791 through 46792), we are finalizing the changes to measure Q111 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years. Note that under Table CC.2, we are finalizing the partial removal of measure Q111 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

TABLE Group E: Previously Finalized Web Interface Quality Measures with Substantive Changes Finalized for the CY 2023 Performance Period and Future Years

The E Tables within this final rule provide the substantive changes finalized for the Web Interface quality measures in CY 2023. The changes that are made to the code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within the final rule due to the availability of these changes to the public. The 2023 CMS Web Interface Measure Coding Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believed are important to communicate to interested parties. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2023 CMS Web Interface Measure Coding Release Notes once posted to review all coding changes.

The PY 2023 eCQM collection type measures had substantive changes that could prove burdensome to collect, therefore, the Web Interface specifications will align with the 2023 MIPS CQM changes for these measures. The CMS Web Interface collection type is only available for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP.

The tables below contain finalized changes for performance year 2023 Web Interface measure specifications to be used in the Shared Savings Program quality reporting.

E.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v11
Web Interface ID:	DM-2
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for nutrition and dietitian clinicians. **Updated guidance: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. **Revised to read**: To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to add encounter codes for nutrition and dietitian clinicians based upon interested parties' feedback, as they may provide nutrition counseling or therapy to patients to help manage diabetes. We proposed to update the guidance/numerator instructions to remove "Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included" because it does not align with the intent of the measure, which is to ensure hemoglobin A1c control in all patients with any diagnosis of diabetes. This update allows the measure to align with its clinical intent, in accordance with the given diabetes diagnosis codes within the denominator criteria of the measure. We proposed to revise the language for the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.
Comment: One commenter supported the proposed substantive changes to measure Q001. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46792), we are finalizing the substantive changes to measure Q001 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.2 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v12
Web Interface ID:	PREV-12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated definition: Added:** coding for manic episodes to the denominator exclusions definition for bipolar depression. **Updated measure numerator: Revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated guidance: Revised to read:** A depression screen is completed on the date of the encounter or up to 14 calendar days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two calendar days after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. An example to illustrate the follow-up plan documentation timing: if the encounter is on a Monday from 3-4 pm (day 0) and the patient screens positive, the clinician has through anytime on Wednesday (day 2) to complete follow-up plan documentation. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. This measure requires documentation that a screening was conducted with a standardized depression screening tool. It is recommended that **both** a score and clinician interpretation of the score is documented, especially when a patient screens positive. At a minimum, the medical record must contain documentation of the tool's name and results of the screening with a score **OR** clinician interpretation of positive or negative for depression. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. A score interpreted as positive requires documentation of a follow-up plan. A score interpreted as negative does not require a follow-up plan. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have been diagnosed with depression or bipolar disorder will be excluded from the measure. **Added:** Follow-Up Plan: For a depression screen deemed positive, the follow-up plan MUST still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician or provider's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure to add a grace period after the end of the encounter to document the follow-up plan, which will allow more flexibility in the clinical workflow giving clinicians time for documentation. This will ensure that those clinicians who meet the intent of the measure which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. We proposed to update the measure definition to improve alignment with measure intent which is to screen for new cases of depression in patients who have never had a diagnosis of depression or bipolar disorder, as well as to clarify the timing requirements of diagnoses for the measure exclusions. We proposed to add coding for manic episodes to the Bipolar Diagnosis codes to align with measure intent which is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator.
Comment: A few commenters supported the proposed substantive changes to measure Q134 and appreciated the ongoing efforts to further clarify the intent and specifications of this measure. The commenters supported the revisions to the guidance, particularly allowing follow-up documentation to occur up to 48 hours after the encounter. **Response:** We thank the commenters for supporting the changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46793), we are finalizing the substantive changes to measure Q134 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.3 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v11
Web Interface ID:	MH-1
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event.
Substantive Change:	**Updated denominator exclusion: Revised to read:** Patients with a diagnosis of bipolar disorder any time prior to the end of the measure assessment period Patients with a diagnosis of select personality disorders any time prior to the end of the measure assessment period Patients with a diagnosis of schizophrenia or psychotic disorder any time prior to the end of the measure assessment period Patients with a diagnosis of pervasive developmental disorder any time prior to the end of the measure assessment period Patients who were permanent nursing home residents any time during denominator identification period or the measure assessment period Patients with a diagnosis of personality disorder emotionally labile any time prior to the end of the measure assessment period **Updated denominator criteria: Added:** coding for preventive medicine encounters.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update coding for the denominator criteria to include preventive medicine encounters in order to engage patients and assess remission of depression. We proposed to add timing information to the denominator exclusions to improve measure clarity and to align with the CQM version of the measure.
Comment: One commenter supported the substantive changes to measure Q370. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46794), we are finalizing the substantive changes to measure Q370 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.4 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v11
Web Interface ID:	CARE-2
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Updated initial population: Revised to read:** Patients aged 65 years and older at the start of the measurement period with a visit during the measurement period. **Updated value set/coding: Added:** coding for physical therapy and occupational therapy visits.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it will align with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we proposed to add occupational and physical therapy evaluation visits as applicable encounters as these clinicians interact with older adults that may be more susceptible to falls. Occupational therapists are "uniquely qualified to address the multifactorial nature of falls, given their knowledge of factors that influence occupational performance."[1] There is a strong body of evidence that supports the role of physical therapists in reducing fall risk and fall prevention as outlined within the American Physical Therapy Association (APTA) handout: https://www.apta.org/patient-care/public-health-population-care/balance-and-falls/research-on-falls#.
Comment: One commenter supported the substantive changes to measure Q318. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46794), we are finalizing the substantive changes to measure Q318 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

[1] Peterson, E. W., & Clemson, L. (2008). Understanding the role of occupational therapy in fall prevention for community-dwelling older adults. OT Practice, 13(3), CE1–CE8. https://www.researchgate.net/publication/286974169_Understanding_the_role_of_occupational_therapy_in_fall_prevention_for_community-dwelling_older_adults.

E.5 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v6
Web Interface ID:	PREV-13
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**Updated initial population: Revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients with a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated denominator: Revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients with a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated submission guidance: Revised to read:** ○ Determine if the patient was previously diagnosed with or currently has a diagnosis of clinical ASCVD, including an ASCVD procedure at any time up through the last day of the measurement period **Removed:** **Active Diagnosis** is defined as a diagnosis that is either on the patient's problem list, a diagnosis code description listed on the encounter, or is documented in a progress note indicating that the patient is being treated or managed for the disease or condition at any time during the measurement period. **Updated denominator exclusion: Removed:** Patients who have a diagnosis of pregnancy at any time during the measurement period. **Updated definition: Added:** Ezetimibe / Rosuvastatin -- Roszet -- Fixed Dose Combination' to Table 1 - Statin Medication Therapy List. **Updated denominator exception: Added:** Patients with documentation of a medical reason for not being prescribed statin therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple sections to remove the word 'active' from the clinical diagnosis of ASCVD. ASCVD is a chronic condition, therefore a diagnosis of ASCVD at any time meets the intent of the initial population. We proposed to remove the pregnancy exclusion to align with U.S Food and Drug Administration (FDA) recommendations that pregnancy be removed as a contraindication in prescribing statins (https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol). We also proposed to update the definitions by adding another medication to the statin medication therapy list for completeness. We proposed to update the denominator exceptions by adding a medical reason for not being prescribed statin therapy to align with American College of Cardiology/American Heart Association (ACC/AHA) guidelines (https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2019/03/07/16/00/2019-acc-aha-guideline-on-primary-prevention-gl-prevention).

Comment: One commenter did not support the removal of pregnancy at any time during the measurement year as a denominator exclusion for measure Q438. The commenter stated that while pregnancy may no longer be considered an absolute contraindication to statin use, the strong indications for statin use in non-pregnant patients are not as clear and tempered by safety concerns in a pregnant patient. Therefore, the commenter stated that this remains a situation where clinical judgement and shared decision making will be the best course of action. The commenter stated that removing pregnancy as an exclusion from the measure may lead to unintended/unconscious bias in the recommendation for care in this situation where careful balance is imperative.

Response: We thank the commenter for their comment but disagree with the commenter. The update to measure aligns with the FDA's guidance that the benefits of statins may outweigh the risks for pregnant patients that are considered high-risk. We note that only patients that meet the denominator inclusion criteria would be eligible for this measure and don't anticipate the inclusion of pregnant people will result in a significant increase in the denominator population. Additionally, the denominator exceptions were updated to include patients with documentation of a medical reason for not being prescribed statin therapy, allowing for flexibility in situations where statins may not be considered appropriate for a patient or where the risk may outweigh the potential benefit of statin therapy.

Category	Description
After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46795), we are finalizing the substantive changes to measure Q438 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.6 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / N/A
Quality#:	110
CMS eCQM ID:	CMS147v12
Web Interface ID:	PREV-7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated measure reporting period: Revised:** Evaluates qualifying encounters that occur during either January through March of the measurement year or October through December of the measurement year to determine if that patient has received the influenza immunization for the relevant influenza season **Updated measure description: Revised to read:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization **Updated denominator: Revised to read:** Equals initial population (All patients aged 6 months and older seen for a visit during the measurement period) **Updated denominator note: Added:** For the purposes of the program, in order to submit on the flu season 2022-2023, the patient must have a qualifying encounter between January 1 and March 31, 2023. In order to submit on the flu season 2023-2024, the patient must have a qualifying encounter between October 1 and December 31, 2023. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period. **Updated measure guidance: Revised to read:** The numerator for this measure can be met by submitting either administration of an influenza vaccination or that the patient reported previous receipt of the current season's influenza immunization. If the performance of the numerator is not met, an eligible clinician can submit a valid denominator exception for having not administered an influenza vaccination. For eligible clinicians submitting a denominator exception for this measure, there should be a clear rationale and documented reason for not administering an influenza immunization if the patient did not indicate previous receipt, which could include a medical reason (for example, patient allergy), patient reason (for example, patient declined), or system reason (for example, vaccination not available). The system reason should be indicated only for cases of disruption or shortage of influenza vaccination supply. Denominator Exception(s) are determined at the time of the denominator eligible encounter during the current flu season. **Removed:** Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (for example, for patient preference) or a system reason (for example, the institution only carries LAIV). **Updated definition: Revised to read: Previous Receipt** – receipt of the current season's influenza immunization from another provider OR from same provider prior to the visit to which the measure is applied
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple sections of the measure to align with the CQM version of the measure. These changes allow for reporting receipt of influenza immunization for the two flu seasons that fall within a performance reporting period. Alignment with the CQM allows for reporting medical exceptions, and avoids eligible clinicians being penalized if not administering the influenza vaccine is medically and clinically appropriate. We proposed to revise the guidance to remove the language for the LAIV formulation to align with current guidelines and will allow for the use of this formulation.

Comment: One commenter did not support the update to the measure reporting period for measure Q110. This proposed change to the measure reporting period does not align with the 2023 eCQM measure. The 2023 performance period eCQM CMS147v12 (measure Q110) numerator statement reads: "Patients who received an influenza immunization OR reported previous receipt of an influenza vaccines between July 1 of the year prior to the measurement period to June 30 of the measurement period." Influenza vaccines usually arrive in nation-wide chain pharmacies in July of each year. Vaccines usually arrive on physician offices in late August or early September. Current CMS Web Interface measure specifications include vaccines administered OR previous receipt of a vaccine beginning in August of the prior year through March 31 of the measurement year. The 2023 MY HEDIS specifications are consistent with eCQM CMS147v12 (measure Q110).

Response: We thank the commenter for their comment and note that the measure was updated to align with the MIPS CQM collection type rather than the eCQM collection type. In doing so, the measure now captures two flu seasons and still allows for reporting of the influenza immunization or previous receipt. Encounters between January 1 and March 31, 2023, will be used to determine whether the influenza immunization was administered for the flu season ending March 31, 2023, including those that were administered during the months of August through December of 2022. Encounters between October 1, 2023, and December 31, 2023, will be used to determine whether the influenza immunization was administered for the flu season ending on March 31, 2024, including those that were administered during the months of August through December of 2023.

Category	Description
After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46796), we are finalizing the substantive changes to measure Q110 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.7 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v11
Web Interface ID:	PREV-5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated initial population: Revised to read:** Women 51 - 74 years of age on the date of the encounter with a visit during the measurement period. **Updated measure guidance: Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data
Comment: One commenter supported the substantive changes to measure Q112. The commenter stated the measure is silent on whether transgender women are included in the denominator and requested guidance. **Response:** We appreciate the commenters input, and will take it under consideration when determining strategies for ensuring inclusion and appropriate clinical care for all patient populations in this measure; however, we recommend using patient sex assigned at birth for purposes of reporting this quality measure. At this time, we recommend following the specification as written and include only those patients who meet the denominator criteria as stated for each component of the posted quality measure. The medical record should substantiate all data submitted. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46797), we are finalizing the substantive changes to measure Q112 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

E.8 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v11
Web Interface:	PREV-6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer **Updated initial population: Revised to read:** Patients 45 to 75 years with a visit during the measurement period **Updated measure guidance: Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure description and initial population to align with the 2021 U.S. Preventive Services Task Force (USPSTF) guidelines that recommend Colorectal Cancer Screenings begin at age 45 rather than beginning at age 50. We proposed to revise the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.

Comment: One commenter supported the substantive changes to measure Q113.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46797), we are finalizing the substantive changes to measure Q113 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

E.9 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v11
Web Interface ID:	PREV-10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **Updated denominator exception: Removed:** denominator exceptions. **Updated numerator: Revised to read:** For Submission Criteria 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. For Submission Criteria 3: Patients who were screened for tobacco use at least once during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated measure definition: Revised to read:** Tobacco Use – use of any tobacco product The 2021 USPSTF recommendation references the US Food and Drug Administration definition of tobacco which includes "any product made or derived from tobacco intended for human consumption (except products that meet the definition of drugs), including, but not limited to, cigarettes, cigars (including cigarillos and little cigars), dissolvables, hookah tobacco, nicotine gels, pipe tobacco, roll-your-own tobacco, smokeless tobacco products (including dip, snuff, snus, and chewing tobacco), vapes, electronic cigarettes (e-cigarettes), hookah pens, and other electronic nicotine delivery systems." The 2021 USPSTF recommendation describes smoking as generally referring to "the inhaling and exhaling of smoke produced by combustible tobacco products such as cigarettes, cigars, and pipes." The 2021 USPSTF recommendation describes vaping as "the inhaling and exhaling of aerosols produced by e-cigarettes." In addition, it states, "vaping products (that is, e-cigarettes) usually contain nicotine, which is the addictive ingredient in tobacco. Substances other than tobacco can also be used to smoke or vape. While the 2015 USPSTF recommendation statement used the term 'electronic nicotine delivery systems' or 'ENDS,' the USPSTF recognizes that the field has shifted to using the term 'e-cigarettes' (or 'e-cigs') and uses the term e-cigarettes in the current recommendation statement. E-Cigarettes can come in many shapes and sizes, but generally they heat a liquid that contains nicotine (the addictive drug in tobacco) to produce an aerosol (or 'vapor') that is inhaled ('vaped') by users." Tobacco Cessation Intervention – Includes brief counseling (3 minutes or less), and/or pharmacotherapy – Note: Concepts aligned with brief counseling (for example, minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the 2023 CMS Web Interface PREV-10 Coding Document for the numerator. Other concepts such as written self-help materials (for example., brochures, pamphlets) and complementary/alternative therapies are not included in the 2023 CMS Web Interface PREV-10 Coding Document and do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **Updated guidance: Revised to read:** The requirement of two or more visits is to establish that the eligible clinician has an existing relationship with the patient for certain types of encounters. To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the measurement period. If a patient has multiple tobacco use screenings during the measurement period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. If a patient uses any type of tobacco (that is, smokes or uses smokeless tobacco), the expectation is that they should receive tobacco cessation intervention: either counseling and/or pharmacotherapy. As noted in Appendix III in the 2021 USPSTF recommendation statement, the current evidence is insufficient to recommend electronic cigarettes (e-cigarettes) for tobacco cessation.

Category	Description
	However, as noted above in the Definition section, the 2021 USPSTF recommendation also references the US Food and Drug Administration definition of tobacco, which includes e-cigarettes, hookah pens and other electronic nicotine delivery systems. Therefore, the measure does consider the use of e-cigarettes and other electronic nicotine delivery systems to be tobacco use. If a patient's tobacco use status is unknown, the patient does not meet the screening requirement and does not meet the numerator for populations 1 or 3. Instances where tobacco use status of "unknown" include: 1) the patient was not screened; or 2) the patient was screened and the patient (or caregiver) was unable to provide a definitive answer. In order to promote a team-based approach to patient care, the tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. This measure contains three reporting rates which aim to identify patients who were screened for tobacco use (rate/population 1), patients who were identified as tobacco users and who received a tobacco cessation intervention (rate/population 2), and a comprehensive look at the overall performance on tobacco screening and cessation intervention (rate/population 3). By separating this measure into various reporting rates, the eligible clinician will be able to better ascertain where gaps in performance exist, and identify opportunities for improvement. The overall rate (rate/population 3) can be utilized to compare performance to published versions of this measure prior to the 2018 performance year, when the measure had a single performance rate. For accountability reporting in the CMS Medicare Shared Savings Program, the rate for population 2 is used for performance. The denominator of population criteria 2 is a subset of the resulting numerator for population criteria 1, as population criteria 2 is limited to assessing if patients identified as tobacco users received an appropriate tobacco cessation intervention. For all patients, population criteria 1 and 3 are applicable, but population criteria 2 will only be applicable for those patients who are identified as tobacco users. Therefore, data for every patient that meets the initial population criteria will only be submitted for population 1 and 3, whereas data submitted for population 2 will be for a subset of patients who meet the initial population criteria, as the denominator has been further limited to those who were identified as tobacco users. **Updated denominator criteria: Added:** coding for registered dietitians and nutritionists.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure to better define and align the lookback period for tobacco cessation intervention and to allow a lookback of 6-months prior to the current measurement period. We proposed to update the denominator statement for Population 2 to clarify the timing of the screening for tobacco cessation intervention. We proposed to update the denominator criteria to include encounter codes for registered dieticians and nutritionists to allow them to screen for tobacco use as part of a comprehensive patient assessment. Additionally, we proposed to remove all denominator exceptions. The measure definition is also being updated to align with 2021 USPSTF recommendations.

Comment: One commenter supported the substantive changes to measure Q226.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46798 through 46799), we are finalizing the substantive changes to measure Q226 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

E.10 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v11
Web Interface ID:	HTN-2
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated guidance: Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance. **Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to revise the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This will reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and will allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This will help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We proposed to add language to ensure that only distinct numeric results are being utilized for the purpose of this measure as ranges and thresholds do not meet the measure's intent.
Comment: One commenter supported the substantive changes to measure Q236 with one exception; the commenter recommended that CMS consider including blood pressure readings documented as average in the measure specifications to ensure alignment with 2023 MY HEDIS measure which is used for patients with Medicaid, Commercial and Medicare Advantage insurance coverage. **Response:** We thank the commenter for supporting the changes to this measure and encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (87 FR 46799), we are finalizing the substantive changes to measure Q236 as proposed for the CY 2023 performance period/2025 MIPS payment year and future years.	

APPENDIX 2: IMPROVEMENT ACTIVITIES

NOTE: In this final rule, for the CY 2023 performance period/2025 MIPS payment year and future years, we proposed to add four new improvement activities, modify five previously adopted improvement activities, and remove six previously adopted improvement activities. These proposals are discussed in detail below. We solicited comments on our proposals.

Table A: New Improvement Activities for the CY 2023 Performance Period/2025 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data
Proposed Activity Description:	Use security labeling services available in certified Health Information Technology (HIT) for electronic health record (EHR) data to facilitate data segmentation.
Proposed Weighting:	Medium
Rationale:	Data segmentation capabilities are used to promote interoperability while preserving confidentiality, honoring consent, and respecting patient privacy preferences. This new activity will promote the adoption of technology certified to the Security tags - summary of care send and Security tags – summary of care – receive criteria at 45 CFR 170.315(b)(7) and (b)(8) in the ONC Health IT Certification Program.[1] Security tagging allows sharing of certain portions of an EHR while not sharing others, such as sensitive information related to substance use disorder treatment. This activity will involve

	clinicians working with their EHR vendors to implement technology meeting the security tags criteria at 45 CFR 170.315 (b)(7) and (b)(8) in practice systems and clinic workflows, and in so doing improving interoperability while protecting patient privacy. Health IT certified to these criteria is not required for participation in the Promoting Interoperability performance category. This improvement activity fills a gap in the Inventory, as there is no existing improvement activity that focuses on security labeling services and/or data segmentation. We proposed weighting this activity medium because this activity may be accomplished by working with clinicians' EHR vendors to implement security tags criteria at 45 CFR 170.315 (b)(7) and (b)(8) in practice systems and clinic workflows. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the Inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	We received many comments in support of the proposed new improvement activities' focus on health equity, and we received several comments in support of this particular proposed new activity as helpful in advancing interoperability while protecting patient data. One commenter had suggestions about implementation of this activity, including encouraging the tagging of "data at the entry level in order to truly advance this work to the next stage."
Response:	We appreciate commenters' support and suggestions. However, we are not adding language regarding the specifics on tagging of data for this activity as we believe it would be communicated best in subregulatory guidance. We have added some minor clarifying language to the activity description in response to a comment from ONC, suggesting that we direct eligible clinicians to the certification criteria in the CFR.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_10**
Subcategory:	Achieving Health Equity
Activity Title:	Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data
Activity Description:	Use security labeling services available in certified Health Information Technology (IT) for electronic health record (EHR) data to facilitate data segmentation. Certification criteria for security tags may be found in the ONC Health IT Certification Program at 45 CFR 170.315(b)(7) and (b)(8).
Weighting:	Medium
New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
Proposed Activity Description:	Create and implement a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population. The plan may include an analysis of sexual orientation and gender identity (SO/GI) data to identify disparities in care for LGBTQ+ patients. Actions to implement this activity may also include identifying focused goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and the Office of the National Coordinator for Health Information Technology [2] US Core Data for Interoperability [USCDI]), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories.
Proposed Weighting:	High

Rationale:	LGBTQ+ individuals face health disparities and challenges navigating and accessing healthcare.[3, 4] Due to lack of clinician training about providing care with cultural humility and sensitivity for LGBTQ+ individuals, several studies indicate that LGBTQ+ patients, especially gender minority patients, have high rates of negative healthcare experiences.[5-7] Compared with heterosexual individuals, LGBTQ+ individuals in the U.S. generally have lower life expectancies, higher rates of cardiovascular disease, gynecologic cancer, breast cancer, body issues and eating disorders, substance use, and mental health conditions, including anxiety, depression, suicidal ideation, and non-suicidal self-injury.[3, 8] In 2015, ONC issued a final rule requiring that certified health IT enable a user to record sexual orientation and gender identity (SO/GI), but users were not required to exchange these data (45 CFR Parts 170 and 171).[9] In the first year after implementation, sexual orientation data were missing for 75% of patients and gender identity data were missing for 65% of patients.[10] Clinicians have increasing opportunities to improve data collection, as adoption of the USCDI Version 2 within certified health IT will offer improved support for the exchange of SO/GI data elements. Increasing patients' and clinicians' comfort with and knowledge about SO/GI data collection can also improve data collection.[3, 11] This improvement activity will fill a gap in the Inventory, which does not currently include an activity focused on improving care for LGBTQ+ patients. We believe this activity has the potential to improve clinical practice and care delivery because training clinicians about serving LGBTQ+ patients can lead to more positive care experiences.[6, 12] Understanding disparities in care access, screenings, and health outcomes and implementing a plan to address identified health disparities can improve the care LGBTQ+ patients receive.[11, 13] We proposed weighting this activity high because clinicians will need considerable time and resources to develop a thorough LGBTQ+ care improvement plan that is informed by data, and to implement it throughout the practice or system. See the definition of high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments	We received approximately 40 comments in general support of this proposed new activity (not including general expressions of support for the health equity focus of proposed Inventory changes) and no comments recommending against the inclusion of this activity. One commenter suggested that this activity should include a requirement for follow-up with the patient.
Response	We appreciate commenters' support. We understand the commenter's suggestion that ideally patient follow-up would be required as a next step for this activity; however, as this activity launches, we believe that patient follow-up need not be essential to the creation and implementation of a successful plan. We encourage the commenter to submit a proposed modification to this activity in the next Call for Improvement Activities cycle.
Final Action	After consideration of the public comments, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_11**
Subcategory:	Achieving Health Equity
Activity Title:	Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
Activity Description:	Create and implement a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population. The plan may include an analysis of sexual orientation and gender identity (SO/GI) data to identify disparities in care for LGBTQ+ patients. Actions to implement this activity may also include identifying focused goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and the Office of the National Coordinator for Health Information Technology [2] US Core Data for Interoperability [USCDI]), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with

	patients, and/or utilizing anatomical inventories when documenting patient health histories.
Weighting:	High
New Improvement Activity	
Proposed Activity ID:	**IA_EPA_XX**
Proposed Subcategory:	Expanded Practice Access
Proposed Activity Title:	Create and Implement a Language Access Plan
Proposed Activity Description:	Create and implement a language access plan to address communication barriers for individuals with limited English proficiency. The language access plan must align with standards for communication and language assistance defined in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (https://thinkculturalhealth.hhs.gov/clas).
Proposed Weighting:	High
Rationale:	We believe the evidence is clear that accurate patient-clinician communication, delivered and received with cultural humility, is an essential aspect of improving equity in healthcare and patient outcomes.[14, 15] According to the 2020 U.S. Census, 8.3 percent of American households speak English "less than very well" and are thus said to be limited English-proficient (LEP). [16] "The ability to communicate with a healthcare clinician can mean the difference between receiving higher or lower quality care."[14] The use of properly trained medical interpreters is superior to use of ad hoc, family, or no interpreters.[17] Use of professional interpreter services improves patient and clinician satisfaction with communication[18] and improves patient safety.[19] A language access plan can help clinician organizations codify the process that will be used to provide services to individuals with limited English proficiency. A language access plan typically contains information on beneficiary needs, defines how interpretation will be provided, outlines how patients and families will be notified about interpretation services, and specifies staff training.[20] The plan may include policies and procedures regarding the use of professional interpreters, high-quality translation of patient materials, and collection of patients' language preference. The plan may also include details on communication with individuals who are deaf, hard of hearing, and deaf-blind.[21] The National CLAS Standards include four standards on communication and language assistance that stipulate: language assistance should be timely and offered at no cost; patients should be informed that language assistance is available; competent individuals provide translation and interpretation services; and materials and signage are printed in commonly used languages.[22, 23] This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on language access. We believe this activity has the potential to improve clinical practice and care delivery and is likely to result in improved patient outcomes, because research demonstrates the importance of accurate clinical communication in achieving positive patient outcomes.[14, 15] We proposed making this activity high-weighted because clinicians will need considerable time and resources to develop a thorough language access plan that is informed by data, and to implement it throughout the practice or system. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments	We received some comments in support of this proposed new activity, agreeing that use of the CLAS standards can help improve patient-provider communication and thus improve the quality of care provided and also help make progress in advancing health equity. One commenter suggested that this activity should include a requirement for follow-up with the patient.
Response	We appreciate commenters' support. We understand the commenter's suggestion that ideally patient follow-up would be required as a next step for this activity. We

	encourage the submission of proposed modifications to this activity in the next Call for Improvement Activities cycle.
Final Action	After consideration of the public comments, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_EPA_6**
Subcategory:	Expanded Practice Access
Activity Title:	Create and Implement a Language Access Plan
Activity Description:	Create and implement a language access plan to address communication barriers for individuals with limited English proficiency. The language access plan must align with standards for communication and language assistance defined in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (https://thinkculturalhealth.hhs.gov/clas).
Weighting:	High
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_XX**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	COVID-19 Vaccine Achievement for Practice Staff
Proposed Activity Description:	Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100% of office staff in the MIPS eligible clinician's practice fully COVID-19 vaccinated according to the Center for Disease Control and Prevention's definition of fully vaccinated (Stay Up to Date with COVID-19 Vaccines Including Boosters | CDC).
Proposed Weighting:	Medium
Rationale:	COVID-19 vaccination rates in the U.S. can be improved significantly, particularly in communities that are disadvantaged and/or underserved by the healthcare system.[24] Disparities in COVID-19 vaccination rates have been observed specifically among healthcare workers, with physicians and advanced practiced staff being more likely to be vaccinated than nurses and support staff. Also, it has been reported that Black and younger health care workers have lower vaccination rates than other groups of healthcare workers.[25] We are recommending this new improvement activity be focused on achieving or maintaining 100% COVID-19 vaccination for practice staff. This improvement activity will fill a gap in the Inventory, which does not currently include an activity focused on COVID-19 vaccination achievement. We believe this activity has the potential to improve clinical practice and is likely to result in improved outcomes and public health, because research demonstrates the importance of vaccination in reducing the severity and spread of COVID-19.[26] We proposed weighting this activity medium, because this activity may be accomplished by vaccinating all staff members and tracking the vaccination status of each office staff member in practice staff records. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the Inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments	While we received many comments in support of all the proposed new improvement activities overall, some commenters raised questions regarding the phrase 'fully vaccinated' and regarding exceptions/vaccine eligibility, including suggesting "that there be an exclusion for staff that have a medical contraindication to vaccination." We also received comments in support of this activity specifically.
Response	We appreciate commenters' support and suggestions. We acknowledge that the activity description as proposed could be confusing. We are clarifying here that, when we proposed this improvement activity, we included a link to the CDC's description of fully vaccinated with the intent to stay aligned. That website stated at the time of our

	proposal, "You are up to date with your COVID-19 vaccines when you have received all doses in the primary series and all boosters recommended for you."[578] As of September 8, 2022, it was updated to state, "You are up to date with your COVID-19 vaccines if you have completed a COVID-19 vaccine primary series and received the most recent booster dose recommended for you by CDC."[579] Additionally, we intended for this improvement activity to be consistent across CMS programs and CDC guidance. Thus, we are clarifying that the proposed language "100% of office staff in the MIPS eligible clinician's practice" means "100% of staff in the MIPs eligible clinician's practice, consistent with CDC clinical considerations," which are summarized here: https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf. Based on the CDC guidance, contraindications currently include a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine • A known diagnosed allergy to a component of the COVID-19 vaccine • For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized or approved in the United States that are based on adenovirus vectors, e.g., AstraZeneca) Therefore, any individual with clinical contraindications should be excluded from this improvement activity. Accordingly, based on comments, we are finalizing a modified version of the activity description to more clearly convey the above. The modified activity description states: Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100% of office staff in the MIPS eligible clinician's practice staying up-to-date with COVID-19 vaccinations in accordance with the Center for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html). Please note that those who are determined to have a medical contraindication specified by CDC recommendations are excluded from this activity.
Final Action	After consideration of the public comments, we are finalizing this activity with modifications as discussed above.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_6**
Subcategory:	Emergency Response and Preparedness
Activity Title:	COVID-19 Vaccine Achievement for Practice Staff
Activity Description:	Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100% of office staff staying up to date with COVID vaccines according to the Center for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html). Please note that those who are determined to have a medical contraindication specified by CDC recommendations are excluded from this activity.
Weighting:	Medium

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Table B: Changes to Previously Adopted Improvement Activities for the CY 2023 Performance Period/2025 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_CC_13**
Current Subcategory:	Care Coordination
Current Activity Title:	Practice Improvements for Bilateral Exchange of Patient Information
Current Activity Description:	Ensure that there is bilateral exchange of necessary patient information to guide patient care, such as OpenNotes, that could include one or more of the following: • Participate in a Health Information Exchange if available; and/or • Use structured referral notes.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 performance period/2019 MIPS payment year (81 FR 77817 through 77830). We propose updating this activity to require the use of OpenNotes to reduce clinician burden because OpenNotes focuses on principles that support direct access to medical records rather than utilizing a specific software or product. OpenNotes aligns with relevant policies described in the 21st Century Cures Act (Pub. L. 114–255) that aim to make direct access to medical records a best practice in the field. Updating this activity to require the use of OpenNotes will reflect advances in policy and practice, particularly regarding the importance of direct patient-clinician communication and ensuring that patients are at the center of their care.
Proposed Revised Activity Title:	Practice Improvements to Align with OpenNotes Principles
Proposed Revised Activity Description:	Adherence to the principles described in the OpenNotes initiative (https://www.opennotes.org) to ensure that patients have full access to their patient information to guide patient care.
Comments:	One commenter asked that an alternative to OpenNotes software be considered but did not make concrete, actionable, or additional suggestions.
Response:	To clarify, OpenNotes is not software; it is an initiative requiring adherence to principles to ensure that patients have full access to their patient information. There is no specific vendor or software for OpenNotes, so practices may choose how to implement OpenNotes concepts. Under the 21st Century Cures Act, all health systems in the United States must be sharing open notes with patients since April 15, 2021, and with third-party applications by October 6, 2022. All EHR vendors that also offer secure online patient portals must make it technically possible for patients to access their notes through electronic "asks." Even before the Information Blocking rule went into effect, most major EHR vendors

	(e.g., Allscripts, Cerner, Epic, and Meditech) enabled sharing clinical notes through patient portals at no additional cost.
Final Action:	After consideration of public comments, we are finalizing this proposed modification as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_13**
Subcategory:	Care Coordination
Activity Title:	Practice Improvements to Align with OpenNotes Principles
Activity Description:	Adherence to the principles described in the OpenNotes initiative (https://www.opennotes.org) to ensure that patients have full access to their patient information to guide patient care.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	IA_CC_14
Current Subcategory:	Care Coordination
Current Activity Title:	Practice improvements that engage community resources to support patient health goals
Current Activity Description:	Select and screen for the health-related social needs (HRSN) that are relevant for your patient population using tools that have been tested with underserved populations. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded question/field for the capture of data. After screening, address HRSNs identified through at least one of the following: • Maintain formal relationships with community- based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Update a guide to available community resources, or work with community partners to provide a community resource guide and provide it to patients who are found to be at risk in one or more HRSN area; or • Record findings of screening and trigger follow-up within the electronic health record (EHR); then analyze EHR data on patients with one or more HRSN needed to identify and implement approaches to better serve their holistic needs through linkages with community resources. HRSNs prioritized by your practice might include health-harming legal needs, which require both health and legal support to resolve, areas such as food and housing insecurity, or needs such as exercise, nutrition, or chronic disease self-management.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 performance period/2019 MIPS payment year (81 FR 77817 through 77830). We are proposing to modify the activity title and description to refer to 'drivers of health,' which encompasses both 'social determinants of health (SDOH)' and 'health-related social needs (HSRN)' concepts. Drivers of health are the multitude of factors that impact each other and overall human health, which often include health behavior, social and economic environment, clinical care, and physical environment.[1] Drivers of health may be direct, such as health behaviors or access to health care, or indirect, such as income, education, or occupation, which may not necessarily impact health in an immediate way.[2, 3] They may also be at the individual or community level.[4] We also proposed to update the list of factors in the activity description to reflect a more comprehensive array of the drivers of health that align with related activities across CMS and HHS by removing "or needs such as exercise, nutrition, or chronic disease self-management" and replacing it with "transportation accessibility; interpersonal safety; legal challenges; and environmental exposures."[1-3] We added language prior to this list noting drivers of health "are not limited" to those in the description, as eligible clinicians can select other drivers of health. We are also proposing to update the activity ID and subcategory to Achieving Health Equity (AHE) due to the connection between drivers of health, health equity, and improved health outcomes.[5, 6] We believe the proposed modifications will better enable eligible clinicians to not only improve clinical

	practice by screening for and addressing drivers of health, but to also receive credit for their efforts.[4] Furthermore, we anticipate such efforts will be associated with improved clinical outcomes because of the recognized impact of drivers of health and other upstream factors on both healthcare and health status.[5-8] Finally, these proposed modifications will also more clearly align this activity with the evidence base described above[1-6] and other CMS work in this area, including the CMS Innovation Center's Accountable Health Communities (AHC) Model, designed to test how "addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs."[7]
Proposed Revised Activity ID:	IA_AHE_XX
Proposed Revised Activity Subcategory:	Achieving Health Equity
Proposed Revised Activity Title:	Practice Improvements that Engage Community Resources to Address Drivers of Health
Proposed Revised Activity Description:	Select and screen for drivers of health that are relevant for the eligible clinician's population using evidence-based tools. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded questions/fields for the capture of data. After screening, address identified drivers of health through at least one of the following: • Develop and maintain formal relationships with community-based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Work with community partners to provide and/or update a community resource guide for to patients who are found to have and/or be at risk in one or more areas of drivers of health; or • Record findings of screening and follow up within the electronic health record (EHR); identify screened patients with one or more needs associated with drivers of health and implement approaches to better serve their holistic needs through meaningful linkages to community resources. Drivers of health (also referred to as social determinants of health [SDOH] or health-related social needs [HSRN]) prioritized by the practice might include, but are not limited to, the following: food security; housing stability; transportation accessibility; interpersonal safety; legal challenges; and environmental exposures.
Comments:	One commenter objected to this modification, seeing it as a 'narrowing' of the scope of this activity, and stated that removing emphasis on care coordination in favor of one aspect of care coordination may limit clinician use of this improvement activity.
Response:	We disagree with this commenter, as we do not believe these modifications 'narrow' this activity. On the contrary, we believe that the modifications broaden the activity. 'Drivers of health' encompasses both 'social determinants of health (SDOH)' and 'health-related social needs (HSRN)' concepts. As discussed in our proposal, drivers of health are the multitude of factors that impact each other and overall human health, which often include health behavior, social and economic environment, clinical care, and physical environment.[1] Drivers of health may be direct, such as health behaviors or access to health care, or indirect, such as income, education, or occupation, which may not necessarily impact health in an immediate way.[2, 3] They may also be at the individual or community level.[4] Also, as proposed, we updated the list of factors in the activity description to both be more comprehensive and to align with related activities across CMS and HHS. We proposed to remove "or needs such as exercise, nutrition, or chronic disease self-management" and replace it with "transportation accessibility; interpersonal safety; legal challenges; and environmental exposures."[1-3] We also proposed to add language prior to this list noting drivers of health "are not limited" to those in the description, as eligible clinicians can select other drivers of health. We expect these to better enable eligible clinicians to not only improve clinical practice by screening for and addressing drivers of health, but to also receive credit for these improvements.

Final Action:	After consideration of public comments, we are finalizing this proposed modification as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_12**
Subcategory:	Achieving Health Equity
Activity Title:	Practice Improvements that Engage Community Resources to Address Drivers of Health
Activity Description:	Select and screen for drivers of health that are relevant for the eligible clinician's population using evidence-based tools. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded questions/fields for the capture of data. After screening, address identified drivers of health through at least one of the following: • Develop and maintain formal relationships with community-based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Work with community partners to provide and/or update a community resource guide for to patients who are found to have and/or be at risk in one or more areas of drivers of health; or • Record findings of screening and follow up within the electronic health record (EHR); identify screened patients with one or more needs associated with drivers of health and implement approaches to better serve their holistic needs through meaningful linkages to community resources. Drivers of health (also referred to as social determinants of health [SDOH] or health-related social needs [HSRN]) prioritized by the practice might include, but are not limited to, the following: food security; housing stability; transportation accessibility; interpersonal safety; legal challenges; and environmental exposures.
Weighting	High
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment); • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed to consolidate IA_BE_7, IA_BE_8, and IA_PM_7 related to participation in a QCDR into a single activity, IA_PSPA_7. We note that this proposed modification is being made in conjunction with our proposals to remove IA_BE_7, IA_BE_8, and IA_PM_7 in Table C. This consolidation will reduce clinician burden by streamlining the choice for a QCDR activity and make IA_PSPA_7 more robust and offer additional examples. We believe this will help to enhance patient engagement, learning and practice improvement, progress in improving health equity, and population health management by creating standard processes to monitor, assess, and improve practice activities. We believe these proposed modifications have the potential to improve clinical practice and are likely to result in improved outcomes, because they focus on

	creating ongoing activities aimed at identifying gaps and improving processes to support patient safety and equitable provision of care. Note that the weighting of the consolidated activity will remain as medium, because the level of effort to attest to this activity will be the same as for IA_PSPA_7. See the definition for medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools, and processes for quality improvement (for example, documented preventive health efforts, like screening and vaccinations) that can be shared across MIPS eligible clinicians or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment); • Use of standardized processes for screening for drivers of health, such as food security, housing stability, and transportation accessibility; • Generation and use of regular feedback reports that summarize local practice patterns and treatment outcomes, including for populations that are disadvantaged and/or underserved by the healthcare system; • Use of processes and tools that engage patients to improve adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision-making capabilities; • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; • Promotion of collaborative learning network opportunities that are interactive; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement, such as comparative analysis across specific patient populations of adverse outcomes after an outpatient surgical procedure and corrective steps to address these outcomes.
Comments:	We received several comments in support of activity consolidation; we received two comments opposing the QCDR activity consolidation with the suggestion that, if the consolidation proceeds, the consolidated improvement activity, IA_PSPA_7, should be changed to a high-weighted activity.
Response:	We appreciate the commenters' input. However, we have carefully reviewed the Inventory and continue to believe that this activity should remain medium-weighted because the activity burden remains the same; no additional requirements have been added. The bulleted list included in the description includes some examples; eligible clinicians may choose one element in the description. They are not all required. To help make this point clearer, we are making a formatting change in the activity description (changing the 'or' to 'OR'), so that eligible clinicians can more easily see that the listed ways in which this activity can be implemented are not all required.
Final Action:	After consideration of public comments, we are finalizing this proposed modification as proposed with the exception of one formatting change to the activity description (changing the 'or' to 'OR').
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_7**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools, and processes for quality improvement (for example, documented preventive health efforts, like screening and vaccinations) that can be shared across MIPS eligible clinicians or groups);

	• Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment); • Use of standardized processes for screening for drivers of health, such as food security, housing stability, and transportation accessibility; • Generation and use of regular feedback reports that summarize local practice patterns and treatment outcomes, including for populations that are disadvantaged and/or underserved by the healthcare system; • Use of processes and tools that engage patients to improve adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision-making capabilities; • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; • Promotion of collaborative learning network opportunities that are interactive; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; OR • Use of QCDR data for quality improvement, such as comparative analysis across specific patient populations of adverse outcomes after an outpatient surgical procedure and corrective steps to address these outcomes.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_10**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of training and receipt of approved waiver for provision opioid medication-assisted treatments
Current Activity Description:	Completion of training and obtaining an approved waiver for provision of medication - assisted treatment of opioid use disorders using buprenorphine.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 performance period/2019 MIPS payment year (81 FR 77817 through 77830). We are proposing to modify this improvement activity to incorporate HHS Office of the Secretary Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (86 FR 22439) updates that removed the 8-hour training requirement for physicians.[9] We are also proposing to add a note limiting the attestation of this improvement activity to once for low-capacity waivers because they never expire and once every 3 years for the expanded waiver. These limitations are in line with the renewal requirements of the waiver (86 FR 22439) and ensure clinicians are able to perform the improvement activity for a 90-day continuous period as required by 42 CFR 414.1360. In addition, we proposed to re-categorize this activity to the Behavioral and Mental Health subcategory, which we believe better reflects the intent of this improvement activity, because it is focused on improving treatment for opioid use disorder, a behavioral and mental health condition. We believe the proposed modifications to this activity have the potential to improve clinical practice and are likely to result in improved outcomes, because it will reduce clinician burden by streamlining the activity to align with federal guidance and ensure that patients are receiving medication-assisted treatment in line with medical guidelines.
Proposed Activity ID	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Revised Activity Title	Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder
Proposed Revised Activity Description:	Complete any required training and obtain or renew an approved waiver for provision of medication-assisted treatment of opioid use disorders using buprenorphine. Note: This activity may be selected once for low-capacity waivers, as these do not expire, and once every 3 years for the expanded waiver, in keeping with renewal requirements.

	• Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence; • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Comments:	We received several comments in support of activity consolidation. But we received two comments opposing the removal of PSPA_20: "Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes." These commenters noted that Inventory changes are burdensome and one commenter stated that the leadership concept here is important enough to warrant a separate activity.
Response:	We believe that the burden reduction accomplished by keeping the Inventory as streamlined as possible outweighs commenters' concerns raised. We received comments in this rulemaking cycle that reflect a desire to see the Inventory consolidated and simplified. This proposal was made in direct response to those comments.
Final Action:	After consideration of the public comments, we are finalizing our proposed modifications as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_19**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff, including leadership, actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence; • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Weighting:	Medium

[1] Melton, C. (2018). *The drivers of health*. https://www.sycamoreinstitutetn.org/drivers-of-health/#:~:text=Our%20social%20and%20economic%20environments,greatest%20predictors%20of%20their%20health.

[2] Drivers of Health. (2022). *The framework*. https://driversofhealth.org/the-framework/

[3] Raphael, K., Frakt, A., Jha, A., & Glied, S. (2019). *Social and health-systems factors that affect health: What's known and knowable? A review of literature*. https://driversofhealth.org/wp-content/uploads/SDH.whitepaper_v8.pdf

[4] Lumpkin, J. R., Perla, R., Onie, R., & Seligson, R. (2021). *What we need to be healthy—and how to talk about it*. https://www.healthaffairs.org/do/10.1377/forefront.20210429.335599/full/

[5] Gómez, C. A., Kleinman, D. V., Pronk, N., Wrenn Gordon, G. L., Ochiai, E., Blakey, C., Johnson, A., & Brewer, K. H. (2021). Addressing health equity and social determinants of health through healthy people 2030. *Journal of Public Health Management and Practice*, *27*, S249-S257. https://doi.org/10.1097/phh.0000000000001297

[6] Artiga, S., & Hinton, E. (2018). *Beyond health care: The role of social determinants in promoting health and health equity*. https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/

[7] Centers for Medicare & Medicaid Services. (2022). *Accountable health communities (ach) model*. https://innovation.cms.gov/innovation-models/ahcm

[8] Thornton, R. L., Glover, C. M., Cené, C. W., Glik, D. C., Henderson, J. A., & Williams, D. R. (2016). Evaluating strategies for reducing health disparities by addressing the social determinants of health. *Health Affairs*, *35*(8), 1416-1423. https://doi.org/10.1377/hlthaff.2015.1357

[9] Cleary, E. M., Smid, M. C., Charles, J. E., Jones, K. M., Costantine, M. M., Saade, G., & Rood, K. M. (2021). Buprenorphine x-waiver exemption - beyond the basics for the obstetrical provider. *American Journal of Obstetrics and Gynecology*, *3*(6), 100451. https://doi.org/10.1016/j.ajogmf.2021.100451

TABLE C: Improvement Activities Proposed for Removal for the CY 2023 Performance Period/2025 MIPS Payment Year and for Future Years

In this rule, we proposed to remove six previously finalized improvement activities from the CY 2023 performance period/2025 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision-making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_BE_7 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we proposed to add "Use of processes and tools that engage patients for adherence to treatment plans; Implementation of patient self-action plans; Implementation of shared clinical decision-making capabilities; Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_BE_7. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_8 and IA_PM_7 in Table C.
Comments:	We received several comments in support of activity consolidation; we received two comments opposing the QCDR activity consolidation as generally burdensome, with the suggestion that, if the consolidation proceeds, IA_PSPA_7 should be changed to a high-weighted activity.
Response:	We appreciate the commenters' input. However, we have carefully reviewed the Inventory and continue to believe that this activity should remain medium-weighted because the activity burden remains the same; no additional requirements have been added. The bulleted list included in the description includes some examples; eligible clinicians may choose one element in the description. They are not all required. To help make this point clearer, we are making a formatting change in the activity description (changing the 'or' to 'OR'), so that eligible clinicians can more easily see that the listed ways in which this activity can be implemented are not all required.
Final Action:	After consideration of public comments, we are finalizing this removal as proposed, making one formatting change to the IA_PSPA_7 activity description.
Current Improvement Activity	
Current Activity ID:	**IA_BE_8**
Current Subcategory:	Beneficiary Engagement

Current Activity Title:	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
Current Activity Description:	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_BE_8 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we are proposing to modify IA_PSPA_7 to add "promotion of collaborative learning network opportunities that are interactive" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_BE_8. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_7 and IA_PM_7 in Table C.
Comments:	We received several comments in support of activity consolidation; we received two comments opposing the QCDR activity consolidation with the suggestion that, if the consolidation proceeds, IA_PSPA_7 be changed to a high-weighted activity.
Response:	We appreciate the commenters' input. However, we have carefully reviewed the Inventory and continue to believe that this activity should remain medium-weighted because the activity burden remains the same; no additional requirements have been added. The bulleted list included in the description includes some examples; eligible clinicians may choose one element in the description. They are not all required. To help make this point clearer, we are making a formatting change in the activity description (changing the 'or' to 'OR'), so that eligible clinicians can more easily see that the listed ways in which this activity can be implemented are not all required.
Final Action:	After consideration of public comments, we are finalizing this removal as proposed, making one formatting change to the IA_PSPA_7 activity description.
Current Improvement Activity	
Current Activity ID:	**IA_PM_7**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR for feedback reports that incorporate population health
Current Activity Description:	Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_PM_7 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we proposed to add "generation and use of regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_PM_7. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_7 and IA_BE_8 in Table C.
Comments:	We received several comments in support of activity consolidation; we received two comments opposing the QCDR activity consolidation with the suggestion that, if the consolidation proceeds, IA_PSPA_7 be changed to a high-weighted activity.
Response:	We appreciate the commenters' input. However, we have carefully reviewed the Inventory and continue to believe that this activity should remain medium-weighted because the activity burden remains the same; no additional requirements have been added. The bulleted list included in the description includes some examples; eligible clinicians may choose one element in the description. They are not all required. To help make this point clearer, we are making a formatting change in the activity description (changing the 'or' to 'OR'), so that eligible clinicians can more easily see that the listed ways in which this activity can be implemented are not all required.
Final Action:	After consideration of public comments, we are finalizing this removal as proposed, making one formatting change to the IA_PSPA_7 activity description.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_6**
Current Subcategory:	Patient Safety and Practice Assessment

Current Activity Title:	Consultation of the Prescription Drug Monitoring program
Current Activity Description:	Review the history of controlled substance prescriptions for 90 percent* of patients using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. *Apply exceptions for patients receiving palliative and hospice care.
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor one, improvement activity is "duplicative." IA_PSPA_6 will be duplicative of the proposal to require the Query of PDMP measure for MIPS eligible clinicians in the Promoting Interoperability performance subcategory (measure PI_EP_2). The removal of this activity is contingent upon the proposal in section IV.A.6.c.(4)(d).
Comments:	One commenter opposed this removal, citing this activity's importance in light of the ongoing opioid epidemic.
Response:	We thank the commenter for their input and emphasize that we continue to believe in the importance of state prescription drug monitoring programs in light of the ongoing opioid epidemic. We refer readers to section IV.A.6.c.(4)(d) of this final rule, where we are finalizing the Query of PDMP measure in the Promoting Interoperability performance subcategory (measure PI_EP_2). With the inclusion of measure PI_EP_2 in the Promoting Interoperability performance subcategory, this improvement activity is duplicative.
Final Action:	After consideration of the public comments, we are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_20**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes
Current Activity Description:	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: • Make responsibility for guidance of practice change a component of clinical and administrative leadership roles; • Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or • Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor one, improvement activity is "duplicative." We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_19 in Table B by adding the phrase "including leadership" to the activity description after "staffing" to capture the essence of IA_PSPA_20. We believe that this activity will be duplicative of IA_PSPA_20 upon the adoption that proposal because it is similar to, but will only represent a partial component of, IA_PSPA_19.
Comments:	We received several comments in support of activity consolidation; we received two comments opposing this removal. Commenters noted that Inventory changes are generally burdensome and one commenter stated that the leadership concept here is important enough to warrant a separate activity.
Response:	We believe that the burden reduction accomplished by keeping the Inventory as streamlined as possible outweighs commenters' concerns. The consolidation of this activity into IA_PSPA_19 will simplify the Inventory and thereby reduce clinician burden as well as broadening IA_PSPA_19 and making it more robust.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_30**
Current Subcategory:	Patient Safety and Practice Assessment

Current Activity Title:	PCI Bleeding Campaign
Current Activity Description:	Participation in the PCI Bleeding Campaign which is a national quality improvement program that provides infrastructure for a learning network and offers evidence-based resources and tools to reduce avoidable bleeding associated with patients who receive a percutaneous coronary intervention (PCI). The program uses a patient-centered and team-based approach, leveraging evidence-based best practices to improve care for PCI patients by implementing quality improvement strategies: • Radial-artery access, • Bivalirudin, and • Use of vascular closure devices.
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor seven, improvement activity is "obsolete." The PCI Bleeding Campaign concluded on August 31, 2021,[1] so this improvement activity will no longer be available as of the conclusion of the 2022 performance period. This proposal will apply beginning with the CY 2022 performance period/2024 payment year.
Comments:	One commenter expressed support for removal of this activity, and suggested that similar initiatives be considered as improvement activities in the future.
Response:	We appreciate the support and may consider the suggestion.
Final Action:	After consideration of the public comments, we are finalizing this removal as proposed.

[1] Quality Improvement for Institutions. (n.d.). *Sunsetting the reduce the risk: Pci bleed dashboard.* https://cvquality.acc.org/initiatives/reduce-the-risk-pci-bleed.

APPENDIX 3: MVP INVENTORY

MVP Development Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854) and CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements and selection of measures and activities within an MVP. In addition, in section IV.A.4. of this final rule, we are finalizing additional MVP policies with regard to MVP development, maintenance, and reporting requirements.

This appendix contains two groups of MVP tables: Group A, which includes five new MVPs and Group B, which includes modifications to seven previously finalized MVPs. We received comments on all Group A and Group B MVPs with the comment summaries and responses embedded in each MVP table.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, each MVP includes a foundational layer that is comprised of population health measures and Promoting Interoperability performance category measures.

In the CY 2022 PFS final rule, we inadvertently omitted the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) from the MVP tables in Appendix 3 (86 FR 66002 through 66031). In the CY 2021 PFS final rule (85 FR 84849 and 84850), as a part of the MVP development criteria, we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described under § 414.1375(b). The ONC Direct Review attestation requirement has been a requirement for the Promoting Interoperability performance category since the first MIPS performance period in CY 2017 (81 FR 77019 through 77028). For these reasons, in the CY 2023 PFS proposed rule (87 FR 46813), we proposed to add the ONC Direct Review attestation requirement described under § 414.1375(b)(3) to all previously finalized MVPs and newly proposed MVPs. We did not receive any comments on

this proposal, and we are finalizing our proposal to add the ONC Direct Review attestation requirement described under § 414.1375(b)(3) to all MVPs as proposed.

In addition, we proposed to include the IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation improvement activity in all MVPs in alignment with policy finalized in the CY 2017 MIPS final rule (81 FR 77179 and 77180): MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary and codified at 414.1480(b)(3)(ii), may attest to this activity and receive an improvement activities performance category score of 100 percent. A couple commenters expressed support for the inclusion of IA_PCMH in all MVPs. The comments and responses are embedded in each of the MVP tables in Group A and Group B. After consideration of the public comments, we are finalizing the inclusion of IA_PCMH Electronic submission of Patient Centered Medical Home accreditation improvement activity in all MVPs as proposed.

MVP Development Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures considered in developing the MVPs are located in the 2022 MIPS Quality Measures List in the QPP Resource Library.[580] In addition, see Appendix 1: MIPS Quality Measures of this final rule for any removals, additions, and modifications to the existing quality measures.
- Existing QCDR measures considered in developing the MVPs were based on the most recent publication of the 2022 QCDR Measure Specification file and is located in the QPP Resource Library.[581] We plan to modify the list of 2023 QCDR measures around December 2022. We refer readers to the CY 2022 PFS final rule (86 FR 65405 through 65408) for additional details regarding QCDR measures and selection of measures within an MVP.
- Improvement activities considered in developing the MVPs are located in the 2022 Improvement Activities Inventory and the 2022 MIPS Data Validation Criteria located in the QPP Resource Library.[582] In addition, see Appendix 2: Improvement Activities of this final rule for any removals, additions, or modifications to the existing activities.
- Existing cost measures considered in developing the MVPs are located in the 2022 Cost Measures Inventory.[583]
- For further details on the population health measures included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability performance category measures adopted in prior rulemaking and included in the foundational layer are located in the QPP Resource Library.[584] In addition, see section IV.A.6.c.(4) of this final rule for policies regarding the Promoting Interoperability performance category measures.

Please note that new quality and Promoting Interoperability performance category measures for inclusion in MIPS beginning with the CY 2023 performance period/2025 MIPS payment year are identified with a caret symbol (^) within the MVP tables in this appendix. Existing quality measures, improvement activities, and Promoting Interoperability performance category measures with revisions are identified with an asterisk (*) within the MVP tables in this appendix. Quality measures identified with a double asterisk (**) are individual measures duplicating a component of the composite Adult Immunization Status measure. An MVP participant can only submit the quality measures with a (**) if the measure is included in an MVP. Please see Appendix 1: MIPS Quality Measures Table A.9 of this final rule for any additional information regarding the Adult Immunization Status measure. Quality measures, Promoting Interoperability attestation requirements, and improvement activities that we are adding in this

[580] See the 2022 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1687/2022%20MIPS%20Quality%20Measures%20List.xlsx.

[581] See https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1697/2022%20QCDR%20Measure%20Specifications.xlsx for QCDR measures.

[582] See the 2022 Improvement Activities Inventory: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1727/2022%20Improvement%20Activities%20Inventory.zip 2022 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1780/2022%20MIPS%20Data%20Validation%20Criteria.zip for improvement activity details.

[583] See the 2022 Cost Measures Inventory: https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2022.

[584] See the 2022 MIPS Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1733/2022%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip for Promoting Interoperability measure details.

final rule to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

Quality measures that are considered high priority (as defined in § 414.1305) are noted with an exclamation point (!) and outcome measures (as defined in § 414.1305) are noted with a double exclamation point (!!). In addition, at § 414.1305, we are finalizing as proposed revisions to the definition of a high priority measure. See section IV.A.6.c.(1)(b)(i) of this final rule regarding expansion of the definition of a high priority measure. Further details on these types of measures are located in the CMS Measures Management System Blueprint Version 17.0.[585] Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

- To determine whether a QCDR measure may be finalized within an MVP, we requested QCDR measure testing data for review by the end of the self-nomination period (that is, no later than September 1 of the year prior to the applicable performance period). If a QCDR was unable to submit testing data that demonstrated their QCDR measure was fully tested by the end of the self-nomination period or otherwise did not meet our requirements, we were unable to finalize the inclusion of the QCDR measure within an MVP. In this final rule, we are finalizing the QCDR measures within the relevant MVPs where evidence of testing data at the clinician level was received and fully tested. We refer readers to CY 2022 PFS final rule for additional details regarding requirements for QCDR measures within the MVP (86 FR 65407 through 65408).
- Consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," each MVP includes improvement activities designed to advance health equity and address and eliminate barriers to care in underserved communities. Improvement activities that include a health equity component are noted with a tilde (~) within the MVP table. The improvement activities that include a health equity component are not required but are available as an option within the MVPs. Improvement activity medium/high weight designations are identified in parentheses after each improvement activity. IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is noted with a percent (%) within the MVP tables below to indicate that attestation to this improvement activity provides full credit for the improvement activity performance category within the MVP.

[585] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.

Group A: New MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Advancing Cancer Care MVP

In the CY 2023 PFS proposed rule (87 FR 46814 through 46816), in support of the Administration's Cancer Moonshot Mission[7] and the importance of cancer care, we proposed and solicited comments on the Advancing Cancer Care MVP. The proposed Advancing Cancer Care MVP focuses on the clinical theme of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practice of oncology and hematology. The summary of the public comments received and our responses for this MVP are embedded within Table A.1.

Quality Measures

We proposed to include eleven MIPS quality measures and two QCDR measures within the quality component of this MVP, which are specific to the clinical topic of cancer by assessing three critical areas: the patient experience of care, end of life care, and appropriate diagnostics along with possible treatment options for different cancer diagnoses. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with oncologic conditions:

- Q143: Oncology: Medical and Radiation – Pain Intensity Quantified: This MIPS quality measure ensures pain intensity is assessed and quantified in those patients receiving chemotherapy or radiation.
- Q144: Oncology: Medical and Radiation – Plan of Care for Pain: This MIPS quality measure ensures a plan of care is in place for those patients experiencing pain while receiving chemotherapy or radiation.
- Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer: This MIPS quality measure ensures appropriate treatment for this patient population in accordance with National Comprehensive Cancer Network (NCCN) guidelines for HER2-positive tumors.
- Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy: This MIPS quality measure strives to improve concordance with RAS (KRAS and NRAS) testing based upon American Society of Clinical Oncology (ASCO) and NCCN guidelines for metastatic colorectal cancer patients, by assessing if gene mutation testing was performed prior to therapy.
  Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies: This MIPS quality measure ensures patients with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation are not treated inappropriately with anti-EGFR monoclonal antibodies.
- Q453: Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better): This MIPS quality measure assesses appropriate end of life care for cancer patients by reducing the utilization of unnecessary chemotherapy.
  Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better): This MIPS quality measure assesses appropriate end of life care for cancer patients by increasing the use of hospice services sooner for patients with advanced cancer.
  Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: This MIPS quality measure ensures proper bone density evaluation for patients with a care plan including androgen deprivation therapy for 12 or more months to promote positive bone health outcomes.
- PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer: This QCDR measure assesses clinical practice guideline compliance, based upon ASCO guidelines, regarding implementation of mutations testing to optimize diagnosis and disease management.
- PIMSH8: Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy: This QCDR measure assesses the use of GCSFs in accordance with current NCCN guidelines for non-small cell lung cancer.

In conjunction with the aforementioned cancer care measures, we proposed to include the following broadly applicable MIPS quality measures that are relevant to cancer care. The quality measures below capture the patient's voice regarding their care and support the mental health of patients that are experiencing a cancer diagnosis:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their

ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey provides direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.

Improvement Activities

Within the improvement activities component of this MVP, we proposed to include thirteen improvement activities that reflect actions and processes undertaken by clinicians who provide cancer care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for cancer patients. The following improvement activities were proposed for inclusion in this MVP:

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_BE_24: Financial Navigation Program
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_17: Patient Navigator Program
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_15: Implementation of episodic care management practice improvements
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_16: Use of decision support and standardized treatment protocols

Cost Measures

Within the cost component of this MVP, we proposed to include the Total Per Capita Cost (TPCC) measure because it captures the overall costs of care after establishing a primary care-type relationship. This includes the care provided to patients by medical, hematological, and gynecological oncologists. The broad focus of the measure, which includes total costs of care for patients with cancer, supports the intent of this MVP to apply to cancer care. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.1: Advancing Cancer Care MVP

Table A.1 serves to represent the measures and activities that are finalized within the Advancing Cancer Care MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[a]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2023 PFS proposed rule (87 FR 46815 and 46816), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, we are finalizing the QCDR measures within this MVP where evidence of testing data at the clinician level was received and fully tested. We removed the pound sign (#) for these measures. Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost

(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q144:** Oncology: Medical and Radiation – Plan of Care for Pain (Collection Type: MIPS CQMs Specifications) **(*)(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(!) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q452:** Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies (Collection Type: MIPS CQMs Specifications) **(*)(!) Q453:** Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) **(!!) Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(!) PIMSH2:** Oncology: Utilization of GCSF in Metastatic Colorectal Cancer (Collection Type: QCDR)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_17:** Patient Navigator Program (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate	Security Risk Analysis	

for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review

Comment: Several commenters supported this MVP. One commenter agreed with the inclusion of the following measures; Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer, Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy, and Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies. A couple commenters expressed support for the inclusion of Q457: Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days in this MVP and a few commenters supported the inclusion of PIMSH8: Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy in this MVP. One commenter supported the inclusion of IA_BE_24: Financial Navigation Program in this MVP and another commenter supported the inclusion of IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings and IA_PSPA_16: Use of decision support and standardized treatment protocols. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: A few commenters recommended delaying finalization of this MVP until the CY 2024 performance year. Two commenters felt this would allow time for practices and vendors to better prepare to implement the MVP. One commenter felt that the additional time would allow for MVP refinement and additional interested parties (oncology) feedback.

Response: At this time reporting of MVPs is optional. This allows flexibility for interested parties to prepare and determine when it is most appropriate for implementation of this MVP. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[586] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A few commenters recommended the MVP be modified to have a narrower scope that would be more specific to the practice of medical oncology only. One commenter requested that this MVP incorporate quality measures that are more aligned with the clinical care associated with surgical oncology as they stated the MVP is heavily skewed towards medical oncology. Additionally, a couple of commenters recommended multiple MVPs be developed that focus on subpopulations of cancer care. One commenter stated the construct of this MVP does not recognize the complexity of cancer care that frequently involves the services of a surgical oncologist, a medical oncologist, and a radiation oncologist and obligates these designated specialists to value therapies, including radiation therapy, that are outside of their scope of practice. They also stated the MVP has the potential to disincentivize appropriate referrals.

Response: While we understand that this MVP may not be applicable to all services and providers within the umbrella of oncology, the goal of this MVP is to focus broadly on the care for patients with cancer. We may consider the inclusion of additional measures through future

[586] See https://qpp.cms.gov/mips/mvp-maintenance-process.

MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements within an MVP. We encourage the commenter to reach out to measure developers/stewards to develop new specialty focused oncology measures for submission to the Call for Measures for possible future implementation. Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: One commenter believes that as currently proposed, this MVP would be of limited value to most urologists who participate in the MIPS program. They stated that several of the quality measures included in the MVP, including the two QCDR measures, are not applicable for urologists and two are only focused on end-of-life care.

Response: The intent of this MVP is to broadly assess the care for patients with cancer and may be most applicable, but not limited to, the practice of oncology and hematology. While the submission and choice of MVP is at the clinician's discretion, we agree that this MVP does not include measures that specifically address urological conditions. We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, we encourage the commenter to participate in the ongoing MVP candidate submission process.

Comment: One commenter expressed concern with the lack of outcome measures proposed within this MVP.

Response: We note the reporting requirements include reporting four quality measures from the MVP, including one outcome measure. If no outcome measure is available that is applicable to the clinician's scope of care, the clinician may report a high priority measure (86 FR 65417). This MVP as proposed contains ten high priority measures of which one is an outcome measure, allowing some flexibility and choice to clinicians in reporting a subset of measures and activities within this MVP. We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements within an MVP. Additionally, we encourage the commenter to reach out to measure developers/stewards to develop new oncology outcome measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter encouraged the development of a quality measure for advancing genetic testing for an inherited mutation, or germline testing, in cancer patients for incorporation into this MVP. Another commenter requested additional quality metrics developed that would be more focused on the care of patients with hematologic conditions. One commenter recommended the inclusion of biomarker testing into cancer diagnosis and treatment.

Response: We encourage the commenters to reach out to measure developers/stewards to develop additional measures addressing advancing genetic testing and biomedical testing for cancer measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter recommended the inclusion of patient-reported measures (PRMs) and PRO-PMs in the MVP. Recognizing outcomes that are most important to patients (for example, symptom management, quality of life) and ensuring care aligns with patient preferences, values, and goals can promote stronger patient engagement and better align incentives. Another commenter wanted to stress the importance of continued development of meaningful patient-reported outcome performance measures (PRO-PMs) that are relevant for inclusion in oncology MVPs, including those related to goal setting and alignment with patient care preferences and beliefs.

Response: We encourage the commenters to reach out to measure developers/stewards to develop PRMs and PRO-PMs oncology specific measures for submission to the Call for Measures for possible future implementation. Please note, the MVP does include Q321: CAHPS for MIPS Clinician/Group Survey which is a broad measure that captures the patient experience and voice.

Comment: One commenter recommended the inclusion of more globally applicable measures relevant to oncology care to ensure that subspecialized oncology groups can meet the case minimums for the measures. They recommended adding the following quality measures; Q110: Preventive Care and Screening: Influenza Immunization, Q130: Medication Management: Documentation of Current Medications, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, and Q402: Preventive Care and Screening: Tobacco Use – Adolescent. Another commenter recommended the addition of Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer, which will expand on the evaluation of care delivered to breast cancer patients.

Response: We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[587] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter questioned the inclusion of Q134: Preventative Care and Screening: Screening for Depression and Follow-up Plan. They felt that distress screening would be more comprehensive, complex, and a broader assessment of patients' needs.

Response: Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan is included in this MVP as a broadly applicable measure that supports the mental health of patients that are experiencing a cancer diagnosis by ensuring early intervention of care if needed. We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, an MVP may only include current MIPS quality measures and QCDR measures that meet all requirements within an MVP. The MIPS quality measure Inventory does not currently include a distress screening measure or other broadly applicable mental health assessment quality measures that are appropriate for this MVP. We encourage the commenter to reach out to measure developers/stewards to develop distress screening measures for submission to the Call for Measures for possible future implementation.

Comment: A couple commenters recommended that, in addition to Q321: CAHPS for MIPS Clinician/Group Survey, this MVP should also include NQF2651 CAHPS® Hospice Survey and NQF005 CAHPS Cancer Care. This would allow clinicians to receive credit for the use of any one of these CAHPS surveys.

Response: We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements within an MVP. We

[587] See https://qpp.cms.gov/mips/mvp-maintenance-process.

encourage the commenters to reach out to measure stewards to submit CAHPS for Cancer Care to the Call for Measures for possible future implementation.

Comment: One commenter recommended the removal of Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy from this MVP and if it is maintained that Qualified Registries and Qualified Clinical Data Registries be allowed to determine which measures are most applicable and feasible for them to support for their clients.

Response: We disagree with the commenter. Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy assesses appropriate use of bone density evaluations for patients with prostate cancer receiving androgen deprivation therapy. The National Osteoporosis Foundation recommends baseline assessments of bone density to preserve bone health in this patient population.[588]

While we recognize there are operational limitations for some third-party intermediaries as it relates to supporting all measures within an MVP, we believe allowing intermediaries to only support specific measures in an MVP creates undue burden on the MVP Participant and limits the clinicians' choice of measures available. Please note that only QCDRs are able to support QCDR measures.

Comment: One commenter requested clarification on how Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups and Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions will be employed in this MVP and identification of any differences in applying the measures to oncologists included within the program.

Response: Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups and Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions are foundational measures included in all MVPs. These measures will not be applied differently to oncologists participating in MVPs or other MIPs programs.

Comment: A couple commenters recommended the addition of PIMSH1: Advance Care Planning in Metastatic Cancer Patients and PIMSH12: COVID Vaccinations. They also recommended the addition of PIMSH4: Patient-Reported Pain Improvement as the measure is a patient reported outcome (PRO) measure that is "critical to oncology care, which leads to more favorable patient care, as well as lowers costs associated with unmanaged pain that often leads to avoidable ED visits and hospitalizations."

Response: We consider PIMSH1: Advance Care Planning in Metastatic Cancer Patients duplicative of Q047: Advance Care Plan, which is included in this MVP. As Q047 is available as a MIPS quality measure, it allows for submission without reliance on a QCDR, making the measure more accessible for reporting.

We thank the commenter for the recommendation related to the inclusion of PIMSH12: COVID Vaccinations and PIMSH4: Patient-Reported Pain Improvement. We may consider the inclusion of these two QCDR measures during future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all testing requirements to be included within an MVP.

Comment: One commenter recommended the inclusion of the following improvement activities relevant to the treatment of cancer to this MVP; IA_CC_13: Practice improvements for bilateral exchange of patient information, IA_PSPA_13: Participation in Joint Commission Ongoing Professional Practice Evaluation initiative, IA_EPA_2: Create and implement a standardized process for providing telehealth services to expand access to care, IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan, and IA_BMH_12: Promoting Clinician Well-Being.

Response: We may consider the inclusion of IA_CC_13, IA_PSPA_13, IA_EPA_2, IA_ERP_4, and IA_BMH_12 in this MVP through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[589] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter requested additional detail and further definition of which 'high-risk' patients might be included in IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high-risk patients realizing that cancer is a complex disease and often requires intensive care management. They also requested information on how the health equity initiatives would contribute to the definition of 'high-risk'.

Response: The objective of IA_PM_14 is to improve health outcomes and patient-centeredness of care for patients at high risk for adverse health outcomes or harm. So, 'high-risk' patients are patients for whom adverse health outcomes or harms are more likely than for other patient populations; this would be any patients for whom this may be the case; for example, later-stage congestive heart failure patients. We do not believe that health equity initiatives would contribute to the definition of the term 'high-risk' as it is being used here.

Comment: A couple commenters recommended the inclusion of IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program in this MVP.

Response: We may consider the inclusion of IA_PSPA_28 in this MVP through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.589 We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple commenters expressed concerns that the use of the Total Per Capita Cost (TPCC) measure within this MVP could lead to unintended consequences such as reduced access or care stinting, due to the greater financial pressure of constrained provider resources. One commenter stated oncology providers in particular are vulnerable to these unintended consequences due to the high variability of patient

[588] See https:/www.bonehealthandosteoporosis.org/patients/diagnosis-information/bone-density-examtesting.
[589] See https://qpp.cms.gov/mips/mvp-maintenance-process.

groups, case mix and disease progression, and rapid advances in patient care. Another commenter stated additional cost measures should be included within this MVP.

Response: We appreciate the commenters' concerns about the inclusion of a cost measure leading to potential unintended consequences. The TPCC measure uses CMS Hierarchical Condition Category new enrollee, community, institutional, dialysis new enrollee, and dialysis community models' risk scores to account for clinical and other patient risk factors. This robust risk adjustment approach accounts for patient heterogeneity that can influence costs out of a clinician's control, and so we continue to believe that the NQF-endorsed TPCC measure is appropriate for use in this MVP. The risk adjustment is based on data in the year prior to each beneficiary-month to account for changing levels of patient severity. Additionally, the TPCC measure includes a specialty adjustment to account for differences in patient case-mix for which different types of clinicians furnish care (for example, primary care clinicians and specialists such as medical oncologists). Regarding the commenter's concern that the TPCC measure might result in care stinting, we note that the measure does safeguard against potential care stinting by including costs of services that occur as consequences of care decisions, such as complications, in the measure calculation. Additionally, the measure uses an attribution methodology where multiple members of the care team can be held responsible for a patient. This encourages shared accountability among clinicians and more efficient care coordination surrounding primary care, including the provision of necessary care. As such, the TPCC measure is able to more accurately represent clinician performance across a broad patient case-mix and ensures that there is no incentive to avoid providing care to patients. We also believe that this MVP helps to create connections between cost measures, quality measures, and activities in MIPS to assess value.

We thank the commenter for the recommendation to include additional cost measures. We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.589 We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Cancer Care MVP* with modification in Table A.1 for the CY 2023 performance period/2025 MIPS payment year and future years. Through the CY 2023 QCDR self-nomination process, which opened on July 1, 2022 and closed on September 1, 2022, several substantive changes were proposed and approved to PIMSH8: Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy. Since the updates to this QCDR measure were not included in the CY 2023 PFS proposed rule, we are not finalizing the inclusion of PIMSH8 in the Advancing Cancer Care MVP. We may consider including the updated QCDR measure in this MVP through future rulemaking.

[a] See Appendix 1, MIPS **Quality Measures**: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Optimal Care for Kidney Health MVP

In the CY 2023 PFS proposed rule (87 FR 46817 through 46819), we proposed and solicited comments on the Optimal Care for Kidney Health MVP. The proposed Optimal Care for Kidney Health MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This MVP would be most applicable to clinicians who treat patients within the practice of nephrology. The summary of the public comments received and our responses for this MVP are embedded within Table A.2.

Quality Measures

We proposed to include eight MIPS quality measures within the quality component of this MVP, which promote the management and risks associated with kidney disease. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with kidney disease conditions:

- Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): This MIPS quality measure assesses diabetic patients for hemoglobin A1c control.
- Q482: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate: This MIPS quality measure represents an intermediate outcome for maintenance hemodialysis patients by assessing for continuous catheter use.
- Q488: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy: This MIPS quality measure assesses for the prescribing of an ACE inhibitor or ARB therapy for patients diagnosed with chronic kidney disease (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria.

In conjunction with the aforementioned nephrological measures, we proposed to include the following broadly applicable MIPS quality measures that are relevant to kidney care. The quality measures below capture the patient's voice regarding their care, the assessment and administration of the influenza and pneumococcal vaccinations, documentation of current medications, and blood pressure control—all of which support the safety and general health of patients that are experiencing disease of the kidney:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q110: Preventive Care and Screening: Influenza Immunization: This MIPS quality measure assesses for the administration or previous receipt of the influenza immunization for pediatric and adult patients.
- Q111: Pneumococcal Vaccination Status for Older Adults: This MIPS quality measure assesses that patients receive the pneumococcal vaccinations.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q236: Controlling High Blood Pressure: This MIPS quality measure promotes controlling blood pressure in patients diagnosed with essential hypertension with a goal to maintain a systolic pressure of < 140 mmHg and diastolic pressure of < 90 mmHg.

In developing this proposal, we also considered including the following quality measure for this MVP. However, we ultimately decided not to include it because the clinical action represented within this measure would most likely be performed by a primary care clinician and would support the referral of the patient to a nephrologist for their initial assessment. Therefore, this measure would likely not be appropriate for this MVP topic due to the quality action being more frequently performed by primary care rather than the nephrologist.

- Q488: Kidney Health Evaluation: This MIPS quality measure assesses patients that are diagnosed with diabetes for receipt of a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) and Urine Albumin-Creatinine Ratio (uACR).

Improvement Activities

Within the improvement activities component of this MVP, we proposed to include thirteen improvement activities that reflect actions and processes undertaken by clinicians who specialize in treating patients with kidney disease

conditions, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care patients with kidney disorders. The following improvement activities were proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_14: Engage Patients and Families to Guide Improvement in the System of Care
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_BE_16: Promote Self-management in Usual Care
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_13: Practice Improvements for Bilateral Exchange of Patient Information
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_16: Use of decision support and standardized treatment protocols

Cost Measures

Within the cost component of this MVP, we proposed two measures: The Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis episode-based cost measure and Total Per Capita Cost (TPCC) measure. The AKI Requiring New Inpatient Dialysis episode-based measure applies to nephrologists and other clinicians providing hemodialysis or dialysis procedures for acute kidney failure during inpatient hospitalizations. This aligns with the intent of the MVP to focus on kidney disease. We also proposed the TPCC measure because it is a broad measure that includes nephrologists and aligns with the similarly broad quality measures included in the MVP. Two episode-based cost measures are currently under development for chronic kidney disease (CKD) and end-stage renal disease (ESRD). The measures would focus on outpatient management of these conditions. The measures could be considered for future inclusion in this MVP.

TABLE A.2: Optimal Care for Kidney Health MVP

Table A.2 serves to represent the measures and activities that are finalized within the Optimal Care for Kidney Health MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[b]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(**) Q110:** Preventive Care and Screening: Influenza Immunization (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High)	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **Total Per Capita Cost (TPCC)**

(*)(**) Q111: Pneumococcal Vaccination Status for Older Adults (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) **(^) Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications)	**IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice Improvements for Bilateral Exchange of Patient Information (Medium) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review

Comment: Several commenters supported this MVP. One commenter supported the inclusion of all of the proposed quality measures. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs. One commenter expressed support of the ongoing development of episode-based cost measures for CKD and other relevant cost measures and their potential future inclusion in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter expressed concern that the current MVP includes only a handful of measures directly related to nephrology. The commenter stated that developing and implementing more outcome measures related to chronic kidney disease (CKD) and end stage renal disease (ESRD) could improve patient care and allow consumers to understand performance on aspects of care more meaningful to them.

Response: While we understand that this MVP may not be applicable to all nephrologists, the goal of this MVP is to focus on different aspects of care that are important for positive clinical outcomes for patients with chronic kidney disease (CKD). Therefore it includes measures aimed at limiting progression of CKD as well as patient-centered transition to kidney replacement therapy those for patients who progress to end-stage renal disease (ESRD) on dialysis in addition to more broadly applicable measures. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter recommended that this MVP include a measure for how well the patient's prescribed treatment fits with his/her values and goals. Without knowing the patient holistically, education may not align treatment with what would fit best with that patient's life.

Response: We thank the commenter for their feedback. We encourage the commenter to reach out to measure developers/stewards to develop additional measures ensuring care is personalized and aligns with the patient's goals for submission to the Call for Measures for possible future implementation.

Comment: One commenter recommended the inclusion of the new Adult Immunization Status measure in this MVP instead of Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults to be consistent with CMS' goal of promoting alignment across measure sets. In addition, the commenter stated that there is evidence to support the utility of the zoster and Td/Tdap vaccines for individuals with kidney disease.

Response: Measures Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults have been included based on feedback specific to this MVP from interested parties during the development process. Therefore, the clinical concepts represented in this MVP are intended to support nephrology with quality measures that are clinically relevant and appropriate for their clinical scope. As the best practices in medicine evolve constantly, we will continuously review MVPs to ensure appropriate alignment of quality measures and MVP topic. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[590] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter disagreed with the inclusion of Q482: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate in this MVP as there are extensive quality measures for dialysis in the ESRD Quality Incentive Program and they stated the MVP is intended to focus on patients with chronic kidney disease who are not receiving dialysis.

Response: This MVP has a broader clinical focus and captures performance driving positive clinical outcomes by providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease, which would include dialysis. By including measures assessing for quality care in dialysis patients, we are creating alignment between programs with similar quality measures be utilized in different care settings, which is a goal we continue to work towards. Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: A few commenters recommended the inclusion of the new Kidney Health Evaluation measure which can be performed by a nephrologist to monitor patients with CKD and diabetes.

Response: As finalized under Appendix 1: MIPS Quality Measures Table A.4, we may consider the inclusion of the Kidney Health Evaluation measure in this MVP through future MVP maintenance and rulemaking processes.

Comment: One commenter recommended the inclusion of IA_PM_21: Advance Care Planning in this MVP.

Response: We may consider the inclusion of IA_PM_21 in this MVP through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[591] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

[590] See https://qpp.cms.gov/mips/mvp-maintenance-process.
[591] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Comment: One commenter recommended the inclusion of IA_PM_13: Chronic care and preventative care management for empaneled patients as a replacement for either IA_PM_11: Regular review practices in place on targeted patient population need or IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high-risk patients. The commenter believes IA_PM_13 better targets the MVP population while still advancing care coordination.

Response: We will consider the inclusion of IA_PM_13 in this MVP through future MVP maintenance and rulemaking processes.

Comment: One commenter expressed concern with the cost measures included in this MVP as they stated the measures hold the nephrologist responsible when there are a multitude of providers involved in patient care. The commenter stated that holding nephrologists responsible and accountable for these costs may have unintended consequences that will result in nephrologists hesitant to initiate dialysis in AKI patients – thus potentially delaying access to clinically necessary care with prolongation of hospitalization and/or other adverse outcomes.

Response: We continue to believe that the TPCC measure and Acute Kidney Injury Requiring New Inpatient Dialysis (AKI) cost measure are appropriate for use in this MVP. The cost measures' attribution methodology reflects the fact that many providers can be involved in patient care; it allows multiple clinicians to be held accountable to promote shared responsibility for a patient's care. For example, if there are multiple TINs who meet the trigger and attribution criteria for a patient with AKI receiving new inpatient dialysis, they can each be attributed to an episode. In addition, attributed clinicians are incentivized to coordinate with other providers playing a role during the episode window. For example, nephrologists who are attributed to AKI episodes are incentivized to engage in discharge planning, arranging follow-up care, kidney education, and other services to reduce the risk of readmission or other complications after discharge. Both measures also safeguard against potential care stinting/delays in provision of necessary care by including costs of services that occur as consequences of care decisions, such as complications, in the measure calculation. Thus, if the nephrologist delays initiating dialysis in AKI patients, that could result in higher rates of high-cost complications, leading to a higher measure score. Additionally, both the AKI and TPCC measures assess costs that are related to the role of the attributed clinician. The TPCC measure is intended to capture costs of care broadly and includes a specialty adjustment to account for differences in cost associated with the case-mix treated by different specialties. The AKI measure includes only clinically related services where the attributed clinician can influence the occurrence, severity, or frequency of services. Both measures align with MVP's clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. We appreciate the concerns about potential unintended consequences and will continue to conduct monitoring for these. We believe that the MVP which creates connections between the quality and cost measures, and improvement activities ensures that clinicians are not assessed solely on cost but also on quality metrics relevant to kidney care.

After consideration of public comments, we are finalizing the *Optimal Care for Kidney Health MVP* as proposed in Table A.2 for the CY 2023 performance period/2025 MIPS payment year and future years.

[b] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.**A.**6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Optimal Care for Patients with Episodic Neurological Conditions MVP

- In the CY 2023 PFS proposed rule (87 FR 46820 through 46822), we proposed and solicited comments on the Optimal Care for Patients with Episodic Neurological Conditions MVP. The proposed Optimal Care for Patients with Episodic Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from episodic neurological conditions. This MVP would be most applicable to clinicians who treat patients within the practice of neurology. The summary of the public comments received and our responses for this MVP are embedded within Table A.3.

Quality Measures

We proposed to include four MIPS quality measures and six QCDR measures within the quality component of this MVP, which focus on a variety of neurological conditions that may impact patient health. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with episodic neurological conditions:

- Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: This MIPS quality measure assesses patients, that are diagnosed with epilepsy and are of child-bearing age, to ensure they receive counseling regarding how the treatment of epilepsy may affect contraception and pregnancy.
- Q419: Overuse of Imaging for the Evaluation of Primary Headache: This MIPS quality measure assesses overuse of the head (CT or MRI) for the evaluation of primary headache.
- AAN5: Medication Prescribed for Acute Migraine Attack: This QCDR measure assesses pediatric and adult patients diagnosed with migraine that were prescribed a guideline recommended, such as US Headache Consortium Guidelines, or FDA approved/cleared treatment for acute migraine attacks.
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions: This QCDR measure evaluates performance outcomes for patients with neurologic conditions. The outcomes from these assessments should reflect an improvement or maintenance of a patient's perceived quality of life. This measure includes patients diagnosed with the following neurologic conditions: amyotrophic lateral sclerosis, attention deficit disorders, autism, cerebral palsy, cognitive impairment and related dementias, developmental delays, headache and migraine, movement disorders, multiple sclerosis, muscular dystrophy, neoplasms of brain and spine, polyneuropathy, seizure and epilepsy, stroke, tic disorders, vertigo, and related neuro-otology disorders.
- AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy: This QCDR measure assesses for patients that had referrals or a discussion of evaluation at a comprehensive epilepsy care center.
- AAN30: Migraine Preventive Therapy Management: This QCDR measure assesses pediatric and adult patients diagnosed with migraine, that occur with a frequency is greater than or equal to 6 days per month/4 attacks per month, receive evidence-based preventive migraine therapy, including therapies prescribed by another clinician.
- AAN31: Acute Treatment Prescribed for Cluster Headache: This QCDR measure ensures patients diagnosed with cluster headache were prescribed an acute treatment, including treatments prescribed by a different clinician.
- AAN32: Preventive Treatment Prescribed for Cluster Headache: This QCDR measure ensures patients diagnosed with cluster headache were prescribed short-term and/or long-term preventive treatment, including treatments prescribed by a different clinician.

In conjunction with the aforementioned neurological measures, we proposed to include the following broadly applicable MIPS quality measures that are relevant to neurological conditions. The quality measures below encourage advance care planning and documentation of current medications, which capture the patient's voice and supports safety for patients that are experiencing episodic neurological conditions:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.

Improvement Activities

Within the improvement activities component of this MVP, we proposed to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities were proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_24: Financial Navigation Program
- IA_BMH_4: Depression screening
- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
  IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

Within the cost component of this MVP, we proposed to include the Medicare Spending Per Beneficiary (MSPB) Clinician measure because it applies to clinicians providing care in inpatient hospitals, including care for patients with neurological conditions. This is in line with the intent of the MVP. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.3: Optimal Care for Patients with Episodic Neurological Conditions MVP

Table A.3 serves to represent the measures and activities that are finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[c]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2023 PFS proposed rule (87 FR 46821 and 46822), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, we are finalizing the QCDR measures within this MVP where evidence of testing data at the clinician level was received and fully tested. We removed the pound sign (#) for these measures. Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs Specifications) **AAN5:** Medication Prescribed for Acute Migraine Attack (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **AAN29:** Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy (Collection Type: QCDR) **AAN30:** Migraine Preventive Therapy Management (Collection Type: QCDR) **AAN31**: Acute Treatment Prescribed for Cluster Headache (Collection Type: QCDR) **AAN32:** Preventive Treatment Prescribed for Cluster Headache (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information

	OR Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review
Comment: Several commenters supported this MVP; a couple commenters expressed specific support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs **Response:** We thank the commenters for their support. **Comment:** One commenter recommended that this MVP and future MVPs include more eCQM options. **Response:** We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years. **Comment:** One commenter recommended the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure. **Response:** We may consider the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[592] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. After consideration of public comments, we are finalizing the *Optimal Care for Patients with Episodic Neurological Conditions MVP* as proposed in Table A.3 for the CY 2023 performance period/2025 MIPS payment year and future years.	

[c] See Appendix 1, MIPS **Quality Measures**: Table Group **A** for further information regarding new MIPS measures and section IV.A.6.c.(**4**)(e) of this final rule regarding new Promoting Interoperability measures.

[592] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Supportive Care for Neurodegenerative Conditions MVP

In the CY 2023 PFS proposed rule (87 FR 46823 through 46825), we proposed and solicited comments on the Supportive Care for Neurodegenerative Conditions MVP. The proposed Supportive Care for Neurodegenerative Conditions MVP focuses on the clinical theme of promoting quality care for patients with cognitive-based neurological disorders such as dementia, Parkinson's Disease (PD), and Amyotrophic Lateral Sclerosis (ALS). This MVP would be most applicable to clinicians who treat patients with cognitive-based neurological disorders within the practice of neurology. The summary of the public comments received and our responses for this MVP are embedded within Table A.4.

Quality Measures

We proposed to include ten MIPS quality measures and three QCDR measures within the quality component of this MVP, which focus on a variety of cognitive-based neurological disorders that may impact patient health. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with cognitive-based neurological disorders:

- Q281: Dementia: Cognitive Assessment: This MIPS quality measure evaluates for the performance of a cognitive assessment for patients diagnosed with dementia.
- Q282: Dementia: Functional Status Assessment: This MIPS quality measure evaluates for the performance of a functional status assessment for patients diagnosed with dementia.
- Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure assesses for the discussion of safety concerns with either the patients diagnosed with dementia or their caregivers. There are two domains of safety that should be addressed to meet performance of the measure which include dangerousness to self or others and environmental risks. If a risk is discovered, it is anticipated that the clinician would document mitigation recommendations to promote safety outcomes for these patients.
- Q288: Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure ensures clinician communication of education on dementia disease management and health behavior with the added support of referrals to additional support resources for patients diagnosed with dementia and their caregivers.
- Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease: This MIPS quality measure evaluates if patients diagnosed with Parkinson's Disease receive an assessment for depression, anxiety, apathy, and psychosis.
- Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease: This MIPS quality measure assesses for the performance of a cognitive impairment or dysfunction for patients diagnosed with Parkinson's Disease.
- Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease: This MIPS quality measure evaluates if patients, diagnosed with Parkinson's Disease, receive referrals for physical, occupational, speech, or recreational therapy.
- Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: This MIPS quality measure assesses patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) to ensure they are offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice).
- AAN9: Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease: This QCDR measure evaluates if patients diagnosed with Parkinson's Disease are queried about symptoms of autonomic dysfunction and if screened positive for autonomic dysfunction receive appropriate follow-up.
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions: This QCDR measure evaluates performance outcomes for patients with neurologic conditions. The outcomes from these assessments should reflect an improvement or maintenance of a patient's perceived quality of life. This measure includes patients diagnosed with the following neurologic conditions: amyotrophic lateral sclerosis, attention deficit disorders, autism, cerebral palsy, cognitive impairment and related dementias, developmental delays, headache and migraine, movement disorders, multiple sclerosis, muscular dystrophy, neoplasms of brain and spine, polyneuropathy, seizure and epilepsy, stroke, tic disorders, vertigo, and related neuro-otology disorders.
- AAN34: Patient reported falls and plan of care: This QCDR measure assesses that patients with the diagnosis of a movement disorder, or caregivers as appropriate, have a plan of care in the instance a fall is

reported. For this measure, a movement disorder includes multiple sclerosis, a neuromuscular disorder, dementia, or stroke.

In conjunction with the aforementioned cognitive-based neurological measures, we proposed to include the following broadly applicable MIPS quality measures that are relevant to cognitive-based neurological disorders. The quality measures below address advance care planning and documentation of current medications, which support the capture of the patient's voice and safety for patients that are experiencing cognitive-based neurological disorders:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q238: Use of High-Risk Medications in Older Adults: This MIPS quality measure supports patient safety by assessing for the use of high-risk medications.

Improvement Activities

Within the improvement activities component of this MVP, we proposed to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities were proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_24: Financial Navigation Program
- IA_BMH_4: Depression screening
- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
  IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance *Care* Planning
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

Within the cost component of this *MVP*, we proposed to include the Medicare Spending Per Beneficiary (MSPB) Clinician measure because it applies to clinicians providing care in inpatient hospitals, including care for patients with cognitive-based neurological conditions. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.4: Supportive Care for Neurodegenerative Conditions MVP

Table A.4 serves to represent the measures and activities that are finalized within the Supportive Care for Neurodegenerative Conditions MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[d]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2023 PFS proposed rule (87 FR 46824 and 46825), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, we are finalizing the QCDR measures within this MVP where evidence of testing data at the clinician level was received and fully tested. We removed the pound sign (#) for these measures. Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **(!) Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **AAN9:** Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **(!!) AAN34:** Patient reported falls and plan of care (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs	**Medicare Spending Per Beneficiary (MSPB) Clinician**

	(Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review	

Comment: Several commenters supported this MVP; a couple commenters expressed specific support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter recommended the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure.

Response: We may consider the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[593] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Supportive Care for Neurodegenerative Conditions MVP* as proposed in Table A.4 for the CY 2023 performance period/2025 MIPS payment year and future years.

[d] See Appendix 1, MIPS **Quality Measures**: Table Group **A** for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new **Promoting** Interoperability measures.

[593] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Promoting Wellness MVP

In the CY 2023 PFS proposed rule (87 FR 46825 through 46828), we proposed and solicited comments on the Promoting Wellness MVP. The proposed Promoting Wellness MVP focuses on the clinical theme of promoting quality care for patients. This MVP would be most applicable to clinicians who treat patients within the practice of preventive medicine, internal medicine, family medicine, and geriatrics. The summary of the public comments received and our responses for this MVP are embedded within Table A.5.

Quality Measures

We proposed to include fourteen MIPS quality measures within the quality component of this MVP, which promote general physical and mental wellness within patients. Preventive care is vital to reducing risk of diseases, disabilities, and death; however, many people within the United States still do not receive the recommended preventive screenings and services. The quality measures below include assessments for appropriate immunization status in addition to representing screenings for cancers, sexually transmitted infections, and osteoporosis, all of which drive quality care for preventive medicine for a broad patient population. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing preventive care:

Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women, 65-85 years of age, who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.

- Q112: Breast Cancer Screening: This MIPS quality measure ensures women have a mammogram to screen and for breast cancer.

Q113: Colorectal Cancer Screening: This MIPS quality measure ensures patients have received appropriate screening for colorectal cancer.

- Q309: Cervical Cancer Screening: This MIPS quality measure assesses women to determine if they were screened for cervical cancer.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure requires that patients have received a one-time screening for hepatitis C virus (HCV) infection.
- Q475: HIV Screening: This MIPS quality measure ensures patients received a one-time test for HIV.
- Q493: Adult Immunization Status: This MIPS quality measure ensures patients are assessed for and/or receive the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines, as recommended.

In conjunction with the aforementioned promoting wellness measures, we proposed to include the following broadly applicable MIPS quality measures that are relevant to promoting wellness. The quality measures below address preventive care and screening by supporting the assessment of body mass index, mental health, tobacco, and alcohol use. Additionally, this MVP includes two quality measures that capture the patient's voice and support clinicians' care goals for optimizing the patient's experience while receiving care for comprehensive health wellness:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, with a BMI documented and who had a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use and if the patient is screened positive for tobacco use then they should receive tobacco cessation intervention.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey would provide direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients, aged 18 years and older, for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. If the patient is screened positive for unhealthy alcohol use, then they should receive brief counseling.
- Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM): This MIPS quality measure evaluates the high value aspects of primary care based on a patient's

relationship with the clinician or practice and allows patients the ability to communicate their perspective of the quality of care received to their clinicians and/or care team.

Improvement Activities

Within the improvement activities component of this MVP, we proposed to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide chronic disease-preventive care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing chronic disease management or preventive care. The following improvement activities were proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_BMH_9: Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
  IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

Within the cost component of this MVP, we proposed to include the Total Per Capita Cost (TPCC) measure because it captures the total costs of care. This broad cost measure aligns with the MVP scope to include a range of measures and activities to promote wellness across different clinical topics. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.5: Promoting Wellness MVP

Table A.5 serves to represent the measures and activities that are finalized within the Promoting Wellness MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[e]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q112**: Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(*)(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **(*) Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) **(^) Q493**: Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_BMH_9:** Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(*) IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes, or other practice improvement processes (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review

Comment: Several commenters supported this MVP. One commenter agreed with the inclusion of Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age in this MVP. One commenter strongly supported the inclusion of Q113: Colorectal Cancer Screening in this MVP as this measure will help ensure patients receive appropriate screening. One commenter agreed with the inclusion of the new Adult Immunization Status measure in this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs. One commenter supported the inclusion of Q475: HIV Screening in this MVP. Another commenter supported the inclusion of Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM).

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter encouraged the development of a quality measure for incentivizing efficient rare disease diagnoses for incorporation into this MVP.

Response: We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all testing requirements to be included within an MVP. We encourage the commenter to reach out to measure developers/stewards to develop efficient rare disease diagnoses related measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter supported the inclusion of this MVP but did not support the inclusion of the following measures in this MVP due to uncertain validity; Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan, Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, Q321: CAHPS for MIPS Clinician/Group Survey, and Q475: HIV Screening. They also did not agree with the inclusion of Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) for application at the actual/intended level of analysis: “Individual Clinician” or "Group Practice" because it lacks validity.

Response: Both measures, Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan, Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan was previously NQF endorsed in and, demonstrated reliability and validity to the Scientific Methods Panel during the NQF endorsement process for existing measures prior to 2020.The Scientific Methods Panel does not define minimum thresholds for reliability and validity, but evaluates whether the measure demonstrates these concepts as specified. Based on information provided from the measure steward, Q475: HIV Screening was determined to be fully tested and an important clinical topic for community health. Additionally, these measures are considered core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) and have been determined to be an important part of patient health and support healthy outcomes. Q321: CAHPS for MIPS Clinician/Group Survey addresses the full patient experience, allowing for direct input from patients regarding their experience with timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff. Inclusion of this measure supports one of our guiding principles of incorporating the patient voice through the inclusion of patient experience and/or patient satisfaction measures.

We are focused on quality measurement to align with what is meaningful to patients and clinicians. Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) addresses the relationship with the primary care clinician or practices offering a broader scope and more meaning to both the clinician and the patient. The measure steward indicated that the 11 constructs assessed by the PCPCM PRO are widely hypothesized to be associated with better personal and population health, equity, quality, and sustainable health care expenditure. It addresses all areas of primary care, comprehensiveness, community, access, coordination, and behavioral health. The measure steward also indicated that the measure has been tested in all types of settings among different age groups and it continues to maintain reliability and validity. The measure is validated in multiple languages and addresses the broad community.

Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: One commenter encouraged the inclusion of the Screening for Social Drivers of Health measure in this MVP.

Response: We may consider the inclusion of the Screening for Social Drivers of Health measure through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[594] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter did not support the inclusion of Q321: CAHPS for MIPS Clinician/Group Survey as including only Q483 would "encourage broader adoption of the PCPCM PRO-PM measure." The commenter stated that promoting the use of the PCPCM PRO-PM in the MVP would be a step toward aligning with the agency's stated goal and provides a consistent and meaningful connection between the Promoting Wellness MVP and value-based payment models.

Response: While the PCPCM PRO-PM measure addresses all areas of primary care, Q321: CAHPS for MIPS Clinician/Group Survey addresses patient experience more broadly. The CAHPS for MIPS Clinician/Group Survey allows for direct input from patients regarding their experience with timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff. While the measures may appear to be similar, we believe these measures have only one overlapping question. Additionally, Q321: CAHPS for MIPS Clinician/Group Survey assesses patient experience with healthcare services delivered in different settings and for a broad spectrum of specific conditions. The PCPCM PRO-PM measure addresses the specific relationship with the primary care clinician or practice offering a broader scope and more meaning to both the clinician and the patient. It addresses all areas of primary care, comprehensiveness, community, access, coordination, and behavioral health.

Comment: One commenter did not support the inclusion of the Adult Immunization Status measure as the commenter believes that current immunization registries and health data information sharing systems must first be fixed to more effectively aggregate patient information, including immunization records to evaluate the quality of the care reliably and accurately. They stated that until this gap in data aggregation and information sharing is addressed, the Adult Immunization Status measure would result in unnecessary administrative time and burden placed on patients and physician practices.

Response: We acknowledge that the measure will set a more stringent performance standard by requiring the reporting of a set of adult immunizations in one multi-performance measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. We believe the measure will encourage improvement in overall vaccination rates more effectively because performance is based on the administration of all four vaccinations rather than focusing on just one vaccination per measure. Additionally, this measure is being proposed as a MIPS clinical quality measure and may be supported by Qualified Registries or Qualified Clinical Data Registries meaning that the data for calculation of this measure may be abstracted from multiple medical data sources and not necessarily reliant on immunization registries. We believe these types of measures drive the continued efforts of the interoperability of health data information sharing systems.

Comment: One commenter recommended the inclusion of IA_PM_11: Regular Review Practices in Place on Targeted Patient Population Needs to this MVP in alignment with CMS' strategic vision and with other CMS initiatives regarding how to help health-related social needs in cancer care.

Response: We appreciate the commenter's suggestion that IA_PM_11: Regular Review Practices in Place on Targeted Patient Population Needs be considered for this MVP. We may do this through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.594 We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter did not support the use of the Total Per Capita Cost (TPCC) measure in this MVP as they stated it holds primary care physicians accountable for costs they cannot control, penalizes physicians for increasing utilization of recommended preventive health measures, and fails to capture long-term cost savings generated by high-quality, longitudinal primary care.

Response: We continue to believe that the TPCC measure is appropriate for use in this MVP. Regarding the commenter's statement that the measure holds clinicians accountable for costs that are outside of their control, we note that the revised attribution methodology effectively identifies the existence of a primary care-type relationship between clinician groups and patients. Specifically, it requires the presence of evaluation and management primary care-type services to have an associated primary care-type service or follow-up evaluation and management service, thus indicating clinician group's sustained involvement with the patient. The TPCC measure also uses CMS Hierarchical Condition Category new enrollee, community, institutional, dialysis new enrollee, and dialysis community models' risk scores to account for clinical and other patient risk factors. This robust risk adjustment approach accounts for patient heterogeneity that can influence costs out of a clinician's control.

Additionally, we disagree with the commenter's concern that the measure penalizes clinicians for provision of recommended services. As noted earlier, the measure includes costs of services that occur as consequences of care decisions in the measure calculation. Therefore, if the attributed clinician group attempts to reduce costs by not providing the necessary primary care services, this could result in higher costs for adverse outcomes such as post-acute care, re-hospitalizations for complications, or emergency department visits, leading to a higher measure score. The measure also uses a year-long risk window where overlapping risk windows can be collapsed so that the same clinician-patient relationship can continue to be evaluated within MIPS performance periods. Using this longer period reflects the commenter's feedback about the need to capture primary care services with longer term benefits to cost savings.

[594] See https://qpp.cms.gov/mips/mvp-maintenance-process.

After consideration of public comments, we are finalizing the *Promoting Wellness MVP* as proposed in Table A.5 for the CY 2023 performance period/2025 MIPS payment year and future years.

[e] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Advancing Care for Heart Disease MVP

In the CY 2023 PFS proposed rule (87 FR 46829 through 46831), we proposed and solicited comments on the previously finalized Advancing Care for Heart Disease MVP. Table B.1 represents the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (86 FR 66014 through 66015) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.1.

We proposed to modify the previously finalized Advancing Care for Heart Disease MVP to include cardiovascular care in general as well as cardiology subspecialists in order to capture a more complete picture of quality care for patients who are at risk of or who have heart disease. Therefore, we proposed to expand the Advancing Care for Heart Disease MVP to include six additional quality measures that encompass the clinical care of electrophysiology, heart failure, and interventionalist subspecialists:

- Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: This MIPS quality measure assesses patients with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism.
- Q377: Functional Status Assessments for Heart Failure: This MIPS quality measure assesses patients with heart failure who completed initial and follow-up patient-reported functional status assessments.
- Q392: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation: This MIPS quality measure assesses the rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation.
- Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision: This MIPS quality measure assesses the infection rate following CIED device implantation, replacement, or revision.
- Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System: This MIPS quality measure assesses annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients with heart failure (HF) or cardiomyopathy.

In conjunction with the aforementioned heart disease measures, we proposed to include the following broadly applicable MIPS quality measure that is relevant to patients receiving cardiovascular care. The quality measure below addresses preventive care and screening of patients for depression:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.

Also, we proposed to add one improvement activity, IA_PM_13: Chronic care and preventative care management for empaneled patients and remove two improvement activities, IA_EPA_4: Additional improvements in access as a result of QIN/QIO TA and IA_PSPA_30: PCI Bleeding Campaign from this MVP. The proposed changes specific to IA_PM_13 and IA_EPA_4 are in response to public comments we received in the 2022 PFS final rule (86 FR 66012). One commenter believed IA_PM_13 was designed to directly address patients assigned to care teams for the purpose of population health management and encourages the adoption of practices and protocols that are essential in high-quality care for chronic diseases. After consideration, we agree that IA_PM_13 is a better choice for this MVP than IA_EPA_4 because of IA_PM_13's direct focus on preventive care and patient empanelment. The commenter also suggested the removal of IA_EPA_4 because the commenter believed it has minimal specificity for the MVP. After consideration, we agree making this change would best provide sufficient provider choice while not including an overwhelming number of improvement activity options in this MVP. The proposal to remove IA_PSPA_30 was made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of the proposed rule and was contingent on those proposals being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we proposed to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

This MVP was previously adopted to be most applicable to clinicians who practice in the following specialties:

- Cardiology
- Internal Medicine
- Family Medicine

With the proposed modifications, these additional clinicians who practice in the following specialties may want to consider reporting this MVP:

- Electrophysiology
- Heart Failure Specialists
- Interventionalists

TABLE B.1: Advancing Care for Heart Disease MVP

Notes: Table B.1 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Advancing Care for Heart Disease MVP. Additions are identified with a plus sign (+) before the quality measure and improvement activity ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[f]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q128**: Preventive care and screening: Body Mass Index (BMI) screening and follow-up plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+)(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**IA_BE_12:** Use of evidence-based tools to support shared decision making (Medium) **IA_BE_15:** Engagement of Patients, Families, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(*)(~) IA_CC_14:** Practice Improvements that Engage Community Resources to Support Patient Health Goals (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(+) IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium)	**Elective Outpatient Percutaneous Coronary Intervention** **ST Elevation Myocardial Infarction with Percutaneous Coronary Intervention** **Total Per Capita Cost (TPCC)**

(*)(!) Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) **(+)(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) **(+)(!!) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) **(+)(!!) Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(+)(^)(!!) Q492:** Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims)	**(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	
Comment: Several commenters supported this MVP. A couple of commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs. One commenter supported the addition of the following quality measures to this MVP: Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy, Q377: Functional Status Assessments for Heart Failure, Q392: Cardiac Tamponade and/or Pericardiocentesis		

Following Atrial Fibrillation Ablation, and Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter recommended that more measures from the cardiology specialty set be added to the MVP to facilitate wider inclusion. They did not agree that the additional quality measures included in this MVP would allow interventional cardiologists to successfully report this MVP as the additional measures are not specific to interventional cardiology. One commenter stated that it is unclear as to whether a single MVP for cardiology that encompasses all cardiovascular care would be most beneficial to clinicians and patients, or if creating discrete MVPs by subspecialty/patient population is more beneficial. They recommended that CMS review data by clinician type to discern if there are any observable differences in performance.

Response: We may consider the inclusion of additional measures through future MVP maintenance and rulemaking processes. Currently, MVP reporting is not required, and we understand that not all clinicians within a subspecialty may be able to report an MVP.

Comment: One commenter stated this MVP seems appropriate for geriatrics health professionals in theory, but it may be difficult for geriatricians to be successful under the MVP framework given the heterogeneity of their patient population.

Response: We agree that this MVP may be suitable for geriatricians and appreciate that some of the quality measures represented within this MVP could be challenging to report due to the heterogeneity of the patients supported by this specialty. This MVP includes measures that are very specific to electrophysiologist; however, there are other quality measures within the MVP that are more generalized cardiac care that may include concepts applicable to geriatricians and the care they provide to their patients. We encourage geriatricians to carefully review the MVP and determine if there are measures within this MVP that are appropriate for their case mix, clinically suitable, and would produce meaningful measure data. It's not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: One commenter did not agree with the addition of Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan to this MVP. They stated that cardiologists and the respective subspecialities treat, assess, or monitor mental health care.

Response: Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan is included in this MVP as a broadly applicable measure that supports the mental health of patients that are experiencing a chronic cardiac diagnosis by ensuring early intervention of care if needed. The CDC indicates that there is "Evidence shows that mental health disorders—such as depression, anxiety, and PTSD—can develop after cardiac events, including heart failure, stroke, and heart attack. These disorders can be brought on after an acute heart disease event from factors including pain, fear of death or disability, and financial problems associated with the event."[595] This measure only requires the screening of patients and a documented plan of care if the patient screens positive, which includes referral to a clinician whose scope would include assessment and treatment of this patient population. Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: One commenter recommended postponing the inclusion of the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System measure until it is in alignment with CQMC's input.

Response: We thank the commenter for their comment. While we endeavor to create alignment between different measure sets, it is not a requirement. We believe that this is an important outcome metric to assess as an administrative claims measure, does not place any burden onto the clinician as the performance data will be calculated for the clinician. We appreciate the CQMC Cardiology Workgroup's input upon their review of the measure. We note that the measure is adjusted for the AHRQ SES Index which captures multiple aspects of social deprivation that can impact patients' health and health outcomes, including poverty and median household income; unemployment; education; and housing value and quality. These factors are deeply rooted in societal disparities, and MIPS providers may have little ability to influence their effect. However, ambulatory providers can work with patients to improve on their continuity of care, adherence to prescribed medications, and access to appointments.

We appreciate that in some circumstances the attribution algorithm will not always accurately reflect the most responsible clinician. In consultation with the TEP and Clinician Committee, we have selected an attribution algorithm that is reasonable under most circumstances. The measure outcome includes acute cardiovascular-related hospital admissions. Note that the measure outcome excludes planned admissions, such as those for planned revascularization, device implantation or ablation, as long as they are not accompanied by a discharge diagnosis that is acute or a complication of care. Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide flexibility and choice in reporting by allowing clinicians to select a subset of measures and activities within an MVP.

Comment: One commenter recommended the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure.

Response: We will consider the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[596] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

[595] See https://www.cdc.gov/heartdisease/mentalhealth.htm.
[596] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Comment: One commenter expressed concerns with including the TPCC measure in this MVP because it assesses cost during a one-year period and focuses on primary-care type services. The commenter also stated a preference to include the MSPB measure in this MVP instead of the TPCC measure because the MSPB measure assesses care immediately before, during, and after a hospital stay.

Response: We continue to believe that the NQF-endorsed TPCC measure is appropriate for use in this MVP. This MVP assesses fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. The TPCC measure evaluates the overall cost of care delivered to a patient with a focus on the primary care-type services, including care related to heart disease. This MVP was previously developed to be most applicable to clinicians specializing in cardiology, internal medicine, and family medicine; these specialties are all included in the TPCC measure attribution methodology. We thank the commenter for their suggestion to include the MSPB measure within this MVP. We encourage the commenter to submit this recommended change via the MVP maintenance process. [597] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* as proposed in Table B.1 for the CY 2023 performance period/2025 MIPS payment year and future years.

[f] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

[597] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Optimizing Chronic Disease Management MVP

In the CY 2023 PFS proposed rule (87 FR 46832 and 46833), we proposed and solicited comments on the previously finalized Optimizing Chronic Disease Management MVP. Table B.2 represents the measures and activities that were finalized within the Optimizing Chronic Disease Management MVP in (86 FR 66021 through 66022) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.2.

We proposed to modify the previously finalized Optimizing Chronic Disease Management MVP to include Q321: CAHPS for MIPS Clinician/Group Survey. While this MVP already included a patient experience measure, Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure, we proposed to add an additional option for assessing the patient experience. The addition of the CAHPS for MIPS Clinician/Group survey measure to this MVP will provide primary care clinicians more flexibility when choosing a patient experience evaluation and allows for the use of a survey vendor. Capturing the patient experience is a priority of the MIPS program and this proposed addition would allow clinicians to choose a patient experience measure that best fits their clinical workflow.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.2: Optimizing Chronic Disease Management MVP

Notes: Table B.2 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Optimizing Chronic Disease Management MVP. Additions are identified with a plus sign (+) before the quality measure ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[g]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3**: Promote use of Patient-Reported Outcome Tools (High)	**Total Per Capita Cost (TPCC)**
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium)	
(*) Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications)	**IA_BE_16:** Promote Self-management in Usual Care (Medium)	
(*) Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQMs Specifications)	**IA_BE_22**: Improved practices that engage patients pre-visit (Medium)	
(*)(!!) Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium)	
(+)(*)(!) Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	**IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium)	
	(*) IA_CC_13: Practice improvements for bilateral exchange of patient information	

(!!) Q398: Optimal Asthma Control (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications)	(Medium) **(*)(~) IA_CC_14:** Practice Improvements that Engage Community Resources to Support Patient Health Goals (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **(*) IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter stated this MVP seems appropriate for geriatrics health professionals in theory, but it may be difficult for geriatricians to be successful under the MVP framework given the heterogeneity of their patient population.

Response: We agree that this MVP may be suitable for geriatricians and appreciate that some of the quality measures represented within this MVP could be challenging to report due to the heterogeneity of the patients supported by this specialty. This MVP includes measures that are relevant for geriatric care, family medicine, and internal medicine. There are quality measures within the MVP that may include concepts applicable to geriatricians and the care they provide to their patients. We encourage geriatricians to carefully review the MVP and determine if there are measures within this MVP that are appropriate for their case mix, clinically suitable, and would produce meaningful measure data. It is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: One commenter requested that this MVP incorporate quality measures applicable to rare diseases.

Response: We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements within an MVP. We encourage the commenter to reach out to measure developers/stewards to develop rare disease related measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter did not support the inclusion of the following measures in this MVP due to uncertain validity; Q047: Advance Care Plan, Q236: Controlling High Blood Pressure, Q321: CAHPS for MIPS Clinician/Group Survey, and Q398: Optimal Asthma Control. They also did not agree with the inclusion of Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) for application at the actual/intended level of analysis: “Individual Clinician” or "Group Practice" because it lacks validity.

Response: Both measures, Q047: Advance Care Plan and Q236: Controlling High Blood Pressure were previously NQF endorsed in and, demonstrated reliability and validity to the Scientific Methods Panel during the NQF endorsement process for existing measures prior to 2020. The Scientific Methods Panel does not define minimum thresholds for reliability and validity but evaluates whether the measure demonstrates these concepts as specified. Additionally, Q236 aligns with Core Quality Measure Collaborative (CQMC) core measure set(s) and has been determined to be an important part of patient health and support healthy outcomes. Q321: CAHPS for MIPS Clinician/Group Survey addresses the full patient experience, allowing for direct input from patients regarding their experience with timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff. Inclusion of this measure supports one of our guiding principles of incorporating the patient voice through the inclusion of patient experience and/or patient satisfaction measures. We are focused on quality measurement to align with what is meaningful to patients and clinicians. Based on information provided from the measure steward, Q398: Optimal Asthma Control was determined to be fully tested and an important clinical topic for pediatric and adult health. Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) addresses the relationship with the primary care clinician or practices offering a broader scope and more meaning to both the clinician and the patient. The measure steward indicated that the 11 constructs assessed by the PCPCM PRO are widely hypothesized to be associated with better personal and population health, equity, quality, and sustainable health care expenditure. It addresses all areas of primary care, comprehensiveness, community, access, coordination, and behavioral health. The measure steward also indicated that the measure has been tested in all types of settings among different age groups and it continues to maintain reliability and validity. The measure is validated in multiple languages and addresses the broad community.

Please note, it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP.

Comment: A couple commenters recommended the inclusion of the new Kidney Health Evaluation measure in this MVP as it is applicable to both nephrologists and primary care clinicians who manage the care of individuals with both diabetes and CKD.

Response: As finalized under Appendix 1: MIPS Quality Measures Table A.4, we will consider the inclusion of the Kidney Health Evaluation measure in this MVP through future MVP maintenance and rulemaking processes.

After consideration of public comments, we are finalizing the *Optimizing Chronic Disease Management MVP* as proposed with modifications in Table B.2 for the CY 2023 performance period/2025 MIPS payment year and future years. We refer readers to Appendix 1: Quality Measure Inventory, where we discuss the finalization of the removal of quality measure Q119: Diabetes: Medical Attention for Nephropathy from the MIPS program. Therefore, in this MVP, we have removed Q119: Diabetes: Medical Attention for Nephropathy from this MVP to reflect this change.

[g] See Appendix 1, MIPS Quality Measures: **Table** Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Advancing Rheumatology Patient Care MVP

In the CY 2023 PFS proposed rule (87 FR 46834 and 46836), we proposed and solicited comments on the previously finalized Advancing Rheumatology Patient Care MVP. Table B.3 represents the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (86 FR 66002 through 66003) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.3.

We proposed to modify the previously finalized Advancing Rheumatology Patient Care MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program. This proposal was made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of the proposed rule and was contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we proposed to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

Also, we proposed to remove improvement activity, IA_BMH_4: Depression screening and add Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, which is a broadly applicable quality measure that encompasses the same concept and assesses an important aspect of care for patients with chronic diseases. We believe Q134 is better suited than IA_BMH_4 for this MVP, because it ensures that all patients without a history of depression or bipolar disorder are being screened for depression and a follow-up plan is discussed if the patient screens positive. Q134 supports depression screening for a more general patient population, allowing early detection and treatment. Additionally, we believed this clinician patient interaction is an important aspect of care for this patient population because depression is a common comorbidity in patients with various rheumatic diseases. Therefore, we proposed to add measure Q134 as it ensures depression screening for each patient.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.3: Advancing Rheumatology Patient Care MVP

Notes: Table B.3 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Advancing Rheumatology Patient Care MVP. Additions are identified with a plus sign (+) before the quality measure and improvement activity ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[h]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*)(**) Q111: Pneumococcal Vaccination Status for Older Adults (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+)(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BMH_2:** Tobacco use (Medium)	**Total Per Capita Cost (TPCC)**

(*) Q176: Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (Collection Type: QCDR) **(!!) ACR14:** Gout Serum Urate Target (Collection Type: QCDR) **(!) ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	**(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter recommended the inclusion of the new Adult Immunization Status measure in this MVP instead of Q111: Pneumococcal Vaccination Status for Older Adults to be consistent with CMS' goal of promoting alignment across measure sets. In addition, the commenter stated that there is evidence to support the utility of the pneumococcal, zoster, and Td/Tdap vaccines for individuals with rheumatic diseases.

Response: Measure Q111: Pneumococcal Vaccination Status for Older Adults was included to ensure that pneumococcal vaccinations are comprehensively assessed and used. We believe the clinical concept represented in this measure supports the Rheumatology specialty with a more targeted approach rather than the broader clinical concept of multiple vaccinations represented within the Adult Immunization Measure.

As pneumonia is a common cause of illness and death for patients with underlying conditions and those being treated with immunosuppressive therapies, we want to ensure this aspect of care is assessed. Pneumococcal Vaccinations play an important role in the management of patients with rheumatological conditions who are at an increased risk for infections because of their underlying condition, comorbidities, and use of immunosuppressive therapies. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[598] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter disagreed with the inclusion of measure Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan and the removal of IA_BMH_4: Depression Screening in this MVP due to the lack of Q134 measure data from a rheumatology specific QCDR.

Response: We disagree with the commenter. We believe Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan is better suited than IA_BMH_4 for this MVP because it ensures that all patients without a history of depression or bipolar disorder are being screened for depression and a follow-up plan is discussed if the patient screens positive. IA_BMH_4 is limited to patients with co-occurring conditions of behavioral or mental health conditions. The measure allows for early detection and treatment of depression, which is an important aspect of care in patients with various rheumatic diseases, as depression is a common comorbidity.

Additionally, this measure is considered a core measure that aligns with Core Quality Measure Collaborative (CQMC) core measure set(s) and has been determined to be an important part of patient health and supports healthy outcomes.

Comment: A couple commenters recommended the inclusion of IA_ BE_ 24: Financial Navigation Program and/or IA_ BE_ 25: Drug Cost Transparency in this MVP, as most of these patients require assistance given the associated costs with the medications used to manage their rheumatologic disease. One commenter recommended the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure.

Response: We agree with the commenters that IA_ BE_ 24: Financial Navigation Program and/or IA_ BE_ 25: Drug Cost Transparency could be considered for this MVP because of the significant costs associated with managing rheumatologic disease. We will consider the inclusion of these activities through future MVP maintenance and rulemaking processes. We will also consider the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.598 We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple commenters expressed concerns with including the TPCC measure in the Advancing Rheumatology Care MVP because the measure does not include costs of Part D prescription drugs. The commenters stated that clinicians could appear to have higher costs if they use more Part B prescription drugs than Part D prescription drugs, compared to other clinicians.

Response: We continue to believe that the TPCC measure is appropriate for use in this MVP starting in performance year 2023. The NQF-endorsed TPCC measure evaluates the overall cost of care delivered to a patient with a focus on the primary care-type services, including care related to rheumatological conditions The measure aligns with the MVP's clinical theme of providing fundamental treatment and management of rheumatological conditions. The TPCC measure includes all Medicare Parts A and B payment-standardized costs, but not Part D prescription drug costs, in its assessment given that the Part D payment standardization methodology was not available when the TPCC measure was undergoing comprehensive re-evaluation. For context, as with Parts A and B payment standardization, Part D costs need to be payment standardized to facilitate meaningful comparisons of resource use within the market-based Medicare Part D program by accounting for non-clinical variation in costs. For more information on the Part D payment standardization methodology please refer to the specifications materials available at https://resdac.org/articles/cms-price-payment-standardization-overview. We appreciate the concerns about how differences in prescribing could affect measure performance and will continue to conduct monitoring to ensure the measure remains valid and reliable. We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes. For example, a rheumatoid arthritis episode-based cost measure is under development and could be considered for future inclusion in this MVP in the future, if the measure is implemented in MIPS.

After consideration of public comments, we are finalizing the *Advancing Rheumatology Patient Care MVP* as proposed in Table B.3 for the CY 2023 performance period/ CY 2025 payment year and future years.

[h] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

[598] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

In the CY 2023 PFS proposed rule (87 FR 46836 and 46837), we proposed and solicited comments on the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. Table B.4 represents the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (86 FR 66024 through 66025) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.4.

We proposed to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program and IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes. These proposals were made in conjunction with our proposals to remove these improvement activities from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of the proposed rule and was contingent on those proposals being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we proposed to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.4: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Notes: Table B.4 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. Additions are identified with a plus sign (+) before the improvement activity ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[i]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(*)(!) Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications) **Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Collection Type: MIPS CQMs Specifications) **(*)(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) **(!) ACEP21:** Coagulation Studies in Patients Presenting with Chest Pain with No Coagulopathy or Bleeding (Collection Type: QCDR) **(!!) ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(!) ACEP52: Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) **(!) ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR)	**IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium) **(*) IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter agreed with the inclusion of a patient experience survey measure in this MVP but recommended a survey measure that is specific to care received in the emergency setting, such as CMS' Emergency Department CAHPS (EDCAHPS) be included instead of Q321: CAHPS for MIPS Clinician/Group Survey.

Response: We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and current QCDR measures within an MVP. We encourage the commenter to reach out to measure developers/stewards to submit their measures to the Call for Measures for possible future implementation.

Comment: One commenter recommended the addition of Q65: Appropriate Treatment for Upper Respiratory Infection (URI) and non-QCDR measures for this MVP to expand the availability of relevant measures and to ensure clinicians can report without having to use a QCDR.

Response: We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[599] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

[599] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Comment: One commenter recommended the inclusion of IA_BMH_12: Promoting Clinician Wellbeing and IA_AHE_8: Create and Implement an Anti-Racism Plan Emergency in this MVP.

Response: We will consider the inclusion of IA_BMH_12 and IA_AHE_8 in this MVP through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter opposed the removal of improvement activities IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program and IA_PSPA_20: Leadership Engagement in Regular Guidance and Demonstrated Commitment for Implementing Practice Improvement Change from this MVP.

Response: The removal of IA_PSPA_6 from the Improvement Activities inventory was proposed because the PI_EP_2: Query of Prescription Drug Monitoring Program (PDMP) has been proposed to become a required Promoting Interoperability performance category measure which would render this activity duplicative in the MVP. The removal of IA_PSPA_20 from the inventory and consolidation of this activity into IA_PSPA_19 has been proposed, as we believe this will help streamline the inventory and reduce clinician burden, broadening IA_PSPA_19 and making it more robust.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MV*P as proposed in Table B.4 for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Improving Care for Lower Extremity Joint Repair MVP

In the CY 2023 PFS proposed rule (87 FR 46838 and 46839), we proposed and solicited comments on the previously finalized Improving Care for Lower Extremity Joint Repair MVP. Table B.5 represents the measures and activities that were finalized within the Improving Care for Lower Extremity Joint Repair MVP in (86 FR 66027 through 66028) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.5.

We proposed to modify the previously finalized Improving Care for Lower Extremity Joint Repair MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program. This proposal was made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of the proposed rule and was contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we proposed to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.5: Improving Care for Lower Extremity Joint Repair MVP

Notes: Table B.5 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Improving Care for Lower Extremity Joint Repair MVP. Additions are identified with a plus sign (+) before the improvement activity ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[j]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_15:** PSH Care Coordination (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	(Medium) **IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: A couple commenters recommended the addition of Q375: Functional Status Assessment for Total Knee Replacement. Although this measure is duplicative of Q470: Functional Status After Primary Total Knee Replacement including both options would allow flexibility and the option for providers to submit an eCQM.

Response: We will consider the inclusion of additional measures through future MVP maintenance and rulemaking processes; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements within an MVP. We agree that having a variety of measures and collection types in the program for reporting provides additional flexibility for clinicians to choose how to report their applicable measures; however, rather than offering duplicate measures, we believe that offering measures with more robust evaluation methods would drive better quality of care provided.

Comment: One commenter suggested that Advanced Orthopaedic Certification (AOC) may be well-suited to serve as an additional improvement activity recognition for MVPs such as Improving Care for Lower Extremity Joint Repair.

Response: Programs such as the Advanced Orthopaedic Certification (AOC) program may meet the requirements to attest to being an IA_PCMH: Patient-Centered Medical Home™ or comparable specialty practice. We would like to note that for MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice at least 50 percent of the practice sites within a group's

TIN must be recognized as a patient-centered medical home or comparable specialty practice. Practices that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as a patient-centered medical home if it meets any of criteria set forth at § 414.1380(b)(3)(ii). IA_PCMH is an available activity option in all MVPs. If the AOC program meets the requirements for IA_PCMH, we encourage the commenter to submit their recommendation to the Call for Activities for possible future implementation in MIPS. After consideration of public comments, we are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* as proposed in Table B.5 for the CY 2023 performance period/2025 MIPS payment year and future years.

[j] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

Patient Safety and Support of Positive Experiences with Anesthesia MVP

In the CY 2023 PFS proposed rule (87 FR 46840 and 46841), we proposed and solicited comments on the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP. Table B.6 represents the measures and activities that were finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP in (86 FR 66030 through 66031) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.6.

We proposed to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to remove IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes. This proposal was made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of the proposed rule and was contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we proposed to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we proposed to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.6: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Notes: Table B.6 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Patient Safety and Support of Positive Experiences with Anesthesia MVP. Additions are identified with a plus sign (+) before the improvement activity ID number and before the Promoting Interoperability title in this table.

If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[k]; existing and Promoting Interoperability performance category quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost

(!!) Q404: Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) **(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) **(!) AQI69:** Intraoperative Antibiotic Redosing (Collection Type: QCDR)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_15:** PSH Care Coordination (High) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

	(+) ONC Direct Review
	Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs. **Response:** We thank the commenters for their support. **Comment:** One commenter recommended that this MVP and future MVPs include more eCQM options. **Response:** We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years. **Comment:** For continuity one commenter requested that IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes be added to this MVP. IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes was removed from the program due to it being combined with IA_PSPA_19. **Response:** We will consider the inclusion of IA_PSPA_19 in this MVP through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[600] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* as proposed in Table B.6 for the CY 2023 performance period/2025 MIPS payment year and future years.

[k] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

[600] See https://qpp.cms.gov/mips/mvp-maintenance-process.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

In the CY 2023 PFS proposed rule (87 FR 46841 and 46842), we proposed and solicited comments on the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. Table B.7 represents the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in (86 FR 66007 through 66008) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.7.

We proposed to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP for the reasons stated earlier in this Appendix 3, to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

TABLE B.7: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Notes: Table B.7 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. Additions are identified with a plus sign (+) before the Promoting Interoperability title in this table. If applicable, new MIPS quality and Promoting Interoperability performance category measures are identified below with a caret symbol (^)[1]; existing quality and Promoting Interoperability performance category measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). Quality measure collection types and improvement activity weights are identified in parentheses after each measure and activity title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications) **(!!) Q409:** Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications)	**(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Intracranial Hemorrhage or Cerebral Infarction**
Foundational Layer		

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

Comment: Several commenters supported this MVP. A couple commenters expressed support for the inclusion of IA_PCMH: Patient Centered Medical Home in all MVPs.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this MVP and future MVPs include more eCQM options.

Response: We encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include measures from different collection types within each MVP to allow flexibility in reporting but are limited to our current inventory of quality measures. We encourage the commenter to reach out to measure developers/stewards to develop eCQMs for the submission to the Call for Measures for possible future implementation and reach out to the measure steward of current measures not available as an eCQM to discuss revisions for possible implementation in future years.

Comment: One commenter recommended the removal of Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy given the recent suppression of performance rates for CY 2022 and past concerns that it is a topped-out measure.

Response: We acknowledge that Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy is currently topped out but is a critical clinical action for stroke prevention for patients that are diagnosed with this type of heart arrythmia. The reason for suppression was due to a typographical error within the denominator exception of the measure specification and not due to an analytic or implementation issue. We agree that the absence of a usable historical benchmark will create the need for a performance period benchmark for CY 2024; however, given the adoption rate of this measure, we believe this will be achievable. We believe the inclusion of this measure will support flexibility and clinician choice when choosing quality measures for this MVP.

Comment: One commenter recommended the removal of Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) as it is outside the scope for neurologists. Another commenter recommended the removal of Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) as the measure specifications target performance to a primary care provider or cardiologist. Further, the commenter stated that all or none of the measures are unlikely to be adopted given complexity and burden, which hinders the ability to generate meaningful quality improvement data.

Response: While we understand this MVP may not be applicable to all neurologists, the goal of this MVP is to support prevention of strokes and promote positive outcomes for patients suffering from strokes, as a medical condition specific MVP. As stated in the introduction of the CY 2022 PFS proposed rule (86 FR 39885 and 39886), cerebral infarction is the 9th most expensive condition treated in United States hospitals making it a high priority condition as it is more common in the aged 65 and older patient population and is the leading cause of serious long-term disability. This MVP was intentionally developed to include other clinician types that may support the prevention and/or treatment of strokes and patient positive outcomes, such as a stroke care team which may consist of neurologists, neurosurgeons, interventional radiologists, and vascular surgeons among other clinician types. As such, we believe Q344 is relevant to this MVP because it may foster a team-based care approach promoting coordination of patient care for stroke prevention, while also being applicable to individual clinician types whose scope of care aligns with the MVP topic.

We believe Q441 is relevant to this MVP as it focuses on risk-reduction therapies for patients with established coronary and other atherosclerotic vascular disease, including peripheral arterial disease, atherosclerotic aortic disease, and carotid artery disease. "Strokes due to larger artery atherosclerosis account for approximately a third of all strokes. One of the main goals in stroke reduction is to control vascular risk factors such as hypertension,

diabetes, dyslipidemia, and smoking cessation."[601] This MVP was intentionally developed to include other clinician types that may support the prevention and/or treatment of strokes and patient positive outcomes. This MVP will be applicable to clinicians whose scope of care aligns with the MVP topic.

Comment: One commenter recommended the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure.

Response: We will consider the inclusion of IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement in MVPs that do not include a relevant patient experience survey measure through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process.[602] We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* as proposed in Table B.7 for the CY 2023 performance period/2025 MIPS payment year and future years.

[1] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.6.c.(4)(e) of this final rule regarding new Promoting Interoperability measures.

[601] See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4536764/.

[602] See https://qpp.cms.gov/mips/mvp-maintenance-process.

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